F-1

A New Colorimetric Development and Validation of Visible Method for Estimation of Cephadroxil in Bulk Formulation

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Abstract:

A simple, sensitive, accurate, precise and economical visible Spectrophotometric method was developed and validated for the estimation of Cephadroxil in Bulk form. The method is based on the reaction of Cephadroxil with MBTH Reagent [3-Methyl-2-Benzothiazolinone Hydrazone] in the presence of ferric chloride giving greenish blue colour chromogen which shows maximum absorbance at 410nm against reagent blank. The Chromogen obeyed Beer's law in the concentration range of 10-50 µg/ml for Cephadroxil. The results of the analysis have been validated statistically and recovery studies.

Keywords: Cephadroxil, MBTH Reagent, Ferric chloride, Visible Spectrophotometric.

F-2

Method Development and Validation of Cilazapril in Bulk Formulation by Fc Reagent

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Abstract:

A simple, sensitive, accurate, precise and economical visible Spectrophotometric method was developed and validated for the estimation of Cilazapril in Bulk form.The method is based on the reaction of Cilazapril with FC Reagent [Folin Ciocalteu] in the presence of Sodium Carbonate producing blue colour which shows maximum absorbance at 725nm against reagent blank. The Chromogen obeyed Beer's law in the concentration range of 10-50 µg/ml for Cilazapril. The results of the analysis have been validated statistically and recovery studies.

Keywords: Cilazapril, FC Reagent, Sodium Carbonate, Visible Spectrophotometric.

F-3

Development and Validation of Microbial Bioassay for Quantification of Cephalexin In Pharmaceutical Preparations

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Abstract:

The aim of this study was to develop and validate a simple, sensitive, precise and cost-effective one-level agar diffusion (5+1) bioassay for estimation of potency and bioactivity of Cephalexin in pharmaceutical preparation which has not yet been reported in any pharmacopoeia. Escherichia coli MTCC-443 were selected as the most significant strain against Cephalexin. Bioassay was optimized by investigating several factors such as buffer pH, inoculums concentration and reference standard concentration. Identification of Cephalexin in commercial sample Cephadex tablet was done by FTIR spectroscopy. Mean potency recovery value for Cephalexin in Cephalexin tablet was estimated as 100.2%. A validated bioassay method showed linearity ($r^2 = 0.999$), precision (Intraday RSD=1.09%, and Interday RSD = 0.94%) and accuracy (99.53%, RSD = 0.306%). Bioassay was correlated with HPLC using same sample and estimated potencies were 100.2% and 99.25%, respectively. Results show that bioassay is a suitable method for estimation of potency and bioactivity of Cephalexin pharmaceutical preparations.

Keywords: Cephalexin, Escherichia coli MTCC-443, Cephadex, Nutrient Agar medium, HPLC, FT-IR

F-4

Method Development and Validation of Cephalexin in Bulk Formulation

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Abstract:

An accurate, precise and economical visible Spectrophotometric method was developed and validated for the estimation of Cephalexin in Bulk form. The method is based on the reaction of Cephalexin with FC Reagent in the presence of 10%

Sodium Carbonate giving greenish blue colour chromogen which shows maximum absorbance at 720nm against reagent blank. The Chromogen obeyed Beer's law in the concentration range of 10-50 µg/ml for Cephalexin. The results of the analysis have been validated statistically and recovery studies.

Keywords: Cephalexin, Folin Ciocalteu reagent, Visible Spectrophotometric.

F-6

Development and Validation of Critical Quality Attributes of a Novel Formulation of Atorvastatin QbD Approach

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Abstract:

The aim of this study was to formulate a novel BCS classII Antihyperlipidemic drug and optimize the critical quality attributes (CQAs) of the same using a Quality by Design (QbD) approach. In this case atorvastatin was the drug of choice. The Quality target product profile (QTPP) was defined based on commercially available product.The material attributes and CQAs were identified by risk assessment as per International Conference of Harmonization (ICHQ9) quality guidelines. Material attributes were found to be the amounts of microcrystalline cellulose (MCC) and Croscarmellose sodium (CCS); the CQAs selected for optimization was dissolution. A screening design with 5 experimental runs was performed for the amounts of CCS and MCC in the range of 11mg- 21mg and 80mg-160mg respectively. Based on the results of screening batches a Response Surface Methodology (RSM) was used for optimization. A full factorial central composite design (CCD) with 10 experimental runs was performed by taking MCC and CCS in the range of 80mg-120mg and 11mg-20mg respectively. Out of these runs batch R1 was found to show a drug release of 92.47% in 30mins with MCC of 120mg and CCS of 16mg.Thus QbD was successfully applied to optimize the CQAs and meet the desired Quality Target Product Profile.

Keywords: QbD; Screening design; Response surface design; full factorial design; central composite design; Atorvastatin.

F-7

Analytical Method Development and Validation for Simultaneous Estimation of Avibactam and Ceftazidime by Rp-Hplc Method

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Abstract:

A simple reverse phase high performance liquid chromatography (RP-HPLC) method has been developed and subsequently validated for simultaneous determination of Avibactam and Ceftazidime in combined dosage form. The separation was carried out using mobile phase consisting of potassium dihydrogenortho phosphate buffer of pH 3.0 and Methanol in the ratio of 30:70 v/v. The column used is InertsilODS (5 µm, 4.6 X 150 mm) with flow rate of 1.0 ml/min using PDA detection at 260 nm. The calibration curves were linear over a concentration range of 1-5 µg/mL and 100-500 µg/mL for Avibactam and Ceftazidime. The retention times of were found to be 3.7 min and 2.05 min respectively. Results of analysis were validated statistically and by recovery studies. The LOD and LOQ value for Avibactam and Ceftazidime was found to be 3, 2.9 ppm and 10.1, 10.03ppm respectively. The linear regression coefficient, slope and intercept of were found to be 0.997, 0999, 3003, 28847, 37313, 38353 respectively. The results of the study showed that the proposed RP-HPLC method is rapid, specific, precise and accurate and is useful for the routine analysis of Avibactam and Ceftazidamide in bulk drug and in its pharmaceutical dosage form.

Keywords: Avibactam, Ceftazidime, RP-HPLC, Methanol

F-8

Analytical method development for the determination of meloxicam by UV Spectroscopy in Pure and in Pharmaceutical Dosage Forms

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Abstract:

A new, simple method indicating UV spectroscopy was developed and validated for the estimation of Meloxicam in pure form and in formulation. The adequate drug solubility was found in ethanol and the maximum absorbance was measured at 365 nm in the wavelength range of (200-400nm), the linear calibration curve was obeyed in the concentration range of (2-25 µg/ml) show regression equation (Y=0.04994x) and correlation coefficient (R^2=0.99909). This method was validated and applied to the determination of Meloxicam in pharmaceutical dosage form, no interference was found from excipients at the selected wavelength and analysis conditions.

Keywords: UV spectroscopy, Meloxicam, Calibration Curve method

F-9

Impurity Profiling and Regulatory Aspects of Sitagliptin Active Pharmaceutical Ingredient

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Abstract:

In the recent year, impurity profiling in any active pharmaceutical ingredient (APIs) has become a paramount criterion in pharmaceutical analysis and quality control, espoused by major regulatory authorities like United States Food and drugs administration (US FDA) CDSCO. Sitagliptin phosphate (monohydrate), a newer dipeptidyl peptidase-4 (DPP-4) inhibitor, an oral hypoglycemic (anti-diabetic) drug intended to be used in type-II diabetes. In the present study an unprecedented effort has been made to analyze the related substances present in the sitagliptin API and was spiked. The whole study was performed by using High performance liquid chromatography (HPLC) with predetermined chromatographic conditions. Two impurities namely Ketoamide and Enamine in various batches were analyzed. The method was validated by using Waters HPLC, Model no. Alliance 2695, with 2998 PDA detector, powered with. Empower-2 software. The acceptance criteria kept between ketoamide and Enamine impurity from system suitability solution was not less than 2.0. Tailing factor of the drug peak from system suitability was not more than 2.0. Relative standard deviation for three replicate injections of reference solution-A was less than 1.0%. The difference between the results of each specified and unspecified impurities from the six different preparations of test solution injections should be ± 0.02 and for the total impurities ± 0.05. The average result of Ketoamide and Enamine impurity was found not more than 0.15%.

Keywords: Sitagliptin phosphate, ketoamide, Enamine, Impurity profiling,

F-10

Method Development for Simultaneous Estimationtion of Ketorolactromethamine and Olopatadine.HCl in eye drops by RP-HPLC & UV Spectrometric Methods

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Abstract:

A simple, fast, precise, selective and accurate RP-HPLC method was developed and validated for the simultaneous determination of Ketorolac tromethamine and olopatadineHCl from stock and formulations. Chromatographic separation was achieved isocratically on a Inertsil ODS Sunfire column (250×4.6 mm, 5µ) using a mobile phase, Methanol and 0.5% Ammonium di hydrogen orthophosphate (PH-3 adjusted with orthophospharic acid) in the ratio of 65:35. The flow rate was 1.1 ml/min and effluent was detected at 250nm. The retention time of Ketorolac and olopatadine were, 3.8 min and 6.1 min respectively. Linearity was observed in the concentration range of 10-600µg/ml with correlation coefficient of 0.999 for both the drugs. Percent recoveries obtained for ketorolac and olopatadine were 100.03% and 100.04%, respectively. UV spectrophotometric (dual wavelength) method, performed at 269nm and 302nm for the determination Ketorolac tromethamine, 279nm and 369nm for the determination Olopatadine hydrochloride. The calibration curves were linear over the range of 10µg - 90µg/ml for both drugs. Both the methods were validated according to ICH guidelines. These methods can be applied for determination of titled drugs in its formulation with good accuracy and precision.

Keywords: Ketorolac tromethamine, Olopatadine hydrochloride, Validation, HPLC, UV

F-11

Method Development and Validation by RP-HPLC for the Estimation of Diclofenac Acid in Capsules

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Abstract:

Diclofenac is a Non Steroidal Anti Inflammatory agent. The Sodium and Potassium forms of Diclofenac are widely available; however the acid form is a new molecule. The objective of the study is to develop and validate a new simple, rapid and sensitive isocratic RP-HPLC method for the determination of Diclofenac acid in capsules. The method employs Waters Alliance HPLC system on Inertsil C8, (100 x 4.0 mm), 5.0µm. For the mobile phase, a mixture of equal volumes of 0.01M Phosphoric acid solution and 0.01M Phosphate buffer adjusted to pH 2.5 was prepared; further mixed with Methanol in the ratio (30:70). The flow rate was 1.2ml/min with isocratic elution and a total run time of 6 minutes. Detection of the compound was carried out at 254nm. Results showed that the retention time of Diclofenac acid was found to be 3.782. The linearity studies range from the concentration range of 125 -1000 µg/ml and this method was validated for accuracy, precision, linearity, ruggedness and robustness as per ICH guidelines. The developed method was found to be accurate, precise and can be useful for routine Quality control analysis. Forced degradation studies are under process.

Keywords: Diclofenac acid, RP-HPLC, ICH, Analytical method validation

F-12

Stress Degradation Behaviour of Adapalene by Validated HPTLC method and Characterization of Its Degradation Product by LC-MS/MS

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Abstract:

A highly sensitive, simple, accurate and precise high-performance thin-layer chromatographic (HPTLC) method was developed and validated for quantitative determination of Adapalene (ADP) in presence of their degradation products. The method employed on percolated Silica Gel G60 F254 aluminium sheets using solvent system toluene: acetone (5: 5, v/v) which gives compact spot of ADP at R_f value 0.58 ± 0.03. The densitometric measurement of ADP bands was carried out at 317 nm in fluorescence mode. The method was validated over a range of 10 – 100ng/band. The linear regression data for the calibration plot showed a good relationship with high correlation coefficients ($r^2 > 0.9981 \pm 0.0006$). The performance of the method was validated for precision, accuracy and robustness. The limit of detection and quantification were 0.39ng/band and 1.17ng/band respectively. ADP was subjected to the ICH prescribed acidic, basic, oxidative, photolytic and thermal stress conditions. The drug undergoes degraded under acidic, basic and oxidation condition with well resolved degradation products. The proposed HPTLC method was utilized to investigate and characterize the degradation product of ADP. These degradation products were isolated and analysed by mass spectroscopy to elucidate structure of degradation products and to predict the degradation pathway.

Keywords: High-performance thin-layer chromatographic (HPTLC), Adapalene, Stress degradation, LC-MS/MS.

F-13

Method Development for the Estimation of Agomelatine in Human Plasma by LC-MS

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Abstract:

A simple and inexpensive RP- HPLC method for the estimation of Agomelatine, in human plasma liquid-liquid extraction procedure and an isocratic chromatography condition using a reversed-phase column provided an assay well suited for real time analyses. The estimation of Agomelatine, in human plasma is carried over a range of 0.0503 ng/mL to 8.0055 ng/mL with the detection of Agomelatine m/z – 244.0 (parent) and 185.10 (product) and internal standard Agomelatine D6 m/z – 250.00 (parent) and 188.10 (product) in positive ion mode. The method exhibited excellent performance in terms of selectivity, linearity, accuracy, precision, recovery, stability, detection limit

and quantitation limit. In addition, the reported method has a short analysis run time, an advantage over previously reported methods.

Keywords: Agomelatine, LC-MS, assay, validation

F-14

Optimizing Extraction Procedure for Simultaneous Estimation of Flurbiprofen and Methyl Salicylate in Topical Gel Formulations by New UV Spectrometric Method

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Abstract:

Flurbiprofen (FLB) and Methyl salicylate (MS), the actives in a commercial topical gel formulation were extracted for their simultaneous estimation. The extraction system was validated for elimination of interferences associated with matrix materials used in the formulation and also compensate for possible interference of one drug by the other during analysis. An efficient extraction procedure was developed for the separation of FLB and MS from the marketed formulation *Brugel* and validated for linearity, range, accuracy and precision. Detection wavelengths of 248 nm and 304 nm were used for recording the absorbance as they represent the absorption maxima of FLB and MS respectively. Simultaneous equations were designed to estimate the unknown concentration of both the components in the marketed formulation. The developed method was validated for linearity, range, accuracy and precision. Linearity was calculated using standard stock solution of MS and FLB in the concentration range of 5 – 30 µg /ml. The accuracy of the method was calculated at concentration levels of 80%, 100%, 120% and the percent recovery determined. The developed method was found to be specific, precise and can be used for routine analysis of marketed gel formulations containing flurbiprofen and methyl salicylate.

Keywords: Flurbiprofen, Methyl salicylate, simultaneous estimation.

F-15

A Validated Method Development for Estimation of Abafungin by 1st Order Derivative Spectroscopy

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Abstract:

The topical antimycotic Abafungin, *N*-{4-[2-(2,4-Dimethylphenoxy)phenyl]-1,3-thiazol-2-yl}-1,4,5,6-tetrahydro-2-pyrimidinamine, is the first representative of a new class of drugs with the name arylguanidines. Abafungin has a broad spectrum of action against dermatophytes, yeasts and moulds. A novel, safe and sensitive method of 1st order derivative spectroscopic method for estimation in UV-region has been developed for the assay of Abafungin in its bulk and tablet formulation. The method have been developed and validated for the assay of Abafungin using ethanol as diluents, which does not, shows any interference in spectrophotometric estimations. All the parameters of the analysis were chosen according to ICH [Q2 (R1)] guideline and validated statistically using RSD and %RSD along with neat chromate grams. Abafungin at its λ max 244nm shows linearity in the concentration range 20-60µg/mL.

Keywords: Method Development, Validation, 1st order derivative spectroscopy, Abafungin, UV Vis Spectrophotometry.

F-16

Analytical method development and validation for the determination of Clopidogrel by UV Spectroscopy in API and pharmaceutical dosage form

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Abstract:

A simple and sensitive spectroscopy method for quantitative determination of Clopidogrel in pure form and in pharmaceutical dosage form was developed. Clopidogrel showed maximum absorbance at 230 nm in 0.1N ethanolic HCl. The linear calibration curve was obeyed in the concentration range of 5 to 40 µg/ml with correlation coefficient of R^2=0.999. The linear regression equation is y=0.026x-0.016. The method has good precision within 2% and average accuracy as 96.68%. No significant interference was observed in the absorbance of drug

in the presence of common excipients and analysis conditions. The method can be employed for the quantitative determination of Clopidogrel in pure and in tablet dosage form, the assay values found were 97.11% and 134.25 %respectively.

Keywords: Calibration curve method, Clopidogrel, UV spectroscopy.

F-17

Simultaneous Estimation of Paracetamol and Mefenamic acid in tablet dosage form by Ultraviolet Spectroscopy method

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Abstract:

Simple, economical, precise and accurate method was developed for the simultaneous determination of Mefenamic acid (MFA) and Paracetamol (PCM) in combined tablet dosage form. The solvent used was 0.1 N Sodium hydroxide and the absorption maxima for Paracetamol and Mefenamic acid were found to be 255 nm and 285 nm respectively. A linear response was observed in the range of 2-12 µg/mL with a correlation coefficient of 0.997 and 0.992 for PCM and MFA respectively. The method has been validated as per ICH Q2 (R1) (International Conference on Harmonization) guidelines. The percentage assay of commercial tablet in combination dosage form of PCM and MFA was found to be in the range of 94.18% and 93.16% respectively. The developed and validated method can be successfully used for the quantitative analysis of commercially available dosage form.

Keywords: Paracetamol, Mefenamic Acid, Simultaneous Equation Method, UV spectroscopy.

F-18

Development and Validation of Analytical Method for Simultaneous Estimation of

Anti-asthmatic Drugs by RP-HPLC

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Abstract:

The presented work describes development of a simple, accurate and reproducible RP-HPLC method for the simultaneous estimation of Montelukast sodium (MONT), Acebrophylline (ACB) and Desloratadine(DSL) in their combined dosage form by using Sodium dihydrogen Phosphate buffer having pH 3.0 adjusted with Orthophosphoric acid (OPA). Mobile phase has been selected as Buffer: Acetonitrile (20: 80). Sample has been prepared in mobile phase, flow rate was 1.0 mL/min, column BDS C18 (250 x 4.6), column temperature 25°C was selected for process, injection volume was 50 µL and spectra were scanned at 210 nm wavelength. Chromatogram has shown sharp and symmetric peaks with retention time 4.469, 6.055 and 7.798 min, respectively. Developed method has been validated for ternary combination through RP-HPLC. LOD was found to be 5.60, 4.28 and 7.19 µg/mL for MONT, ACB and DSL, respectively. LOQ was found to be 16.97, 12.98 and 21.79 µg/mL. Precision values were expressed as % RSD which were found to be less than 2% Relative Standard Deviation (RSD) for this method. Percentage assay values for the market formulation (BIGPHYLIN-PLUS) were calculated as 101.05, 99.94 and 100.12%, respectively. All the validation parameters are found within ICH specified limits. Hence, it can be applied for routine analysis of Montelukast sodium (MONT), Acebrophylline (ACB) and Desloratadine (DSL) in pharmaceutical formulations.

Keywords: Montelukast; Desloratadine; Acebrophylline; Simultaneous estimation; Validation.

F-19

Development and Validation of RP-HPLC Method for Simultaneous Estimation of Fexofenadine Hydrochloride, Montelukast Sodium, and Ambroxol

Hydrochloride

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Abstract:

A novel combination of Fexofenadine HCL, Montelukast sodium and Ambroxol HCL is used in the treatment of allergic rhinitis, bronchial asthma and chronic obstructive pulmonary disease. A simple, rapid, accurate and reproducible method has been developed on this combination of FEX, MLK and AMB by RP-HPLC. In this method Sodium dihydrogen phosphate buffer

was adjusted to pH 6.5 by using Orthophosphoric acid. Mobile phase was Acetonitrile: Buffer in proportion of 70:30. Dilutions were prepared by using mobile phase as diluents. Flow rate was set at 1 mL/min; Column C18 (150× 4.6mm, 5µm *id.*) was selected. Injection volume of 50 µL was injected and spectra were scanned at wavelength of 210 nm. The retention time was found at 2.775, 5.261 and 9.529 min for FEX, MLK and AMB respectively. Analytical Method Validation was performed on the above developed method for ternary combination by HPLC. The method was found Linear over a concentration range 10-30, 10-50, 5-25 µg/mL for FEX, MLK and AMB respectively. LOD was found to be 1.1179, 2.2437 and 0.9903 µg/mL, and LOQ was found to be 3.381, 6.799 and 3.001 µg/mL, whereas percent relative standard deviation was 0.023, 0.032 and 0.034 for FEX, MLK and AMB, respectively. Percentage purity in marketed formulation was found to be 99.42, 97.31 and 100.88% for FEX, MLK and AMB, respectively. In the absence of official monograph these validated methods can be used for determination of all these three drugs.

Keywords: Simultaneous estimation, Method development and validation, RP-HPLC,

F-20

Development and Validation of HPTLC method for simultaneous estimation of Hydrochlorothiazide and Telmisartan using Quality by Design

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Abstract:

The purpose of the present study was to develop a simple, fast, precise and accurate HPTLC method for simultaneous estimation of Hydrochlorothiazide and Telmisartan using Quality by Design approach. Plackett Burman design was used as a screening design with resolution as response and seven factors to work on it. Three Critical Method Parameters were obtained from the design. Further studies were done by applying Response Surface Methodology. Box-Behnken design was applied as optimization design, considering proportion of non-polar phase, concentration of modifier and migration distance as factors and each factor was varied at three levels. The chromatographic separation was performed using aluminium backed pre-coated with silica gel $60F_{254}$ as stationary phase and toluene: methanol : triethylamine (7:3:0.3 v/v/v) as mobile phase. The quantification was carried out at wavelength of 281 nm. The method was validated as per ICH Q2(R1) guideline. Rf value of Hydrochlorothiazide and Telmisartan was found to be 0.26±0.02 and 0.67±0.02 respectively. Linearity was found in the range of 10-50 ng/band for Hydrochlorothiazide and 30-150 ng/band for Telmisartan. Correlation coefficient for Hydrochlorothiazide and Telmisartan was found to be 0.9959 and 0.9991 respectively. The LOD and LOQ for Hydrochlorothiazide were found to be 0.94 ng/band and 9.44 ng/band respectively and for Telmisartan the LOD and LOQ were found to be 1.77 ng/band and 17.73 ng/band respectively. Percentage recovery was found to be in range of 98.74-99.11 % for Hydrochlorothiazide and 98.94-99.59 % for Telmisartan.

F-21

Simultaneous Estimation of Amlodipine Besylate (AMB) And Olmesartan Medoxomil (OLM) From Marketed Formulations by UV-Spectrophotometric methods

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Abstract:

Analytical chemistry may be defined as the science and art of determining the components of materials in terms of the elements or compound contained. Analytical techniques plays an important role in assuring and maintaining the quality of substance and are critical components of Q.A./Q.C. Review of literature revealed that although there are few methods reported for estimation of Amlodipine Besylate (AMB) and Olmesartan Medoxomil (OLM) singly and combined. However, no method is so far reported for simultaneous estimation of these drugs in combined dosage form by the current spectrophotometric. In present study we are planned to develop UV-Visible spectrophotometric method for the estimation of OLM in pure and formulated tablet dosage form. The spectrophotometric method for simultaneous estimation employed first derivative spectrophotometric method for analysis using methanol as a solvent. AMB has absorbance maxima at 239 nm and OLM has absorbance maxima at 256 nm. Both these drugs obey Beer's law in the concentration range of 5-35 µg/ml (AMB) and 5-40 µg/ml (OLM). The recovery studies ascertained the accuracy of the proposed method and the results were validated as per ICH guidelines. The results were found satisfactory and reproducible.

Keywords: Amlodipine Besylate (AMB) and Olmesartan Medoxomil (OLM), UV-Visible Spectrophotometric, Beer's Law

F-22

Forced Degradation Studies and Validated Stability-Indicating HPTLC Method for Determination of Dicyclomine HCl and Paracetamol

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Abstract:

A simple, precise, accurate and stability-indicating HPTLC method was developed for simultaneous estimation of Paracetamol and Dicyclomine HCl in bulk and pharmaceutical dosage form. The developed method involves the use of HPTLC plates pre-coated with silica gel $60F_{254}$ on aluminum sheet as the stationary phase and Toluene: Methanol: Acetic acid (7.0: 2.0: 0.5 v/v/v) as the mobile phase. Densitometric scanning was carried out at 249nm for Paracetamol and 540nm for Dicyclomine HCl using Camag TLC scanner III. Both the drugs were subjected to acid and alkaline hydrolysis, oxidation, thermal and photolytic degradation. Paracetamol was found to be stable under the conditions of forced degradation studies employed but Dicyclomine was found to be susceptible to oxidative degradation. The calibration curve was linear over the range of 200-800ng/spot for Paracetamol and 2000-7000ng/spot for Dicyclomine HCl. The method was validated as per the ICH guidelines and it was found to be stability-indicating as quantification, separation and resolution was obtained satisfactorily. The developed HPTLC method can be employed for the determination of Paracetamol and Dicyclomine in their fixed dose combinations.

Keywords: Paracetamol, Dicyclomine HCl, HPTLC, acid hydrolysis, alkaline hydrolysis, oxidation, stability-indicating, ICH guidelines.

F-24

Comparison and evaluation of freely supplied government and ethically marketed antihypertensive drug (Atenolol)

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Abstract:

The main aim of present research work is to compare and evaluate the quality standards of generic and branded antihypertensive drug (Atenolol).The drugs are evaluated and results showed that branded and generic meet the pharmacopoeial specifications. Further all tablets passed weight variation, Hardness, Thickness, Friability, Disintegration, Dissolution, Assay parameters as per pharmacopoeia. Hence it can be concluded that branded and generic drugs of antihypertensive are equal. Hence health care professionals are sincerely suggested to prescribe generic drugs so that every individual can reach the coast of drugs and maintain health.

Keywords: Atenolol, in-vitro studies& physicochemical test.

F-25

Development of Reverse Phase Chromatographic Method for Determination of Known and Unknown Impurities in a Multicomponent Pharmaceutical Dosage Form.

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Abstract:

A simple, precise, accurate, simultaneous and specific RP-UPLC method developed with effective resolution for active pharmaceutical ingredients in a multicomponent pharmaceutical formulation containing Non-Steroidal Anti-Inflammatory Drug (NSAID) and analgesic category. This method was developed using Acquity HSS T3, C18, 2.1 × 150 mm column.A mobile phase used in this method was combination of 700 mL of

0.1% Trifluoracetic acid and 300 mL of Acetonitrile in Mobile Phase A and Mobile Phase B was 1.0 mL of TFA in 1000 mL of water. The flowrate was 0.3 mL/min and detection wavelength was carried out at 220 nm for NSAID and 260 nm for Analgesic drug where all related compounds eluted and monitored. The known and unknown impurities were well resolved from main peaks, proving this impurity analysis test method is specific. The developed method was validated as per USP and International Conference on Harmonization (ICH) guidelines. The current method has proven specificity, linearity and accuracy. The degree of reproducibility as results obtained by deliberate changes in the method parameter and variety of condition has proven the method is robust and rugged.Hence, this method was found to be suitable for the quantification of known and unknown impurities.

Keywords: RP-UPLC, Validation.

F-26

Simultaneous Estimation of Anti-Asthmatic Drugs In Pure and Pharmaceutical Dosage Form by UV Spectroscopy Method

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Abstract:

Asthma is a common long-term inflammatory disease of the airways of the lungs. There are many drug combinations available in market for treatment of asthma and so many have been being developed. In the present work, we have developed a simple, precise, accurate and specific analytical method for the combination of anti-asthmatic drugs (Doxofyline, Monteluklast and Levocetirizine dihydrochloride) by UV spectroscopy.The λ_{max} for doxofyline, montelukast and levocetirizine were found at 273.3, 283.1 and 231.05 nm, respectively. The method was developed using Vierdot's Method and First Order Derivative Spectrophotometry. The developed method was validated according to the ICH guidelines. In Vierdot's method LOD was found to be 1.18, 1.12, 0.97 µg/mL for DOXO, MONT and LEVO respectively. LOQ was found to be 3.59, 3.39, 2.94 respectively. % RSD was calculated which less than 2 were showing good precision. % Mean Recovery was found to be99.88, 99.71, 100.50% for DOXO, MONT and LEVO respectively by first derivative method. The percentage assay for the market formulation was found to be 99.84% by Vierdot's method and 100.27% by First order derivative method. The results for validation parameters were within ICH specified limits.

Keywords: Asthma, Vierdot's, Precision, LOD, LOQ.

F-27

Stress Stability Behaviour of Indomethacin

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Abstract:

Stress testing is an essential step in the design of a regulatory compliant stability program for both the drug substances and the products. Over the years, the regulatory requirements of stress testing have been extended to generic drugs, so the subject has attracted global interest.Stress testing also helps in building knowledge space to avoid unanticipated market recalls due to stability failures. Also, ANVISA of Brazil has approved 'Resolution RDC 53/15'in December 2015, which has outlined specific requirements for product registration and post-approval change submission with regard to reporting, identification and qualification of degradation products in drug products. The guideline emphasizedthat extent of drug degradation in the product should be greater than 10%.The current study aimedto perform stress testing of indomethacin in both solution as well as solid state to explore the degradation pathway. In solution stress study, the drug was found more labile in hydrolytic as well as photolytic conditions. Further, 3 monthssolid stress study revealed that the drug is prone to degrade in alkaline medium under accelerated stability condition (40˚C/75% RH). To simulate the alkaline condition, drug was kept with solid base stressor (sodium carbonate) in the ratio of 1:2. The drug was found stable under acidic and neutral conditions in solid state. The degradation products were separated on a C-18 column in a gradient mode using stability indicating method.

Keywords: Stability indicating method, Indomethacin, Stress testing, Degradation products

F-28

Simultaneous Estimation of Doxofyline, Montelukast and Levocetirizine Dihydrochloride in Pure and Pharmaceutical Dosage Form by RP-HPLC Method

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Abstract:

Effective method development ensures that laboratory resources are optimized, while methods meet the objectives required at each stage of drug development. Method validation is the process of demonstrating that analytical procedures are suitable for their intended use. In the present work, we have developed a simple, precise, accuarate and specific analytical method for the combination of Doxofyline (DOXO), Monteluklast (MONT) and Levocetirizine dihydrochloride (LEVO) by RP-HPLC technique. The λ_{max} for Doxofyline, Montelukast and Levocetirizine were found at 230, 254 and 280 nm, respectively. The method was developed using Agilent (4.6×250 mm) column and PDA detector. The developed method was validated according to the ICH guidelines. The develop method was found linear over a concentration range 10-50 µg/ml with R^2 values 0.9998, 0.9999 and 0.9999 for DOXO, MONT and LEVO respectively. LOD values were determined as 3.0, 6.01 and 7.2 µg/ml for the drugs where as LOQ values were found to be 11.9, 17.62 and 22.7 µg/ml respectively. For precision studies % RSD values were calculated as 0.055 for DOXO, 0.087 for MONT and 0.071 for LEVO. Retention times were determined as 4.425, 7.409 and 8.558 respectively. Percentage estimation for DOXO, MONT and LEVO was found to be 101.21%, 98.90% and 100.4% respectively in market formulation. All the validation parameters were found to be within ICH specified limits.

Keywords: Method development, Precision, LOD, LOQ, market formulation.

F-29

Compatibility of Ambroxol with Excipients

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Abstract:

Generally, excipients are inert in nature and have no direct pharmacological action. But, they can impart useful properties to the formulation. However, they can also give rise to inadvertent and/or unintended effects, such as increased drug degradation. Physical and chemical interactions between drugs and excipients can affect the chemical nature, the stability and bioavailability of drug products, and consequently, their therapeutic efficacy and safety. Chemical interactions result from reactive functional groups that interact directly with the active pharmaceutical ingredients. Alternatively, they may contain impurities or residues, or form degradation products may cause decomposition of the drug substance. Free amine containing drugs are more susceptible to degradation in the presence of reactive impurities like peroxide, formaldehyde, acids, nitriles, nitrates, etc. To explore the same, ambroxol was selected as a model drug which contain free amine group and is marketed as tablets, capsules and syrups. To establish drug-excipient interaction, accelerated stability study was done at 40 ºC /75% RH for 1 and 3 months. The drug and excipient kept in ratio was 1:2 in both wet and moist conditions. A stability indicating method was employed for the purpose of analysis of samples. Significant changes were seen in case of tartaric acid and glycine, when kept together with the drug. The stress degradation study was also revealed that the drug was more susceptible to oxidative and photo basic conditions.

Keywords: Ambroxol, Excipients, Impurities, Peroxides, Interaction products

F-30

Development of validated HPLC-UV method for simultaneous estimation of fourdrugs prescribed in fixed dose combination as Antidiabetic and antihypertensive

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Abstract:

A simple, sensitive, fast, and economical HPLC method was developed and validated for Simultaneous estimation of two fixed dose combinations frequently prescribed in diabetes (Metformin plus Glibenclamide) and hypertension with dyslipidemia (Amlodipine plus Atorvastatin)in Human plasma for the first time. The validated HPLC method was used to quantify the concentration of selected actives in ultra filtrate. Optimum separation conditions were obtained with Water's Nova pack Phenyl (150 mm × 4.6 mm, i.d., 5.0 µm) column with mobile phase consisting of 0.1 % Phosphoric acid (pH 3.0) and acetonitrile (ACN) in gradient mode with column oven temperature maintained at

30 °C and elution monitored by a UV detector at 227 nm. Protein precipitation was employed to extract the selected analyte form human plasma. The recoveries were more than 90% for all analytes in cold aqueous 10%trichloroacetic acid (TCA) and acetonitrile. The optimized HPLC-UV was validated in the calibration range of 10-10000 ng mL-1 for Metformin, 25-5000 ng mL-1 for amodipine, 50 10000ng mL-1 for glibenclamide and 10-5000 ng mL-1 for atorvastatin. The mean relative error was least when weighing of 1/×2 was applied for calibration curve. The accuracy of samples for six replicate measurements at LLOQ level was within limit. The precision and accuracy of samples for six replicate measurements at LLOQ level was within limit. The validated method was applied for quantitation of selected analytes in ultrafiltrate from protein binding experiments. A four to five fold increase in unbound fraction was observed when spiked to human serum albumin. Further the unbound fraction of highly albumin bound drugs was increased nearly to double when incubated with Gly-HSA as compare to HSA.

Keywords: Metformin; Glibenclamide, amlodipine; atorvastatin; HPLC-UV; Protein Binding, Glycated human serum albumin.

F-31

Development and validation of Sitagliptin and Simvastatin tablets by using RP-HPLC method

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Abstract:

A simple, precise and accurate RP-HPLC method has been developed for simultaneous estimation of Sitagliptin phosphate and Simvastatin. In RP-HPLC method, mixture of pH 4.0 sodium phosphate buffer and acetonitrile in the ratio of 20:80 v/v was selected as a mobile phase and equal proportions of water and acetonitrile with one drop of phosphoric acid was selected as solvent which gives good resolution and good peak shapes for Stagliptin and Simvastatin. The flow rate was set at 1.0 ml/min, and the detection was carried out with UV detector at 250 nm. Sunfire C18 250 × 4.6 mm, 2.5 µm column was used for the separation. The total run time required was 20 mins. The linearity and range was established over the range of 25-150 µg/ml and 10-60 µg/ml concentration range Stagliptin and Simvastatin. The correlation coefficient of Stagliptin and Simvastatin was found to be 1. The method validation data showed excellent results for accuracy, precision, linearity, specificity, limit of detection, limit of quantification and robustness. The present method can be successfully used for routine quality control analysis.

Keywords: Sitagliptin, Simvastatin, RP-HPLC, Validation.

F-32

Development of validated HPLC method for simultaneous estimation of valsartan and nateglinide and its application to protein binding studies

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Abstract

In this research work, an attempt was made to study alteration in glycated serum albumin binding of valsartan and nateglinide using validated HPLC-UV method and ultrafiltration as in vitro protein binding study model. The chromatographic conditions involved stationary phase Kromasil-100 C18 (100 x 4.6 mm, 3.5 µm) with mobile phase of 10 mM phosphate buffer, acetonitrile, isopropyl alcohol in the ratio of 30:65:5 as isocratic mode at a flow rate of 0.8 mL/min; and the eluent was monitored at 218 nm. Protein precipitation technique was used to extract the drugs from human plasma. The calibration curve was found linear in the range from 50 to 5000 ng/mL. Glycation of human serum albumin was achieved at different concentration levels using D-(þ)-glucose and glycated human serum albumin (Gly-HSA) were prepared. Valsartan and nateglinide were not affected the plasma protein binding of each other when studied using HSA. The unbound fraction of valsartan and nateglinide was increased to 10–20 times when spiked with Gly-HSA. About 20% increase in unbound fraction of valsartan was observed when spiked with 10 µg/mL of nateglinide. Furthermore, the unbound fraction of nateglinide was increased nearly to 10% more when incubated with Gly-HSA as compare to recombinant human serum albumin.

Keywords: HPLC-UV, valsartan, nateglinide, simultaneous estimation, Gly-HAS, Protein precipitation technique, human plasma.

F-33

Formulation and Evaluation of pH Dependent *In-Situ* Nasal Gel ofLoratadine

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Abstract:

Nasal drug delivery route is a feasible alternative to oral or parenteral administration for some of the drugs because of high permeability of nasal epithelium, rapid drug absorption across the membrane and avoidance of hepatic first-pass metabolism. The aim of the present study was to formulate and evaluate the pH dependent in-situ nasal gel of Loratadine toincrease residence time and enhance the bioavailability of drug with better therapeutic outcome. This mucoadhesivenasal drug delivery system may overcome the first pass metabolism and subsequently improve the bioavailability of Loratadine. Nine different in-situ formulations were developed using different pH sensitive polymeric ratios of Xanthan gum and Carbopol 934. All formulations were evaluated for parameters like pH, clarity, rheological study, stability studies and in vitro drug release. All formulation found to be in clear sol form and pH ranges from 5.3±0.063 to 7.3±0.022 i.e. no mucosal irritation is expected as pH was in acceptable range. The drug content was > 93%. Adequate mucoadhesive strength ranging from 0.59±0.018 to 2.36±0.013 to provide prolong adhesion. In-vitro drug release study showed that the F7 formulation could release the drug for up to 8 hrs with all formulation showing Higuchi kinetics. Stability studies at different test conditions showed that gels were stable over the 6 months period.

Keywords: Nasal drug delivery, Loratadine, pH sensitive, gels.

F-34

Analytical Method Development and Validation for the Simultaneous Estimation Of Paracetamol Aceclofenac and Serratiopeptidase in Tablet Dosage Form By UV Spectrophotmetric Method

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Abstract:

The drug combination paracetamol (PARA), Aceclofenac (ACE) and serratiopeptidase (SERRA) is used as anti-inflammatory, analgesic and anti-pyretic. The present work is aimed to develop a simple and economical UV Spectrophotmetric method for the determination of Paracetamol, Aceclofenac and Serratiopeptidase simultaneously in single step process. The method was based on employing simultaneous equation method for analysis of the drugs. The absorption maxima of the drugs were found to be 243, 273 and 278 nm for PARA, ACE and SERRA respectively in a common solvent, phosphate buffer pH 6.8. The absorbances of paracetamol, aceclofenac and serratiopeptidase were measured and the absorptivity values were determined at all the three wavelengths. The concentrations of three drugs in the mixture were calculated by using a set of three equations. PARA, ACE and SERRA obeyed beer's law in the concentration range of 5-45 µg/ml, 1-9 µg/ml and 0.25-1.25 µg/ml respectively. The method was validated for various parameters accuracy, precision, linearity, specificity, limit of detection, limit of quantification, ruggedness, robustness according to ICH guidelines. The results were found to be comply with the acceptance criteria for all the validation parameters. The low %RSD values in indicate good precision and high recovery values shows the excellent accuracy of the method. The developed method is a direct UV spectrophotometric method without derivatization, extraction and evaporation for simultaneous estimation of PARA, ACE and SERRA. Hence it is concluded that the proposed assay method can be successfully employed in the routine analysis of paracetamol, aceclofenac and serratiopeptidase in combined commercial dosage forms

F-35

Development and Validation of Spectrophotometric Method and Stability Indicating Hptlc Method for the Estimation of Edoxaban Tosylate Monohydrate in Its Synthetic Mixture

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Abstract:

A simple, sensitive and reproducible UV-Visible spectrophotometric method was developed and validated for the estimation of EdoxabanTosylate Monohydrate in its synthetic mixture. Methanol was used as a solvent. The method was found to be linear in the range of 5-25 µg/ml at λ_{max} 289 nm and the regression coefficient value was found to be 0.9999. For EdoxabanTosylate Monohydrate LOD and LOQ values were found to be 0.654 µg/ml and 1.982 µg/ml. The method was validated with respect to linearity, precision, recovery in accordance with

the ICH guidelines. The method was successfully applied for estimation of EdoxabanTosylate Monohydrate in its synthetic mixture. A stability indicating HPTLC method was developed and validated for estimation of EdoxabanTosylate Monohydrate in its synthetic mixture. Chromatographic separation was performed on pre-coated silica gel $60F_{254}$aluminium plate using the mobile phase methanol: ethyl acetate: triethylamine (6:4:0.1 v/v/v). The R_f value for EdoxabanTosylate Monohydrate was found to be 0.53 ± 0.03. The spots were scanned densitometrically at 295 nm. HPTLC Method was validated according to the ICH guidelines Q2(R1). The linear regression analysis data for the calibration plots showed a good linear relationship with r^2 0.9984 in the concentration range of 20-100 ng/band for EdoxabanTosylate Monohydrate. Percent recovery of drug was found in the range of 99.5 – 100.61% by developed method. Limit of detection and limit of quantitation was found to be 1.021 ng/band and 3.095 ng/band for EdoxabanTosylate Monohydrate, respectively. One degradation product was separated in acidic, alkaline and oxidative degradation conditions. The method was applied to estimate EdoxabanTosylate Monohydrate in its synthetic mixture.

F-36

Survey on Awareness Level of Consumers in Food Labelling and Safety

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Abstract:

The purpose of the study was to investigate the impact on awareness level of food safety and labels. The study sought to extend empirical evidence on the association between brand loyalty and product-related factors like packaging, price and brand awareness. The study adopted a quantitative survey approach and was conducted in schools, colleges and malls. Data was elicited from a conveniently selected sample of 1088 consumers who purchased various brands of food items. Data was analysed by investigate the impact of packaging and brand awareness. Packaging and labelling showed significant positive relationship with brand awareness, which implied their significant predictive influence on labelling. The results suggest that implementation of the brand awareness in order to enhance consumers safety.

Keywords: Food labelling, Consumer's knowledge, Nutrition, Health, Pre-packaged foods

F-37

Development and Validation of RP-HPLC Method for Simultaneous Estimation of Empagliflozin and Linagliptin in Tablet Formulation

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Abstract:

A simple, rapid, accurate and precise method has been developed for the simultaneous estimation of Empagliflozin and Linagliptin in bulk and in pharmaceutical dosage forms by reversed-phase high performance liquid chromatography. The separation was carried out on C18 column, using mobile phase consisting of a mixture of potassium dihydrogen orthophosphate buffer: methanol in the ratio 70: 30 and pH adjusted to 3.0 using orthophosphoric acid. The flow rate was adjusted to 1 ml/min. UV detection was carried out at a wavelength of 210 nm. The retention time of Empagliflozin and Linagliptin was found to be 2.253 min and 3.026 min respectively. Linear response obtained for Empagliflozin was in the concentration range 25-125 µg/ml (r^2 = 0.999) and Linagliptin in the range 5-25 µg/ml (r^2 = 0.999). LOD for both the drugs were 18 µg and 1.9 µg respectively and LOQ for both the drugs were found to be 61 µg and 6.4µg respectively. The method was validated according to ICH guidelines with respect to linearity, precision, accuracy, reproducibility, LOD, LOQ and robustness. The results obtained for accuracy, precision, LOD and LOQ were within the limits. Thus, the proposed method can be successfully applicable to the pharmaceutical preparations containing the above mentioned drugs.

Keywords: Empagliflozin, Linagliptin, Validation, HPLC.

F-38

Biomass from *Fusarium venenatum* and preliminary characterization of bioactives: Exploration of Hypolipidemic potential

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Abstract:

Fusarium venenatum derived mycoprotein (biomass)

marketed under the trade name Quorn has been designated as a source of first class protein with low cholesterol. Our previous study, demonstrates the significant antihyperlipidemic potential of biomass in acute Triton X-100 induced hyperlipidemic model in rats and anti-oxidant activity by DPPH assay. The biomass was produced through cost effective fermentation process in Vogel's mineral medium using sucrose as the carbon source, optimized using Central Composite Response Surface Design (CCRSD). In the current study, hypolipidemic potential of biomass was studied in the chronic high fat diet induced hyperlipidemic model in rats. The high fat diet fed rats showed significant increase in plasma lipid levels [total cholesterol (TC), triglycerides (TG), very low density lipoproteins (VLDL), low density lipoproteins (LDL)] with decreased high density lipoproteins (HDL) levels. Biomass (100, 200 and 400 mg/kg) and simvastatin (10 mg/kg) administered orally reduced the elevated serum lipids (TC, TG, VLDL, LDL), restored the decreased HDL and improved the atherogenic index ($p<0.01$) & also decreased the liver enzymes levels (SGOT, SGPT) comparable to standard treated group. LC-MS analysis of methanolic extract of biomass showed two major peaks (Compound 1: m/e 209.10 and Compound 2: m/e 329.25). Spectral matching with NIST libraries indicated that compound 2 may be structurally similar to pregnenolone, a naturally occurring steroid& compound 1 may be 4-aminothiophenol, N,S,-diacetyl (m/e 209.10). In conclusion, the study proves the hypolipidemic potential of biomass derived from *F.venenatum* in preclinical acute and chronic animal models.

Keywords: Fusarium venenatum, LC-MS analysis, High Fat Diet, Antihyperlipidemic activity

F-39

RP-HPLC Method Development and Validation for Estimation of Avanafil in Tablet Dosage Form

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Abstract:

A simple, accurate, precise, and reproducible Reverse Phase High Performance Liquid Chromatography (RP-HPLC) method was developed for the determination of Avanafil in tablet dosage form. The chromatographic separation was achieved on Inert sustain C18 column (250 mm × 4.6 mm id, 5 µ). The mobile phase used was Water and Acetonitrile in the ratio of (65:35%v/v) containing 0.1% TFA. The influence of mobile phase composition, injection volume, mobile phase pH, flow rate, temperature and detector wavelength was investigated. Retention time was found to be 10.77 min. Method was linear over the range of 5-100 µg/ml with regression coefficient 0.9994. The method was validated for system suitability, accuracy, precision, linearity and specificity. Validation studies reveals that the developed method is specific, rapid, reliable and reproducible hence it can be applied for routine quality control analysis of Avanafil in tablet dosage forms. The method was validated as per ICH guideline (ICH, Q2 (R1).

Keywords: Avanafil, HPLC, Validation

F-40

Simultaneous Estimation and Validation of Sofosbuvir and Velpatasvirin Tablet Dosage Form by RP-HPLC Method

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Abstract:

A simple, accurate, rapid and precise isocratic reversed phase high performance liquid chromatographic method has been developed and validated for simultaneous determination of Sofosbuvir and Velpatasvir in tablet dosage form. The chromatographic separation was carried out on C18 (250*4.6, 5µm) column with a mixture of Water: acetonitrile in the ratio of 40:60 %v/v containing 0.2 % Trifluroacetic acid as mobile phase. The influence of mobile phase composition, injection volume, mobile phase pH, flow rate, temperature and detector wavelength was investigated. The retention times were found to be 2.71 and 6.46 min for Sofosbuvir and Velpatasvir respectively. Calibration plots were linear over the concentration range 5-30 µg/ml with regression coefficient 0.999 for Sofosbuvir and 20-120 µg/ml with regression coefficient 0.999 for Velpatasvir. The method was validated for system suitability, accuracy, precision, linearity and sensitivity. The proposed method can be successfully used for quantitative analysis of pharmaceutical dosage forms. No interference from any component of pharmaceutical excipient was observed. Validation studies revealed that method is specific, rapid, reliable and reproducible. The high recovery and low relative standard deviation confirm the suitability of meth-

od for routine determination of Sofosbuvir and Velpatasvir in tablet dosage form.

Keywords: Sofosbuvir, Velpatasvir, HPLC, Validation.

F-41

Development and validation of Reverse Phase High Performance Liquid Chromatographic Method For Simultaneous Estimation Of Sacubitril And Valsartan In Tablet Dosage Form.

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Abstract:

A simple, accurate, rapid and precise isocratic reversed phase high performance liquid chromatographic method has been developed and validated for simultaneous determination of Sacubitril and Valsartan in tablet dosage form. The chromatographic separation was carried out on Kromasil C8 (250*4.6, 5µm) column with a mixture of Water: Acetonitrile in the ratio of 40:60 %v/v containing 0.1 % v/v Trifluro acetic acid as mobile phase. The influence of mobile phase composition, injection volume, mobile phase pH, flow rate, temperature and detector wavelength was investigated. The retention times were found to be 6.28 and 7.61 min for Sacubitril and Valsartan respectively. Calibration plots were linear over the concentration range 9.6-115.2 µg/ml with regression coefficient 0.999 for Sacubitril and 10.4-124.8 µg/ml with regression coefficient 0.999 for Valsartan. The method was validated for system suitability, accuracy, precision, linearity and sensitivity. The proposed method was successfully used for quantitative analysis of pharmaceutical dosage form. No interference from any component of pharmaceutical excipientwas observed. Validation studies revealed that method is specific, rapid, reliable and reproducible. The high recovery and low relative standard deviation confirm the suitability of method for routine analysis of Sacubitril and Valsartan.

Keywords: Sacubitril, Valsartan, HPLC, Validation.

F-42

Analytical Method Development and Validation for the Estimation of Vildagliptin in Bulk and Its Dosage Form Using UV Spectrophotometer

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Abstract:

A simple, rapid, precise and economical Analytical method development has been developed for quantitative vildagliptin in manufactured tablet formulation. The stock solution and subsequent dilution of vildagliptin was done in 0.1% NaOH. Solution of vildagliptin in 0.1% NaOH showed absorption maxima at 216.00 nm. The drug obeyed Beers-Lamberts Law in the concentration range of 1-100 µg/mL with Coefficient of correlation (R2) was 0.997. The standard the method can be adopted in routine analysis of vildagliptin in bulk and tablet dosage form.

Keywords: Vildagliptin, Method Validation, Spectrophotometric

F-43

Separation and Estimation of six AT_1- Receptor Blockers in Presence of Hydrochlorothiazide by HPLC Technique in Their Pharmaceutical Formulations

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Abstract:

For the first time sensitive and a speedy isocratic RP-HPLC method was developed for the separation and quantitative development of six AT_1-receptor antagonists namely Telmisartan (TELM), Losartan (LOSA),Valsartan (VALS), Olmesartan (OLME), Irbesartan (IRBE), Fimasartan and Atenolol (ATEN) along with thiazide diuretics mostly Hydrochlorothiazide (HCTZ). The chief advantage of developed method was that the eight individual drugs and even combination with HCTZ can be determined by a single chromatographic system without alteration in detection wavelength and mobile phase composition. The RP-HPLC method was developed by using Welchrom C_{18} column (4.6 X 250 mm, 5 µm) as a stationary phase with the mobile phase mixture of phosphate buffer with pH-3.3 and acetonitrile in the fraction of 50:50 v/v. The mobile phase was pumped at a flow

rate of 1 mL/min. The wavelength of the UV detection was done at 230 nm. The total run time was seven minutes and the elution window of only four minutes. The calibration curves were linear (r^2 = 0.9999) in all cases. The percentage relative standard deviation (% RSD) was less than 2 % and average recovery was above 99.95 %. This novel method was statistically validated as per ICH guidelines. The optimized method has been proved to be linear, accurate and robust. Hence the method can be recommended for routine quality control analysis.

Keywords: AT1- receptor antagonists, standard deviation, Quality control, Olmesartan, Irbesartan, Fimasartan

F-44

Study of Forced Degradation Behavior of Nitrate Esters of Paracetamol by LC-MS and Development of the Degradation Pathway

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Abstract:

The present study is based on the comprehensive forced degradation of novel nitrate esters of paracetamol. The drug molecules (TRB12 and TRB13) were subjected to solid state stability studies at accelerated conditions (40°C±2°C and 75%RH±5%RH) for a period of 3 months. The drug molecules (TRB12 and TRB13) were subjected to various stress conditions of hydrolysis (acidic, alkaline, and neutral) as well as oxidation conditions at 80°C as defined by ICH guideline Q1A (R2). The percent degradation after 8h stress studies for acidic degraded TRB 12 and TRB13 was found to be 17.9±1.76% and 15.9±1.89% respectively whereas % degradation for alkaline degraded TRB12 and TRB13 was found to be 16.51±1.47% and 15.9±1.54% respectively. In case of neutral degradation studies the percent degradation for TRB12 and TRB13 was found to be 19.4±1.97% and 11.1±2.16% respectively. In order to isolate and characterize the degradation products obtained during the forced degradation studies. The products formed under different stress conditions were investigated by LC and LC–MS. The LC method used for the separation of the degraded products involved the C18 column and the mobile phase comprises of acetonitrile: water in the ratio of 80: 20.The method so adopted was accurate, precise, specific and selective. The products were characterized through LC–MS fragmentation studies. The LC-MS m/z values and the fragmentation pattern for TRB13 and TRB12 showed maximum degraded products in case of acidic hydrolysis and minimum degraded products were observed in case of alkaline hydrolytic degradation. Based on the results obtained through these studies, a more complete degradation pathway for the drug could be proposed.

Keywords: Nitrate ester of paracetamol (TRB12 and TRB13), Stability indicating assay, Forced degradation study, LC-MS study and Degradation pathway.

F-45

Development and Validation of an HPLC Method for Quantification of Eugenol in Extract of *Syzygiumaromaticum L*

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Abstract:

Eugenol is one of the important constituents in clove (*Syzygiumaromaticum L.*) which has wide range of medicinal value. A simple, sensitive and precise RP-HPLC chromatographic methodwas developed and validated for estimation of Eugenol in *Syzygiumaromaticum*. The separation was achieved by using InerstilODS-4 (250 mm× 4.6 mm, 5µm) column with mobile phase composed of 0.1% O-PA (Ortho-Phosphoric acid) in water(pH- 2.5) and acetonitrile with gradient elution. The method was validated as per the ICH guidelines for linearity, accuracy, robustness, solution stability, specificity and precision.Linearity (r^2≥0.999) was observed for the Eugenol in 50-150% concentration range. Relative standard deviation values for method precision and intermediate precision studies were found to be1.05. Average analytical recoveries were observed as 101.14%. The standard solution and test solution were stable up to 20 hours at room temperature. This method was developed for both standard eugenol and eugenol present in extract.

Keywords: *Syzgiumaromaticum L.,* **Eugenol, ICH Guidelines, HPLC.**

F-46

Stability Indicating RP-HPLC Method for Determination of Inempagliflozin and Linagliptinin Bulk and Pharmaceutical Dosage

Forms

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Abstract:

The present method describes the development of a validated HPLC (Schimadzu) for determination of inEmpagliflozinand linagliptin in presence of pharmaceutical excipients. Seperation was carried out on Enable C18 (4.6 x 250mm, 5mm) by using mobile phase consisting of a mixture of buffer : :Methanol: Acetonitrile: Ortho Phosphoric Acid(60:20:20) with the flow rate of 1.0mL/min. UV detection was performed at 234nm and retention time was found to beEmpagliflozin - 2.11 min &Linagliptin -5.12 min. The method was validated for linearity, accuracy and precision .Linearity concentrations of Empagliflozinis 25-150 µg/ml, Linagliptin is 30-180 µg/ml with correlation coefficients 0.996 & 0.999. The mean recoveries were found in the range of 100.03% and 100.27% and the % RSD of method precision was found to be within the acceptance criteria, hence the method is more accurate and precise. The Limit of Detection and Limit of Quantification for Empagliflozinare 3.29&9.97 respectively and for Linagliptin are 2.83&8.59. No interfering peaks were found in the chromatogram indicating that excipients used in tablet formulations did not interfere with the estimation of the drug by proposed HPLC method.

Keywords: HPLC, Empagliflozin and Linaglitin, Stability Studies.

F-47

Stability Indicating RP-HPLC Method for Determination Of Fenoprofen In Bulk And Pharmaceutical Dosage Forms

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Abstract:

The present method describes the development of a validated RP-HPLC for determination of fenoprofen in presence of its degradation products and other pharmaceutical excipients. Seperation was carried out on HPLC (Schimadzu) Enable C18 (4.6 x 250mm, 5mm)by using mobile phase consisting of a mixture of buffer Methanol:Acetonitrile (80:20% v/v) with the flow rate of 1.5ml/ min UV detection was performed at 270nm and retention time was found to be 5 min. The method was validated for linearity, accuracy and precision. Linearity for fenoprofen was in the range of 10-80 µg/mL with a correlation coefficient value of 0.9999. The mean recoveries were found in the range of 99.85% and 100.27% and the % RSD of method precision was found to be within the acceptance criteria, hence the method is more accurate and precise. The Limit of Detection and Limit of Quantification were 2.082 and 6.92µg/mL respectively indicate the sensitivity of the method. No interfering peaks were found in the chromatogram indicating that excipients used in tablet formulations did not interfere with the estimation of the drug by proposed HPLC method.

Keywords: HPLC, Fenoprofen, Stability Studies.

F-48

Method Development and Simultaneous Estimation of Antihypertensive Drugs in Newly Formulated Controlled Release Dosage Form

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Abstract:

The primary objective of the present work was to formulate a controlled release tablet formulation using a natural gum and to evaluate the same. The rationale for selecting the natural gum as release retardant materials is that they have an advantage when compare to the synthetic or semi-synthetic materials in terms of biocompatibility, cost, versatility, etc. Five formulations of controlled release tablets were prepared by direct compression method and they were evaluated for hardness, friability and weight variation. Comparative dissolution study was performed for the formulated products. The dissolution studies showed that the formulation F4 showed a controlled release which extended upto the 12th hour. The percentage drug release was found to be upto 97% of the three drugs. A simple, sensitive and specific RP-HPLC method was developed for the simultaneous estimation of hydrochlorthiazide, amlodipine and losartan in the formulated tablet dosage form. Separation was achieved using Phenomenex Kinetex C_{18} (5µ, 100A, 250×4.6mm) column. The mobile phase was ACN : 0.1% OPA in water in the ratio 40:60, with a flow rate of 1.0ml/min, moni-

tored at 230nm. The selected chromatographic conditions were found to give effective separation of hydrochlorthiazide, amlodipine and losartan with retention time of 2.8min, 4.1min and 4.5 min respectively. The validation paramerers- accuracy, precision, LOD, LOQ, robustness and system suitability were found to be within the acceptable limits. Thus the proposed method was found to be accurate, precise, reproducible and specific.

Keywards: Controlled release formulation, Natural gum, Hydrochlorthiazide, Amlodipine, Losartan

F-49

Development and Validation of Stability indicating HPTLC Method for Simultaneous Estimation of Metformin Hydrochloride and Teneligliptin Hydrobromide Hydrate in Bulk and Pharmaceutical Dosage Form

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Abstract:

A selective, precise, and accurate High-performance thin-layer chromatographic (HPTLC) method has been developedfor simultaneous estimation of Metformin hydrochloride and Teneligliptin hydrobromide hydrate in bulk and pharmaceutical dosage form. The method was performed using precoated silica gel plate 60 F_{254} using Toluene : Ethanol : GAA : TEA (4 : 4.5 : 0.5 : 0.5 v/v/v/v) as the mobile phase. The peak was recorded at 241 nm. Stability studies were performed on API to develop stability indicating HPTLC method. The drugs were subjected to change undervarious environmental conditions such as acidic hydrolysis, alkaline hydrolysis, thermal degradation, oxidation etc. to determine their effect on the stability of drugs. The method was validated as per the International Conference on Harmonization (ICH).The R_f value of MET and TEN were found to 0.49 and 0.69 respectively. Linear responses were observed in the concentration range of 1000 - 3500 ng/band for MET and 1000 - 3500 ng/band for TEN. The % RSD for precision and robustness was found to less than 2%. The results of accuracy of MET and TEN were found to 100.80 and 101.06 % respectively. The resolution was good and content of MET and TEN in formulation were found 98.62 % and 99.14 % respectively. MET and TEN were more prone to acidic hydrolysis as compared to other degradation.The developed method successfully separated drug substances from degradation products formed under various stress conditions.

Keywords: Stability indicating HPTLC, Metformin hydrochloride and Teneligliptin hydrobromide hydrate

F-50

Quality by Design Approach for Development and Validation of Stability Indicating HPTLC Method for Estimation of Metformin HCL and Ursodeoxycholic Acid in Pharmaceutical Formulation

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Abstract:

The present work is regarding QbD approach for HPTLC chromatographic method for analysis of Metformin HCL and Ursodeoxycholic acid in their combined dosage form which is useful in treatment of obesity induces Diabetes mellitus.The standard solution of Metformin HCL and Ursodeoxycholic acid were applied in band width 6 mm using Hamilton 100 µl syringe on pre coated silica gel aluminum plate 60 F_{254} using automatic application device. DoE concept was used for optimizing HPTLC conditions; where in the critical factors were identified using Taguchi design.The applied Box Benhnkon experimental deign for the optimization of selected parameters. The separation was achieved by mobile phase Toluene: Ethanol: Acetone: Formic acid (4.5:2:2.5:0.85 v/v/v/v). $R_f$values of Metformin HCL and Ursodeoxycholic acid were found to be 0.19 and 0.8 respectively. The detection was carried out at 234 nm and 700nm for MET and URSO respectively. Linear responses were observed in the concentration range of 5000-40000 ng/band for Metformin HCL and 1500-12000 ng/band Ursodeoxycholic acid. Developed method was validated for linearity, accuracy, precision, limit of detection and limit of quantification according to ICH guidelines. Accuracy of method was determined by recovery studies and showed % recovery between 98 to 102%. Intraday and Interdayprecision were performed and mean %RSD were found to be less than 2. The developed method successfully separated MET and URSO from its degradants. MET and URSO were more prone to acidic and alkaline hydrolysis as compared to other degradation respectively.

Keywords: Stability indicating HPTLC, Quality by design, Metformin HCl, Ursodeoxycholic acid

F-51

Validated Stability indicating RP- HPLC Method To Investigate Degradation Profile and Optimization Of Degradation Study For Tenofovir

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Abstract:

Tenofovir, an antiretroviral drug known as reverse transcriptase inhibitor, was evaluated for its degradation behavior. The study involved optimization of forced degradation conditions and development of a stability indicating assay method (SIAM) for tenofovir using the design of experiment (DoE) approach. Chromatographic separation was achieved on Kromasil C18 (150×4.6 mm, 5µm) column using methanol: 10mM Ammonium acetate buffer pH 8.5; (60:40) as mobile phase with flow rate of 1 mL/min at 260 nm wavelength. Tenofovir showed degradation at acid hydrolysis, alkaline and oxidative condition while it was stable to photolysis and thermal stress condition. Separation of Tenofovir and degradation products was carried out by using developed RP-HPLC method. The optimization of forced degradation conditions, like hydrolytic and oxidative, was done by application 3^n full factorial designs, which helped to obtain the desired drug degradation. The proposed method was successfully validated as per ICH Q2 (R1) guidelines.

Keywords: Degradation, RP-HPLC, Stability indicating, Tenofovir

F-52

Modification in RP HPLC Analytical Method for the Assay of Sennosoids

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Abstract:

The Sennoside A and Sennoside B are official in Indian Pharmacopoeia and United State Pharmacopeia. The modification in the HPLC analysis of herbal extract of senna alkaloid was made. The remarkable results with repeatability in the peak area of sennoside A and sennoside B were observed. The analysis of senna extract, for the determination of percent purity was performed using reverse phase HPLC method. The method was selected with a little modification and the analysis for the assay was performed using a stainless steel column of 250mm ×4.6mm, C18, 5µm, make: SPOLAR SHISEIDO. Mobile phase was a mixture of 83 volumes of a 1 %(v/v) solution of glacial acetic acid and 17 volumes of acetonitrile and it was allow to flow at 1ml per minute and the λ max was 350 nm, injection volume was 10µL and the column temperature was ambient. A 0.3 % (v/v) solution of acetic acid with PH adjusted to 5.9 with 1 M sodium hydroxide was selected as diluent. The system suitability parameters complies and peak area was obtained in 7 digits.

Keywords: Senna, Herbal drug, RP-HPLC, Alkaloid, Sennoside A, Sennoside B, Assay, Analytical method

F-53

Development and Validation of RP-HPLC Method for Simultaneous Quantitative Estimation of Selected Anti-Retroviral Drugs in Nanoformulation

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Abstract:

In this work a simple, precise and economical Reverse Phase-High Performance Liquid Chromatographic method has been developed for the simultaneous quantitative estimation of Etravirine and Elvitegravir in nanoparticulate formulations. The chromatographic conditions were optimized and validated according to the standard ICH guidelines. The separation was done on a C18 column (250 mm x 4.6 mm, 5 µm) using Methanol and phosphate buffer of pH (5.6) as the mobile phase in the ratio 78:22 V/V in the isocratic mode at a flow rate of 1ml/min for a short run time of 13min. The detection wavelength was 285nm and the column temperature was maintained at 27°C. The retention times were 8.2min and 9.6min for Etravirine and Elvitegravir respectively. The LOD were 4.83mcg/ml and 14.63mcg/ml while LOQ were 9.25mcg/ml and 28.02mcg/ml for Etravirine and Elvitegravir respectively. The developed method was linear over 10 to 160 mcg/ml with regression coefficient of 0.999 for each. The method was also validated for specificity, precision, accuracy, sensitivity, recovery, robustness and system suitability.

Keywords: Quantitative estimation, validation, anti-retroviral, Etravirine and Elvitegravir

F-54

Development and Validation of Newer Analytical Methods for The Estimation Of Trioxsalen In Pharmaceutical Dosage Forms

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Abstract:

Simple, sensitive, and reproducible spectrophotometric and spectrofluorimetric methods were developed for determining the Trioxsalen content in bulk and in tablet dosage form using an experimental design approach. Methanol was the solvent selected for this method. Trioxsalen shows maximum absorbance at 248 nm in UV region. The fluorescence intensity was measured at 445 nm after excitation at 248 nm. The percentage purity of Trioxsalen in tablet dosage form was determined using spectrophotometric method is 100.66% and by spectrofluorimetric method is 99.33%. Developed methods were validated according to ICH guidelines.The proposed methods can be used for the routine quality control analysis of Trioxsalen in its pharmaceutical dosage form.

Keywords: Trioxsalen; UV; Fluorimetry; methanol; method development; validation

F-55

Quality by Design Approach for Development of UV Spectroscopic Method in the Estimation of Teneligliptin in Bulk

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Abstract:

Quality by design (QbD) is a systemic approach to drug development which begins with predefined objective, and uses science and risk management approaches to gain product and their process understanding and ultimately process control. Teneligliptin is an extremely effective and long term DPP-4 inhibitor that improves postprandial hyperglycaemia and dyslipidaemia. The objective of this present study was to develop and validate simple, rapid, precise, accurate, and economical UV spectrophotometric methods for the estimation of Teneligliptin. The method was developed using a different solvents such as water, methanol and acetonitrile and other critical parameter for analysis such as wavelength, scan speed, slit width, and method. UV spectrophotometric method was performed using UV/ Visible spectrophotometer with a spectral bandwidth of 0.1 cm and 1cm quartz cells. The maximum absorbance of Teneligliptin was observed at 245nm within 10-60 µg/ml concentrations, the r^2 was 0.997. Analytical quality by design approch for development of UV spectroscopic method in the Simultaneous estimation of Teneligliptin in bulk can be employed successfully for routine analysis of drug belongs to ant diabetic category.

Keywords: Quality by Design, Teneligliptin, Drug development.

F-56

Cleaning Validation of Amoxicillin Sodium 250 mg Injection

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Abstract:

Cleaning validation is to verify whether the cleaning procedure used at Pharmaceutical parenteral manufacturing department is able to limit the drug residues to predetermined acceptable level. The purpose of this study is to estimate and determine whether levels of the drug "Amoxicillin" following the activity is within the MACO limits and is not being carried over during the next product activity. To achieve this, a HPLC Spectrometry method was developed and validated by using various validation parameters like Accuracy, Precision, Linearity, LOD, LOQ and Intermediate precision as per ICH guidelines. The recovery study was carried out using sterile swab. Further Swabbing time and swabbing pattern were validated for through cleaning process. Cleaning of equipment used in manufacturing of Amoxicillin was done as per suitable cleaning procedure and the cleaning validation rinse and swab samples were collected from the hot spots in the equipment. The samples were analysed by the validated HPLC Spectrometry method at 220 nm. Validation results proved that the amount of Amoxicillin

was within MACO limits. The validated analytical method HPLC Method can be used for the routine analysis of Amoxicillin. The cleaning procedure thus followed, was able to limit the drug residues to a set acceptable level. **Keywords**: HPLC, Amoxicillin, MACO

F-57

Development of a Stability Indicating HPLC Method for Canagliflozin Based on Quality by Design (QbD) Approach.

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Abstract:

A qualitybydesign (QbD) approach to method development can potentially lead to a more robust/rugged method due to the emphasis on risk management. Literaturesurvey reveals that no analytical methods using QbD approach was available estimation of canagliflozin. An attempt was made to develop and validate a stability indicating assay method using Reverse Phase HPLC which is simple, precise and accurate using isocratic elution through QbD approach. QbD approach uses critical method variables such as Buffer, pH, Organic Phase-% ACN, flow rate and interactions between these variables provide impact on response elements such as NTP, Retention time and tailing factor which were evaluated using ANOVA. The method was validated for linearity (1.25 µsg/ml – 3.75 µg/ml.), accuracy, precision and sensitivity. The chromatographic separation was achieved on C18 inertsil ODS 250mm×4.6mm×5um column, using buffer (Potassium dihydrogen orthophosphate pH 3): ACN as mobile phase and detection was carried out at 290 nm Using PDA detector. The Method was validated and successfully subjected to various force degradation conditions.

Keywords: Canagliflozin, QbD, Stability indicating assay method, validation.

F-58

Spectrophotometric, HPTLC and Stability Indicating RP-HPLC Methods For Simultaneous Estimation Of Moxifloxacin And Dexamethasone In Pure And Ophthalmic Dosage Form

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Abstract:

Novel spectrophotometric, HPTLC and stability indicating RP-HPLC methods were developed for simultaneous estimation of Moxifloxacin (MOX) and Dexamethasone (DEX) in ophthalmic dosage form. For UV method by simultaneous equation method, wavelengths selected for analysis are 294 nm (λ_{max} of MOX) and 241 nm (λ_{max} of DEX) using water and acetonitrile in the ratio of 50:50 v/v as solvent. For HPLC method, the mobile phase used was 0.02M acetate buffer (pH was 4, adjusted with 0.1% triethylamine) and acetonitrile in the ratio of (60:40 v/v). Analysis was carried on Sheiseido C18 column (250 x 4.6 mm, 5 µm), at a flow rate of 1.2 mL/min. The chromatogram was recorded at 254 nm. The elution order was 2.144 min and 4.732 min for MOX and DEX respectively. For HPTLC method, mobile phase with acetonitrile: water: ammonia in the ratio of 8:1:0.5% v/v/v solution was selected. Amount of mobile phase used was 9.5 mL per run. The chamber was saturated for 30 min. Sample was applied at a constant rate of 0.1 µL/s having scan speed of 20 mm/s with band width of 8 mm, at 25±0.5°C temperature and 50-60% relative humidity. The retardation factor of MOX and DEX were observed at 0.09±0.01 and 0.74±0.01 respectively. The wavelength for detection of analyte was fixed at 266 nm. The stability of the drugs for HPLC method was examined under different stress conditions such as acidic, alkaline, peroxide, thermal, photolytic and neutral conditions. Developed methods were validated as per ICH guidelines and were found to be within the limits.

Keywords: Moxifloxacin, Dexamethasone, HPTLC, RP-HPLC, Validation.

F-59

Implementation of QbD Approach for Development and Validation of Stability Indicating Assay Method for Estimation of Empagliflozin

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Abstract:

A Quality by Design (QbD) based simple, precise and

stability indicating HPLC method was established and validated for estimation of Empagliflozin. In this QbD approach Full Factorial design based on critical method parameters such as buffer pH,% Organic phase, flow rate were evaluated and its interaction effects on the response variables like Retention time, No. of theoretical plates and Tailing factor was examined. Chromatographic separation was accomplished with isocratic RP-HPLC chromatography using Inertsil ODS-2 column 250 x 4.6 mm, 5µ using Ammonium Acetate buffer (pH=4.5): Acetonitrile (50:50) as mobile phase and detection was done by using PDA detector at 225 nm. The QbD based method was successfully developed and validated, it can be used as Stability Indicating Assay Method

Keywords: RP-HPLC, Validation, Quality by Design (QbD), Stability Indicating Assay Method.

F-60

Method Development And Validation Of UV Spectrophotometric And Stability Indicating RP-HPLC Methods For Simultaneous Estimation Of Moxifloxacin Hydrochloride and Ketorolac Tromethamine In Bulk And Opthalmic Dosage Forms

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Abstract:

Simple, precise, accurate and reproducible UV-Spectrophotometric and Stability indicating RP-HPLC methods were developed for simultaneous estimation of Moxifloxacin HCl (MOX) and Ketorolac tromethamine (KET) in bulk and ophthalmic dosage forms. UV Spectrophotometry was carried out by using linearity range in between 2-10 µg/mL for MOX and KET with correlation co-efficient > 0.990. The solvent used was distilled water: acetonitrile (50:50 v/v). The wavelengths were found to be 295 nm for MOX and 322 nm for KET. The isobestic point was found to be 308 nm. The separation of these two drugs using RP-HPLC was achieved on a SHISHEDO C18, 250 x 4.6 mm, 5 µm size column with a mobile phase consisting of acetonitrile and acetate buffer (45:55 v/v) at pH 4.0 and flow rate of 1 mL/min and UV detection at 308 nm. The retention times were observed to be 2.418 and 3.827 minutes for MOX and KET respectively. Linearity was found to be 10-50 µg/mL and 10-50 µg/mL for MOX and KET respectively. The two developed methods were statistically validated according to ICH guidelines. The stress testing of the drugs individually is carried out under acidic, alkaline, oxidation, photo-stability and thermal degradation conditions and its degradation products were studied. The two developed methods were successfully validated for accuracy, precision, linearity, limit of detection, limit of quantification & robustness. Hence, these two methods can be used for simultaneous estimation of MOX and KET in bulk and ophthalmic dosage forms.

Keywords: Moxifloxacin HCl, Ketorolac Tromethamine, UV Spectrophotometry, RP-HPLC.

F-61

Bio-Analytical Method Development and Validationof Iloperidone in Human Plasma by LC MS/MS

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Abstract:

Iloperidone is an anti-psychotic drug which is used for the treatment of schizophrenia. Abio-analytical LC MS/MS method was developed for the estimation of Iloperidone in human plasma using prednisolone as internal standard. Chromatographic separation was achieved on Hibar® C_{18} (5µ, 150×4.6mm) as stationary phase and the mobile phase was Acetonitrile: 10mM Ammonium formate (85:15 v/v) at a constant flow rate of 0.5ml/min. at ambient temperature and the injection volume was 10µL. The total run time was 5min and the retention time of Iloperidone is 3.55min. The method shows selectivity and linearity. The detection and quantitation limit were established at 0.15ng/ml and 0.5ng/ml respectively, intra-day and inter-day, precision and accuracy fulfill acceptance criteria. The method shows to be stable for the studied parameters. Therefore a rapid, specific and sensitive LC MS/MS method for quantification of Iloperidone in human plasma was developed and can be used for Bio-equivalence studies.

Keywords: Iloperidone, LCMS/MS, Human Plasma

F-62

Quantitative RP-HPLC Determination and Sampling of Etodolac Residue for Cleaning Validation in Production Area

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Abstract:

A simple reverse phase high-performance liquid chromatographic method for the determination of etodolac residues from manufacturing equipment surfaces has been developed and validated. Chromatographic method involves isocratic elution using a Thermolab C_{18} analytical column with the mobile phase composed of 0.15% formic acid: methanol (20:80, v/v), flow rate 1.0 mL min^{-1} and UV detection at a wavelength of 273 nm at ambient temperature. The method is found to be linear, accurate, precise, sensitive and selective for the determination of low levels of etodolac on equipment surfaces. Etodolac residues are removed from stainless steel and Teflon surfaces by swabbing with one cotton swab with polypropylene stick, premoistened in methanol. Recovery study was performed over a range of 30-500 µg 25cm^{-2}. Using this method, the mean recovery of etodolac from spiked absorbed swab samples contained in high density polyethylene bottles was found to be 99.88 %, with a relative standard deviation (RSD) of 0.402 %. The recoveries of etodolac from '180 Grit' stainless steel and Teflon plates were found to be 89.92 and 93.65 %, with RSDs of 1.03% and 2.997% respectively. Stability studies demonstrate that etodolac is stable on swabs in the unextracted 'dry' form for at least 2 day and less stable in the extracted 'wet' form, on the stainless equipment surfaces and Teflon surfaces. Therefore, it is recommended that the equipment be swabbed immediately after completion of the cleaning process and the extracted swabs be analyzed immediately.

Keywords: cleaning validation, etodolac residues, swab sampling.

F-63

Development and Validation of Stability Indicating Rp-Hplc Method for the Estimation of Fosfomycin Trometamol in Its Bulk and Pharmaceutical Dosage Form

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Abstract:

Fosfomycin Trometamol is an antibiotic used in treatment of urinary tract infection. The presently study is aimed at developing and validating a new chromatography method for its determination in both pure form and in pharmaceutical formulation. Fosfomycin trometamol has heterocyclic nitrogen but has no conjugated double bond in its structure. In the presently study a pre- chromatographic derivatization of Fosfomycin trometamol was done by forming an ion-pair complex of the heterocyclic nitrogen using acidic dye methyl orange and phthalate buffer of pH-6. The yellow ion pair complex was extracted with chloroform and it was further extracted with 0.001M HCL. The resulting solution was estimated chromatographically at 507nm. The developed method was validated according to ICH guideline. The ion-pair complex obeyed Beer's law in the range of 30-70 µg/ml with a correlation coefficient of 0.994. Agilent ace C_{18} column was used as stationary phase in this work. The optimized method was achieved at 1ml/min flow rate using mobile phase composition of Acetonitrile: Potassium dihydrogen phosphate 10mm (pH-3.0) (60:40). Recovery of the method was found to be satisfactory with a %RSD < 2 and other parameters were also within validation limits. Stability indicating assay method was performed by using acid, base, hydrogen peroxide and thermal hydrolysis. The developed method was successfully applied to determine Fosfomycin trometamol in sachet formulation without any matrix interference. The developed method was found to be sensitive, specific and reproducible for the determination of the drug in bulk and formulation.

Keywords: Stability indicating RP-HPLC,Fosfomycin Trometamol.

F-64

Stability Indicating RP-HPLC Method Development for Estimation of Teneligliptin in Tablet Dosage Form

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Abstract:

The present work describes stability indicating RP-HPLC method for determination of Teneligliptin in formulation. Method was developed and validated for the determination of teneligliptin tablet by using a mobile phase consisting of methanol: pH 7.2 phosphate buffer in ratio70:30. The column was used

ACE 'C$_{18}$' (150 x 4.6 x 5µ) with the flow rate of 1ml/min using detection wavelength 245nm. The retention time of teneligliptine was found to be 5.7 min respectively. Results ofthe method was found to be linearity and rangecorrelation coefficient is r2 = 0.9993. The accuracy was found in 98% to 100%. The precision was found to be (99.93% ±1.27).ruggedness was found to be (100.29% ± 0.61). The force degradation studies were carried in various stress conditions like acidic hydrolysis, alkaline hydrolysis, oxidative hydrolysis, neutral hydrolysis, humidity, UV-light, and hydrolysis and robustness testing by using placket-burman design values were also within the prescribed limits (<2%). The degraded peaks were observed in nearly all stress conditions and the mass balance approach was applied for quantification. Teneligliptin was found to be labile to all hydrolytic conditions. The result of the study showed that the proposed method was found to beprecise, accurate, and a stability indicating one and can be adopted for the routine determination of teneligliptin in pharmaceutical dosage forms.

Keywords: HPLC, method development, validation, forced degradation

F-65

Stability indicating assay method for estimation of Memantineand Donepezilusing High Performance Liquid Chromatography

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Abstract:

To develop and validate stability indicating method for analysis of Memantine HCl(MEM) and Donepezil HCl (DONE). The chromatographic separation was performed on Younglin System with Primesil C$_{18}$ (4.6 x 250mm,5µm)column using mixture of Acetonitrile:0.05%Ortho Phosphoric acid(80:20v/v) pH adjusted to 2.50 with 0.1% triethylamineflow rates (1ml/min) with a short run time 12min.& detected by UV Detector.The Retention time of MEM and DONE were estimated 8.41 min. and 10.71 min respectively. Method was found to be linear over the range between 10.0 to 40.0 mg/ml respectively.% Purity thusfound 100.56% and 99.94% for MEM and DONE respectively. The ranges of linearity 10-50µg/ml for both drugs were exhibited for the assay. The linear calibration curves were found over the entire range linearity (r2 = 0.999 for MEM and r2 = 0.579 for DONE)&101.17% for MEM and 101.61% for DONE mean % recovery was found. The % RSD for Intra & Inter-Day Precision was NMT than 2 for both drugs. In stress degradation studies, the percent degradation for MEM was 9.67% Acid, 22.73% Base, 33.11 Oxide, 68.98% water while for DONE68.98% Acid, 32.90% Base, 46.19% Oxide &50% in waterwhich is in agreement with ICH Limit.A new, sensitive, simple, and stability indicating high performance liquid chromatographic method has been developed and validated for determination of MEM and DONE shows good resolution within run time of 12 minute.

Keywords: Memantine HCL, Donepezil HCL, RP-HPLC, Stability assay method

F-66

Development of stability indicating assay method for estimation of Domperidone and Pantaoprazolein tablet by RP-HPLC

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Abstract:

Present study deals with determination of Domeperidone (DOM) &Pantoprazole (PTZ) in theircombined dosage form.RP-HPLC method was developed using Younglin system with PremesilC$_{18}$ (4.6 x 250mm, 5µm) column and UV detector in a gradient mode with the mobile phase comprising of Methanol: Water(60:40v/v)pH2.5 adjusted with 0.05% OPA. 0.7ml/min flow rate and monitoring of effluent were done at 285.0nm for DOM and PTZ estimation in combined dosage form. The retention time were found to be 4.16 and 8.05 for DOM and PTX respectively with run time of 10 minutes.The dynamic range of linearity 1-5µg/mL for PTZ and 30- 150 µg/mL for PTZ and DOM respectively. The linear calibration curves were found over the entire range linearity (r2 = 0.9992 for DPD and r2 = 0.9992 for PTZ) and 99.82 % for DPD and 99.91 % for PTZ mean % recovery was found with % RSD was NMT 2 for both estimations which fully agrees by system suitability in good agreement with labeled claimed of formulation. The % RSD for Intra & Inter-Day Precision was NMT than 2 for both drugs. The developed method was accurate, precise, rugged and linear as per ICH guidelines.

Keywords: DOM, PTZ, RP-HPLC

F-67

Method Development and Validation of High Performance Liquid Chromatographic Method for Bosentan in Rat plasma

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Abstract:

A simple and sensitive high performance liquid chromatographic (HPLC) method was developed for quantification of Bosentan in rat plasma. Terbutaline was used as an internal standard (IS). The present method used Solid phase extraction of Bosentan from rat plasma. Separation was carried out on reversed-phase C_{18} column (250 × 4.6 mm, 5µ) and the column effluent was monitored by UV detector at 276 nm. The mobile phase used was acetonitrile: 50mM ammonium acetate (pH 7.0), (80: 20 % v/v) at a flow rate of 1.0 mL min^{-1}. This method was linear over the range of 50.0– 1000.0 ng mL^{-1} with regression coefficient greater than 0.99. The method was found to be precise, accurate and specific during the study. The method was successfully applied for pharmacokinetic study of Bosentan in rats.

Keywords: High performance liquid chromatography; Bosentan Rat Plasma.

F-68

Analytical Method Development in Quantitation of Pharmaceuticals by Sophisticated Techniques

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Abstract:

Analytical method development and validation plays an important role in the discovery, development, and manufacture of pharmaceuticals Several problems are encountered during synthesis of drug and drug products. Examples of typical problems that can be minimized or avoided are synthesis of impurities that co elute with the analyte peak in an HPLC assay. The needs of pharmaceutical industry an attempt has been made to develop some new reverse phase chromatographic methods of analysis for some important active pharmaceutical ingredients and its impurities. The drugs related for the present study is Sertraline. A number of solvents, chemicals and catalysts are used in the manufacturing process of bulk drugs. The carryover of these solvents, chemicals and catalysts need to be assessed as their amounts are detrimental to human health and limits are specified as per regulatory guidelines. Synthesis of Sertraline involves the use of solvents, chemicals and catalysts which can be potential impurities carried over in the final API post synthesis. These impurities include 1-napthol and 4-(3,4-dichlorophenyl)-1-tetralone also referred as tetralone intermediate of Sertraline (IST) for Sertraline. The present study is undertaken with respect to the above mentioned criteria and the objective is to develop and validate RP-HPLC method with K_2HPO_4 Buffer pH 3 with OPA AND 0.1% TEA and ColumnACE EXCEL C-18 AR(100 mm× 4.6mm, 2µ) for the simultaneous estimation of Sertraline and its synthesis related impurities like 1-naphthol, 4-(3,4-dichlorophenyl)-1-tetralone.

Keywords: coelute, carryover, tetralon, simultaneous

F-69

Method Development and Validation of Simultaneous Estimation of Pregabalin and Tapentadol by Using RP-HPLC Method

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Abstract:

A simple, accurate, precise and highly selective Reverse Phase High Performance Liquid Chromatographic (RP-HPLC) method was developed and validated for Pregabalin and Tapentadol. Chromatographic separation was achieved isocratic ally using Waters alliance 2695 separation module, X Bridge C_{18} (100 x 4.6 mm, 5m) at temperature 30°C. Flow rate selected was 1ml/min. Both drugs are identified with UV visible PDA detector at 210nm. Mobile phase employed was Phosphate buffer of P^H 6.85 and Acetonitrile in the ratio of 55:45 which resulted best resolution and sensitivity. Developed method was validated in terms of linearity, range (187.5-1125 µg/ml for Pregabalin and 175-750 µg/ml for Tapentadol), precession (correlation coefficient is less than 0.999), robustness, accuracy (recovery of Pregabalin and Tapentadol were 100.77% and 99.9% respectively). The validation of proposed method was verified by recovery studies and can be applicable in routine pharmaceutical analysis.

Keywords: Pregabalin, Tapentadol, Phosphate buffer P[H] 6.85 and RP-HPLC method

F-71

A Novel Reverse Phase (UPLC) Analytical Method Development and Validation for The Simultaneous Estimation of Paracetamol and Aceclofenac in Dosage Form

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Abstract:

Development and validation of LC method for simultaneous estimation of combination of Paracetamol and Aceclofenac in pharmaceutical dosage form. The chromatographic separation was performed on UPLC Intersil BDS C_{18} (250 mm × 4.6 mm and 3µm) column using isocratic elution of methanol: ammonium acetate buffer (pH 3.4) adjusted with triethylamine (80:20) at flow rate 1ml/min with ambient temperature. The peak intensity of PCM and ACF observed at λ 248 and 278 respectively both drug observed at λ 265 nm with UV detection. The retention time of PCM and ACF was found 2.9 and 5.2 respectively and simultaneous estimation of both drug observed at 265 nm. The linearty range of PCM and ACF were found 10-50µg/ml and 2-10 µg/ml respectively. This method was validated for accuracy, linearity, prescion, robustness. Furthermore no interference was observed with extra pharmacopoeial dosage form for simultaneous estimation of combination of PCM and ACF.

Keywords: Paracetamol (PCM), Aceclofenac (ACF), UPLC, ICH Guideline, methanol (MeOH), RP-LC

F-72

Development And Validation Of Ahighly Sensitive LC-MS/MS Method For The Estimation Of Dienogest In Commercial Formulations

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Abstract:

Our objective is to develop and validate ahighly sensitive LC-MS/MS method for the estimation of Dienogest in its formulations.Dienogest is an orally-active semisynthetic progestogen which also possesses the properties of 17α-hydroxyprogesterone. It is a derivative of 19-nortestosterone and has anti androgenic properties. It is primarily used as a contraceptive in combination with ethinyl estradiol, or in other combination form pills. Dienogest is commonly marketed as 2 mg tablets with a brand name of endoheal, endofit, dienofem, dinogest,dinofirstetc.Chromatographic separation was carried out on a Zorbax SB-C18 (150 x 4.6 mm, 3.5µ particle size) column using 10 mMammonium formate and methanol in the ratio of (10:90, v/v) with a flow rate of 0.5 ml/min. Detection was carried out by triple quadrupole mass spectrometry with electro spray ionization (ESI) in positive mode with proton adducts at m/z 312.00>135.05and retention time of drug was found to be 3.981 min respectively. The method was linear in the concentration range of 0.6-90 ng/ml. The r^2 value was found to be 0.9991. The proposed method was validated by performing linearity, recovery, specificity, robustness, LOD/LOQ and interday / intraday precision. The LOD and LOQ values were found to be 0.4 ng/ml and 0.6 ng/ml respectively.

Keywords: Dienogest, Formulation, LC-MS/MS

F-73

Development and Validation of Chromatographic Method for Simultaneous Estimation of Canagliflozin and Metformin Hydrochloride in Bulk and Tablet Dosage Form

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Abstract:

The discovery of new drug combinations and the ongoing update of international regulations for the safety and efficacy of pharmaceutical formulation demand the development of new analytical methods for these combinations. Combined-dose tablet formulation containing Metformin hydrochloride (MET) and Canagliflozin (CANAG) has recently been introduced in the market and a literature survey revealed a limited number

of high-performance liquid chromatography (HPLC) and spectrophotometric methods reported, but no High-Performance Thin-Layer Chromatographic (HPTLC) method for the simultaneous estimation of these drugs in pharmaceutical formulation. The present work describes the development and validation of an HPTLC method for the simultaneous determination of MET and CANAG in a combined dosage formulation. The chromatography was performed on precoated silica gel 60 F 254 plates using methanol: toluene: ethylacetate: ammonia (2:4:4:0.1) as mobile phase. A thin layer chromatographic (TLC) scanner set at 254.0 nm was used for direct evaluation of the chromatograms in reflectance/absorbance mode. The drugs were satisfactorily resolved with Rf 0.15 for MET and 0.50 for CANAG. The method was validated according to The ICH guidelines. The calibration plot was linear between 0.5–3.0 µg/band for MET and 50–300 ng/band for CANAG respectively. Accuracy and precision of the proposed method were evaluated by recovery studies and intra-day and inter-day precision studies respectively. In stability testing, MET and CANAG were found to be susceptible to acid hydrolysis and alkaline degradation. Because the method could effectively separate the drugs from their degradation products, it may be used as a stability-indicating method.

Keywords: Metformin Hydrochloride, Canagliflozin, HPTLC, Validation.

F-74

Development and Validation of Stability Indicating Assay Method for Determination of Methocarbamol in tablet by RP-HPLC

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Abstract:

The present study describes the development of a stability indicating RP-HPLC method for the analysis of Methocarbamol. The samples separated on a Thermo Scientific acclaim™120, C_{18} (100X 4.6mm, 5µm) by isocratic run using, [Ammonium acetate buffer (pH 6.5): Methanol: Acetonitrile (80:10:10) as mobile phase], with flow rate of 1.0mL/min, at wavelength of 273nm for analysis of Methocarbamol. The precession, ruggedness and robustness values were also with in prescribed limits. Methocarbamol was exposed to acidic, basic, oxidative and thermal stress conditions and the stressed samples were analyzed by proposed method. Chromatographic peak purity results indicated the absence of co-eluting peaks with the main peak of methocarbamol, which demonstrated the specificity of assay method for estimation of methocarbamol in presence of degradation products. The proposed method can be used for routine analysis of Methocarbamol.

Keywords: Methocarbamol, RP-HPLC, Method development.

F-75

HPLC as a Tool for Prediction of Interaction between Sensitive Drug and its Possible Degradants in Combined Dosage Forms

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Abstract:

Combined dosage formulations consisting of two ester drugs present together are likely to exhibit difficulties during the analysis under acidic conditions due to possible hydrolysis. These could lead to formation of degradants interacting within themselves, leading to misleading results. One such combination of aspirin and clopidogrel have demonstrated variation in results due to formation of possible degradants. When subjected to stress conditions and subsequently analysis by HPLC Method, higher peak areas for aspirin than corresponding standard was observed, which could be attributed to unpredictable formation of components. This could be due to compounds or fragments formed in the acidic solution that have a significant difference in absorptivity. Variations could be seen in HPLC studies but not with Absorbance ratio UV-Spectrometric technique. Also, under hydrolytic and photolytic conditions, clopidogrel degradation was found to increase in presence of aspirin. Hence it is essential to use a medium or solvent to prevent degradation and possible interactions between degradants. Validated HPLC Method used for the study comprised of mobile phase mixture of methanol and 10mM phosphate Buffer (80:20) pH 7.0 and C-18 Column. Retention time for aspirin and clopidogrel

was found to be 2.1 and 7.3 min respectively with flow rate of 1 mL/min. For the absorbance ratio method mixture of methanol and 0.1 N HCl (1:1) was used. The results showed that unlike HPLC method, UV-spectrophotometric method does not demonstrate the effect of possible interference between the drug and possibly structurally related degradants.

Keywords: Aspirin, Clopidogrel, Hydrolysis, Degradation

F-76

Analytical Method Development and Validation for the Deterination of Sulfaquinoxaline by UV Spectroscopy in API and Pharmaceutical Dosage Form

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Abstract:

A simple and sensitive spectroscopy method for quantitative determination of Sulfaquinoxaline in pure form and in pharmaceutical dosage form was developed. Sulfaquinoxaline showed maximum absorbance at 250 nm in 0.1 N NaOH solutions. The linear calibration curve was obeyed in the concentration range of (0.5-10) µg/ml show regression equation Y=0.089x + 0.037 with correlation coefficient of (R^2=0.998). The method has good precision within 2% and average accuracy as 99.25±2.67. No significant interference was observed in the absorbance of drug in the presence of common excipients and analysis conditions. The method was employed for the quantitative determination of Sulfaquinoxaline in pure and in tablet dosage form, the assay values found were 100±0.79 and 100.40±0.20 respectively.

Keywords: Calibration curve method, Sulfaquinoxaline, UV spectroscopy.

F-77

Analytical Method Development for the Determination of Levofloxacin by UV Spectroscopy in Pure and In Pharmaceutical Dosage Forms

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Abstract:

A new, simple method indicating UV spectroscopy was developed and validated for the estimation of LEVOFLOXACIN in pure form and in formulation. The adequate drug solubility was found in distilled water and the maximum absorbance was measured at 290 nm in the wavelength range of (200-400nm), the linear calibration curve was obeyed in the concentration range of (2-16 µg/ml) show regression equation (Y=17.00x) and correlation coefficient (R^2=0.993). This method was validated and applied to the determination of Levofloxacin in pharmaceutical dosage form, no interference was found from excipients at the selected wavelength and analysis conditions.

Keywords: UV spectroscopy, Levofloxacin, Calibration Curve method

F-78

An HPLC-UV and Fluorescence Method for the Detection of Three Pharmaceuticals in Various Water Systems

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Abstract:

A new, fast and economical HPLC method was developed for the analysis of carbamazepine, fluoxetine, and venlafaxine in water samples. A reverse-phase HPLC assay was used with UV-Vis and fluorescence detectors. Samples were passed through Gemini C18-110A (250 x 4.60 mm, 5 µm) column at a flow rate of 1.0 mL/min. From spiking experiments, limit of detection (LODs) and limit of quantification (LOQs) for carbamazepine was 0.01 µg/L and 0.1 µg/L, for fluoxetine was 1 µg/L and 0.1 µg/L and for venlafaxine were 1 µg/L and 0.1µg/L, respectively. HPLC can be used to detect the trace amount of pharmaceuticals in water. The technique requires no derivatization steps, requires less time and is more cost-effective.

Keywords: HPLC, solid phase extraction,

carbamazepine, fluoxetine, venlafaxine.

F-79

Quantitative Estimation of Gingerol, Psoralen and Allicin in Antipsoriatic Gel by HPTLC Method

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Abstract:

The present study deals with the quantitative estimation of developed polyherbal antipsoriatic gel formulation. The active ingredients, 6-gingerol, allicin and psoralen were estimated in gel by using HPTLC method. The mobile phase selected for HPTLC work was Toluene: Ethyl acetate: n-Hexane: Glacial acetic acid in the ratio of 7:3:2:0.5 v/v which gives best resolution. In the proposed method solubility of all the phytoconstituents were found in methanol and hence standard stock solutions having concentration gingerol (1000ng), Allicin (500ng) and Psoralen (2000ng per band) were applied on TLC plates using Linomat 5 sample applicator. Sample gel stock solution was prepared by dissolving 2gm of gel in 100 ml of methanol to get the stock solution of sample gel (200000ng/band). For linearity study, r^2 value for marker constitituents 6-gingerol, allicin and psoralen were found to be 0.985, 0.976 and 0.982 respectively. The quantitative estimation was carried out by comparing the gel components with their respective marker compounds. The % estimated constituents in 100g gel formulation were found to be 6-gingerol (75%), allicin (159%), psoralen (83%). Present research work is under patent process.

Keywords: Psoriasis, Antipsoriatic gel, HPTLC.

F-80

UV-Spectrophotometric Simultaneous Determination of Telmisartan and Hydrochlorothiazide in Combined Tablet Dosage Form by Simultaneous Equation and Absorbance Ratio Methods

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Abstract:

In the present research, two new, sensitive, precise, accurate and simple UV-Spectrophotometric methods have been developed and validated for simultaneous estimation of Telmisartan and Hydrochlorothiazide in combined tablet dosage form. Method A involved simultaneous equation method, where absorbances values at two wavelengths 300 nm ($\lambda_{max}$of Telmisartan) and 275 nm ($\lambda_{max}$of Hydrochlorothiazide)by the binary mixture of the two drugs in dimethylformamideis used for formation of simultaneous equations. Whereas, Method B involved Absorbance Ratio Method, where ratio of absorbances values at two wavelengths 280 nm (iso-absorptive point) and 275 nm ($\lambda_{max}$of Hydrochlorothiazide) by the binary mixture of the two drugs in dimethylformamide is used for formation of Q-absorbance equations. Beer's law is obeyed in the concentration range of 4-22 µg/ml for Telmisartan and 4-18 µg/ml for Hydrochlorothiazide. Both intra-day and inter-day precision was found to be well below 2% RSD. The average percentage recovery was found 99.17% & 99.07% for Telmisartanand 99.21% & 99.44% for Hydrochlorothiazide for Method A and Method B respectively. The developed method was successfully applied to the simultaneous determination of Telmisartan and Hydrochlorothiazide in combined tablet dosage form.

Keywords: Validation, Telmisartan, Hydrochlorothiazide, simultaneous equation, absorbance ratio.

F-81

Simultaneous Estimation of Telmisartan, Hydrochlorothiazide, Amlodipine Besylate in Tablets by Chemometric Assisted Spectrophotometric Analysis

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Abstract:

A chemometric method was developed by application of Partial Least Square regression to simultaneous estimation of Telmisartan, Hydrochlorothiazide and Amlodipine Besylate in tablet preparations. Calibration set was prepared considering seven sets, each set with twenty-four mixed solutions and twenty-one ternary mixed solutions were prepared as a validation set. The absorbance data matrix for training set was ob-

tained by recording absorbance within wavelength range 220-320 nm at 2nm intervals. The developed method was validated according to ICH Q2 (R1) guidelines and results were reported. The developed and validated multivariate method was successfully tested for laboratory mixtures as well as commercial tablet formulation of Telmisartan, Hydrochlorothiazide and Amlodipine Besylate.

Keywords: Telmisartan, Hydrochlorothiazide, Amlodipine Besylate, Chemometry, Partial least squares (PLS).

F-82

Stability Indicating Rp-Hplc Method Development And Validation For The Simultaneous Estimation Of Reserpine, Dihydralazinesulphate, Hydrochlorothiazide In Bulk And

Formulations

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Abstract:

A simple, rapid, precise and accurate isocratic RP-HPLC stability indicating method has been developed and validated for simultaneous estimation of Hydrochlorothiazide, Dihydralazine sulphate and Reserpine in bulk and pharmaceutical dosage form. The proposed RP-HPLC method was carried out on Hypersil ODS (250 x 4.6 mm, 5m) column as stationary phase by using mobile phase consisting of OPA: Acetonitrile: MeOH proportion of 50:45:5 %(v/v) pH adjusted to 3.6was used. Mobile phase was pumped through chromatographic system at a flow rate of 0.8ml/min. The UV detection was carried out at 216 nm. The retention time was found to be 2.087, 2.759, and 4.036 for DHS, Reserpine, and HCTZ respectively. The combination drug product was exposed to hydrolysis (Acid and base hydrolysis), oxidative, thermal stability, photo stability and neutral conditions to apply stress. The method was validated in accordance with ICH guidelines. The linearity of the proposed method was investigated in the range of 25–150 µg/ml (r2= 0.9999) for HCTZ, 25–150 µg/ml (r2= 0.9996) for DHS and 0.25–1.5µg/ml (r2= 0.9998) for reserpine. The limits of detection were 0.72µg/ml,0.02 µg/ml and 0.12 µg/ml DHS, Reserpine and HCTZ respectively. The limits of quantitation were 2.19µg/ml,0.05 µg/ml, 0.35 µg/ml for DHS, Reserpine and HCTZ respectively. The mean recoveries obtained for DHS, Reserpine, and HCTZ were 100.4% and 100.50%, and 100.36% respectively. Based on results obtained from the analysis of forced degraded sample using proposed Method, it can be concluded that developed RP-HPLC method will be successfully applicable to for simultaneous estimation of DHS, Reserpine ,HCTZ in presence of their degraded products.

Keywords: DHS, Reserpine and HCTZ. Forced degradation study, stability indicating RP-HPLC method

F-83

A New RP-HPLC Stability indicating LC Method Development and Validation Study of Phenylephrine, Ambroxol and Desloratadine in Pure and Pharmaceutical Dosage Form

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Abstract:

A Stability indicating reversed-phase HPLC method has been developed and subsequently validated for simultaneous estimation of Phenylephrine (PHYL), Ambroxol (AMB) and Desloratadine (DESL) from their combined dosage form. The proposed RP-HPLC method utilizes a Hypersil BDS C18 (250×4.6 mm i.d, 5µ particle size) column and mobile phase consisting of Phosphate buffer (adjusted to pH 3.5 with triethylamine): acetonitrile: methanol (50:20:30 %v/v/v). The flow rate was set at 0.9 ml/min and detection was carried out at 225 nm using PDA detector. The retention times were found to be 2.368 min for PHYL, 3.942 min for AMB and 5.409 min for DESL respectively. PHYL, AMB, DESL and their combination drug product were exposed to stress conditions and the stressed samples were analyzed by the proposed method. The described method was linear over a concentration range of 6.25-37.5µg/ml for PHYL, 75-450µg/ml for AMB and 6.25-37.5µg/ml for DESL respectively with correlation coefficient values of 0.999. The proposed RP-HPLC method was statistically evaluated in all parameters as per ICH guidelines and found to be sensitive, accurate, precise, reliable, robust and specific which can be applied for routine quality control analysis of Phenylephrine, Ambroxol and Desloratadine in pure and their combined tablet dosage form.

Keywords: RP-HPLC, Stability indicating, Validation, Simultaneous estimation

F-84

Development and Validation of a Dissolution Method for Ranolazine in Pharmaceutical Dosage Form Using RP-UPLC

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Abstract:

A new ultra-performance liquid chromatography method was developed for the dissolution of Ranolazine in Pharmaceutical Dosage Form. The dissolution test was performed using paddles (USP apparatus II) at a stirring speed of 75 rpm and 900 mL of the different dissolution media pre-heated to 37 °C ± 0.5 °C. Manual sampling aliquots of 10 mL were withdrawn at 5, 10, 15, 30 min. Chromatographic separation was achieved on Acquity UPLC BEH Shield RP18,2.1X50mm,1.7 µm column using an isocratic mode mobile phase consisting of a mixture of Buffer : ACN 75:25%V/V. Flow rate was set at 0.3 ml/min with a detection wavelength of 310 nm. The method was validated over the concentration ranges from 100 to 300 µg / ml. Calibration plots were linear for Ranolazine with a correlation coefficient greater than 0.998. The percentage drug release for Ranolazine was found to be 99.02%. So this method was suitable for analysing the formulation. The proposed method was successfully applied for the determination of Ranolazine in pharmaceutical formulations. The low flow rate, short analysis time, and simple mobile phase composition make the method cost effective, rapid, nontedious, and successfully employed for simultaneous determination of Ranolazine in commercial pharmaceutical products.

Keywords: Ranolazine, UPLC and Dissolution.

F-85

Determination of Imatinib Mesylate by UPLC

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Abstract:

Imatinib is potent selective inhibitor of protein tyrosine kinase BCR-ABL, platelet derived growth factor receptor and the receptor kinase C-KIT. It was approved for treatment of chronic myeloid leukemia (CML) by U.S FDA. In this current research UPLC method was developed for determination of Imatinib Mesylate. The method was developed using mobile phase of Acetonitrile: Ammonium Acetate Buffer (pH 6.7) at the ratio 70:30 with flow rate of 0.7 mL/min. Imatinib Mesylate was detected using UV detector at 230nm and integration was performed using Chromeleon software. Parameters like linearity, accuracy, specificity, precision, robustness and ruggedness was performed as per ICH guidelines. Imatinib Mesylate percentage purity was found to be 99.8%. The calibration curve obtained by plotting peak vs area was linear over the concentration range of 1-100 µg/mL with correlation coefficient of 0.995. Accuracy was determined with percentage recovery of 99.4%. The intra-day and inter-day precision has relative standard deviation of 0.36 and 0.36 respectively which was within the limit of NMT 2%. The validated method is simple, rapid, precise and accurate for determination of Imatinib. Thus, it can be concluded that this method can be used for routine quality control analysis of Imatinib in tablet formulation.

Keywords: Imatinib, UPLC, ICH, FDA guidelines, percentage recovery.

F-86

Simultaneous Determination of Albendazole and Praziquantel Using Zero Order Spectrophotometry Absorbance Correction Methods in Veterinary Pharmaceutical Formulation

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Abstract:

The present study describes a simple, accurate, precise and cost effective UV-VIS Spectrophotometric method for the estimation of albendazole (ABZ) and praziquantel (PZQ) by absorbance correction method. The simultaneous determination of albendazole (ABZ) and praziquantel (PZQ) was performed by absorbance correction method using two different wavelengths i.e. 217nm & 295.4nm. Both the drugs were dissolved in methanol for estimation. A linear response was observed in the range of 4-14µg/ml with a regression coefficient of 0.999. The method was then validated for different parameters as per the ICH (International Conference for Harmonization) guidelines.

The detection limits (LOD = 4 µg/ml for both the drugs) for absorbance correction method were determined and presented the best analytical features. The recoveries of ABZ and PZQ from the synthetic samples were near to 100 ± 5%. The methods were applied in veterinary pharmaceutical formulation whose mass ratio ABZ: PZQ is 12:1; the results obtained were according to nominal content.

Keywords: Albendazole, Praziquantel, UV-VIS, Absorbance Correction Method, LOD

F-88

Crystal Engineering of 5-Fluorouracil cocrystal: Structural Analysis and Evaluation

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Abstract:

Crystal engineering comprises rational design and fabrication of crystal structures offering diverse prospects to selectively enhance the biopharmaceutical properties of drugs via cocrystallization processes. The present study is focused on the preparation, characterization and evaluation of 5-Fluorouracil (5-FU)co-crystalwith coformeraspartic acid (AP) using cocrystallization approach.Characterization of the prepared co-crystal was done by using analytical tools such as differential scanning calorimetry (DSC), fouriertransform infrared spectroscopy (FT-IR), powder X-ray diffraction (PXRD).DSC thermogram of 5-FUAP cocrystalshowed single sharp melting endotherm at 250ºC, which wasdifferent from the melting points of drug and coformer.FT-IR study indicated interaction between carbonyl group of drug and carboxylic acid groupof coformer. Appearance of new peaks in PXRD pattern confirms the formation of new solid forms. Crystal structure of cocrystal wasdetermined using material studio software (Biovia) from PXRD. *In-vitro* permeation studies were determined using Franz-type diffusion cells using dialysis membrane, and in *ex-vivo* using rat skin and HaCaT cell line, which showed improvement in membrane permeability. Equilibrium solubility and disk intrinsic dissolution rate of cocrystalwas found to be more as compared with pure drug. Evaluation of this solid form was done using different cancer cell line (MCF-7, Hela and Caco-2). All the results indicate that 5-flououracil cocrystal possess better antitumor efficacy than free drug. Thus, cocrystallization approach has been found to be a viable technique, toimprove the permeability, dissolution limited bioavailability.

Keywords: Cocrystallization, 5-Fluorouracil, Bioavailability

F-89

Intrinsic Stability Study and Forced Degradation Profiling Of Tapentadol Hydrochloride by RP-HPLC-DAD

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Abstract:

A novel, simple, accurate and precise RP-HPLC-DAD method for determination of tapentadol in presence of its degradation product has been developed and validated. The separation was achieved on a ZORBAX Eclipse Plus C18 (250 × 4.6 mm, 5 µm), using mixture of acetonitrile and 0.1% aqueous formic acid in gradient mode as mobile phase at flow rate of 1.0 mL. The DAD detection wavelength was 272 nm. The linearity was obeyed over a concentration range of 5-25 µg.mL^{-1} with correlation coefficient of 0.999. The method was validated for accuracy, precision, robustness, limit of detection, limit of quantitation, specificity, stability and system suitability parameters. Forced degradation of drug was performed in various stress conditions like acid, alkali, oxidation, thermal and photolytic conditions. It was degraded appreciably in acidic and alkaline conditions but it was not degraded significantly in neutral condition. No degradation was observed in thermal, oxidative and photolytic degradation. The drug was successfully determined in presence of its degradation products.

Keywords: Tapentadol hydrochloride; intrinsic stability; forced degradation profiling

F-90

Method development and validation for simultaneous Estimation of metformin HCl and Empagliflozin by Reverse Phase HPLC Method in Bulk and Tablet Dosage Form

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Abstract:

The purpose of the investigation was to develop a simple, rapid and accurate RP-HPLC method to determine assay of Metformin Hydrochloride And Empagliflozin in Bulk and synthetic mixture. The chromatographic separation was performed on Inertsil ODS 3v. Eluents were monitored on PDA detector at a wavelength of 255 nm using a methanol:buffer (50:50v/v). The column temperature was maintained at 30°C. Validation parameters such as system suitability, linearity, precision, accuracy, specificity, limit of detection (LOD), limit of quantification (LOQ), Stability of sample and standard stock solutions and robustness were studied as reported in the ICH guidelines. The retention time for Metformin Hydrochloride And Empagliflozin was 2.463 min and 4.216 min respectively. Assay method further evaluated for Metformin Hydrochloride and Empagliflozin analysis at low concentration of analyte and found limit of detection is 0.48 and 0.016 ppm respectively and limit of Quantitation is 1.49 and 0.049 ppm respectively. The percentage recovery of Metformin Hydrochloride and Empagliflozin was 99.64% and 99.47% respectively. The %RSD for Metformin Hydrochloride and Empagliflozin was less than 2. Linearity of Metformin Hydrochloride and Empagliflozin performed from 25% to150% and the R2 is 0.999, intercept and slope found to be y = 41111x + 7297.3 and y = 40743x + 864.81 respectively. The method was fast, accurate, precise and sensitive hence it can be employed for routine quality control of Metformin Hydrochloride and Empagliflozin containing drug in quality control laboratories and pharmaceutical industries

F-91

Method development and Validation for Simultaneous Estimation of Sildenafil and Duloxetine by Reverse Phase HPLC Method in Bulk and Tablet Dosage Form

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Abstract:

A simple, fast and precise reverse phase, isocratic HPLC method was developed for the separation and quantification of Sildenafil and Duloxetine in pharmaceutical dosage form. The quantification was carried out using Xterra RP 18 (4.6 x 150mm, 5.0µm)enhanced polar selectivity column and mobile phase comprised of potassium dihydrogen phosphate buffer and acetonitrile in proportion of ratio 40:60(v/v) and degassed under ultra-sonication. The flow rate was 1.0 mL/min and the effluent was monitored at 244nm. The retention time of Sildenafil and Duloxetine were 3.078 and 2.064 respectively. The method was validated in terms oflinearity, precision, accuracy, and specificity, limit of detection and limit of quantization. Linearity of Sildenafil and Duloxetine were in the range of 100 to 300µg/mL and 30 to 90µg/mL respectively. The percentage recoveries of both the drugs were 98.7% and 99.8% for Sildenafil and Duloxetine respectively from the tablet formulation.The method was found to be precise, accurate and specific during the study. The proposed method enables rapid quantification and simultaneous analysis of both drugs from commercial formulations without any excipients interference. The method can be used for routine analysis of marketed products of Sildenafil andDuloxetine in combined tablet formulation

F-92

Development and validation of stability indicating HPLC-UV assay method for acetretin capsule: improvement in official HPLC method

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Abstract:

Acitretin is a photosensitive oral retinoid with very limited data available on its degradation. The official HPLC method for acitretin determination was insufficient to resolve the degradation products generated during stability studies. Therefore, an isocratic RP-HPLC–UV method was developed for the determination of acitretin in the presence of its related impurities and degradation products. Efficient chromatographic separation was achieved on a C18 column with mobile phase containing 0.3% (v/v) glacial acetic acid with acetonitrile (ACN) and isopropyl alcohol (IPA) in an isocratic ratio of 70:30 at a flow rate of 1.0 mL/min with the eluent monitored at 360nm. The method was validated for specificity, linearity, precision, accuracy and robustness. The calibration plot was linear over the concentration range of 50–150 µg/mL with a correlation coefficient (r^2) of 0.999. The degradation rate constant (K), half-life (t1/2), and t90 were calculated. Degradation of acitretin followed pseudo-first-order kinetics. The drug was found to be less stable under acidic and photolytic degradation conditions: the photolytic degradation constants for acitretin in sunlight and UV light were 0.002698% and 0.0008402% min^{-1}, respectively. The LOD for acitretin and the known impurities were at a

level below 0.02%. The method shows consistent recoveries for ACTR (99.8%–101.2%) and also for its known impurities (97.2–101.3%). The method was found to be accurate, precise, linear, specific, sensitive, rugged, robust, and useful for characterizing the stability of this chemical.

Keywords: Acitretin, SIAM, HPLC, degradation

F-93

Analytical Method Development and Validation for the Simultaneous Estimation of Salbutamol Sulphate, Guaifenesin and Ambroxol Hydrochloride by RP-HPLC Method in Commercial Oral Liquid Dosage Form

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Abstract:

Salbutamol is a bronchodilator, Guaifenesin is an expectorant and Ambroxol is a mucolytic. Combination of these drugs is used in the formulation of cough syrups. In the literature there is no method reported for the simultaneous estimation of the drugs in oral liquid dosage form. Hence the present work is aimed to develop reverse phase HPLC method for the simultaneous determination of Salbutamol sulphate (SAL), Guaifenesin (GUA) and Ambroxol hydrochloride (AMB) in oral liquid dosage form and validation of the developed method. The chromatographic separation of the drugs was achieved with the mobile phase system Sodium dihydrogen phosphate buffer pH 3.0: Acetonitrile: Methanol in the ratio of 65:10:25 with the flow rate of 1 mL/min and injection volume 10µL. An Inertsil C8-3 (250 4.6mm, 5µm) was used and the Detection wave length was 276 nm. This system produced sharp peaks with good resolution, minimum tailing and satisfactory retention times of Salbutamol sulphate, Guaifenesin and Ambroxol hydrochloride were found to be 3.157, 9.949 and 11.883 minutes respectively indicating the suitability of system. The developed method was validated for various parameters accuracy, precision, linearity, robustness and specificity as per ICH guidelines. The results of validation pararmeters were in agreement with the acceptance criteria. The satisfactory results of validation shows the method is suitable for the intended analysis. Hence the developed method for simultaneous estimation of Salbutamol sulphate, Guaifenesin and Ambroxol hydrochloride said to be rapid, simple, accurate, precise, sensitive, robust and specific that can be successfully applied for the routine analysis of Salbutamol sulphate, Guaifenesin and Ambroxol hydrochloride in their marketed oral liquid dosage form.

F-94

Development and Validation of a Gas Chromatographic Method for Residual Solvent Determination in Herbal Extract

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Abstract:

As per GMP, control of residual solvents in plant extracts and herbal formulations is mandatory. Residual solvents or Organic volatile impurities (OVIs) in plantextractsand herbal formulations can be determined by gas chromatography with Flame ionization detector (GC-FID). Major advantages of gas chromatography (GC) arehigh efficacy and reduction in analysis time due to faster temperature ramping capabilities combination with shorter capillary GC columns. In present study, GC method for determination of ethanol at residual levels in plant extract was developed using flame ionization detector. Separation was carried out on Agilent HP-5 column (30m × 320µm × 0.25µm coating thickness), using Agilent 7820A GC system. Nitrogen was used as a carrier gas in split mode by direct injection method. The retention time for standard ethanol was found to be 2.792 minutes. The linearity was found to be in the range of 2-10µLmL^{-1}. The method was validated according to ICH guidelines. The level of ethanol in plant extract was found to be within the ICH limit. The method described is simple, sensitive, reliable, rugged and reproducible for detection and quantitation of ethanol in plant extracts as well as herbal formulations.

Keywords: Plant extracts, herbal formulations, OVIs, residual solvent, gas chromatography.

F-96

RP-HPLC Method Development and Validation for the Simultaneous Estimation of Hydrochlorothiazide, Hydralazine Hydrochloride and Reserpine in Pharmaceutical Formulation

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Abstract:

A simple, accurate, precise and rapid reversed-phase HPLC method has been developed for the simultaneous estimation of hydrochlorothiazide, hydralazine hydrochloride and reserpine in a marketed formulation. The chromatographic separation was carried out with the aid of Agilent HC-C18 (150mm×4.6mm, 5µm) analytical column at temperature 40°C using a mixture of triethylamine buffer (0.7 % pH 3.0 adjusted with orthophosphoric acid), acetonitrile and methanol (50:40:10 v/v) as mobile phase at a flow rate of 0.6 mL/min and detector wavelength at 271 nm. The retention time of hydrochlorothiazide, hydralazine hydrochloride and reserpine was found to be 5.226, 3.984 and 10.789 minutes, respectively. The validation of the developed method has been done for its specificity, linearity, accuracy, precision, limit of detection and limit of quantitation according to ICH guidelines. The linear ranges for hydrochlorothiazide (HCTZ), hydralazine hydrochloride (H.HCl) and reserpine (RES) were found to be 3-15 and 2-10 µg/mL, respectively. Limit of detection and limit of quantification for HCTZ were 0.025 and 0.074 µg/mL, for H.HCl 0.011 and 0.034 µg/mL, for RES 0.014 and 0.043 µg/mL, respectively. The proposed RP-HPLC method is very simple, accurate and can be used for routine analysis of hydrochlorothiazide, hydralazine hydrochloride and reserpine in bulk drug and marketed formulations.

Keywords: Simultaneous estimation, Hydrochlorothiazide, Hydralazine hydrochloride, Reserpine, HPLC

F-97

Development, Validation of Dissolution Tests and Analytical Method Validation for Oxcarbazepine Bulk Drug and Tablet Dosage Form

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Abstract:

This study describes the development and validation of dissolution tests Oxcarbazepine tablet and Analytical method by HPLC. The appropriate conditions were determinate after testing *sink* conditions, dissolution medium, and agitation intensity. The apparatus used in dissolution of tablets are USP type II apparatus (paddle method). The best dissolution conditions tested, for the products were applied to evaluate the dissolution profiles. The parameters of difference factor, similar factor, and dissolution efficacy were employed.The objective of the validation of analytical procedure is to demonstrate that it is suitable for its intended use. The regulatory authorities emphasize on the validation parameters such as accuracy, precision, specificity, ruggedness, robustness, linearity, range, detection limits, quantitation limits and system suitability parameters.Optimal conditions to carry out the dissolution tests were 900 ml of 0.8% sodium lauryl sulphate in water as dissolution medium. The paddle was operated at 50 rpm and 75 rpm. The cumulative percentage drug released from the formulations was found to be 100.19%. The accuracy was found to be 99.40 ± 0.33 and the LOQ was determined to be 3 µg/ml with acceptable precision of 1.02 % RSD. The developed and validated dissolution tests satisfactorily describes the time-course of the drug release. The obtained results provided adequate dissolution profiles. The proposed developed HPLC method can be applied for identification and quantitative determination of Oxcarbazepine in bulk drug and dosage forms

Keywords: Oxcarbazepine, Validation, Dissolution, HPLC

F-98

Qbd Approach to Analytical Method Development &Validation of Deflazacort by HPLC

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Abstract:

Deflazacort is an oxazoline derivative of prednisolone with anti-inflammatory &immunosuppressive activity. The present study describes the development of HPLC method and validation for the analysis of Deflazacort bulk & formulation using a quality by design approach. An experimental design based on two key components of the RP-HPLC method (mobile phase and Flow rate) is presented. The stock solution Deflazacort was made in methanol and absorption maximum of standard solution of Deflazacort was found be 243 nm. The chromatographic condition was optimized with design expert software 10.0 version, using Box-Behnken Design (2 factors, 3 levels, 15 runs),

i.e.; column C18, mobile phase -Acetonitrile: water (70:30), flow rate was 1 ml/min. The described method was linear ($r^2 = 0.995$) with range 6-30µg/ml. The precision, ruggedness and robustness values were also within the prescribed limits (<1% for system precision and <2% for other parameters). Stress degradation studies performed using acid, base, peroxide, & photolytic methods helped in separating the degradation products of Deflazacort. The results successfully demonstrated the utility of QbD for optimizing the chromatographic conditions for developing highly sensitive liquid chromatographic method &for routine analysis in quality control laboratories for Deflazacort.

Keywords: Deflazacort, Experimental Design, Degradation study

F-100

Synthesis and Characterization of Thieno [2,3-*d*] Pyrimidine Derivatives as Anti-hyperlipidimic Agents

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Abstract:

Hyperlipidemia is a major cause of various cardiovascular complications occurring due to increased lipid content in blood. Thienopyrimidine ring is a new target for development of anti-hyperlipidimic drugs. In this study we have synthesized thienopyrimidine moiety based compounds (DH-1 to DH-4) and evaluated them against Triton-X 100 induced hyperlipidemia in rats. The new thienopyrimidine derivative DH-1, DH-2, DH-3 and DH-4 were synthesized from Gewald products. Different Gewald derivative were synthesized and further cyclisation with formamide. Cyclized compounds were treated with phosphorus oxytrichloride for the chlorination. These compounds were evaluated against Triton-X (100 mg/kg) (single dose) induced hyperlipidemia in rats. Ezitimibe (7.5mg/kg), DH-1 (20 mg/kg), DH-2 (20 mg/kg), DH-3 (20 mg/kg) and DH-4 (20 mg/kg) were suspended in 0.5% DMSO solution and administered orally for the 7 days in Triton treated groups. The blood samples were collected on 8th day and estimated for TC, TGs HDL-c, LDL-c level in blood. Test compounds DH-1, DH-2, DH-3 and DH-4 were administered at dose of 20 mg/kg. These have significantly decreased the TGs, TC, LDL-c and increased the HDL-c level against the triton induced hyperlipidemia in rats. The present study concluded that oral administration of DH-1, DH-2, DH-3 and DH-4 showed better results to reduce hyperlipidemia. Further, DH-1 (20 mg/kg) has provided more beneficial effect as compared to DH-2, DH-3 and DH-4 (20 mg/kg) in triton induced rats.

Keyword: Hyperlipidemia, Triton, Total Cholesterol, Triglycerides, HDL-c, LDL-c.

F-101

Degradation study of montelukast sodium and its marketed formulation in oxidative and accelerated stability test conditions

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Abstract:

Oxidative stability of pharmaceutical solids is really important, because oxidation is the second most degradation pathway for pharmaceuticals. This study was aimed to understand the degradation behaviour of the selected drug in different oxidative conditions like hydrogen peroxide, AIBN, metals (Fe^{3+}), Fenton's reagent and O_2 environment. Montelukast sodium (leukotriene receptor antagonist) was selected for this study as a model drug, as its chemical structure is more prone to oxidation reactions. The degradation was also evaluated under ICH recommended accelerated stability conditions (40 °C/75% RH) in the solid state to explain the presence of any degradation product in the formulation mixtures. Oxidative degradation products formed under variety of oxidative stressors in solution state were critically compared with the solid state results. A total of nine degradation products (MTK 1-9) were formed in drug substance and its formulation kept under controlled oxygen environment at room temperature. The formed degradation products were separated on a C-18 column in a gradient mode. Comprehensive mass fragmentation pattern of the drug was established by direct injection, and through collection of HRMS and multi-stage tandem mass spectrometric (MS^n) data. LC-HRMS studies were carried out on the stability samples containing the degradation products using the same method as employed for HPLC study. The collated information was utilized for the characterization of all nine degradation products. Eventually, degradation pathway of the drug was established under the investigated conditions, and mechanisms for the formation of each degradation product were proposed.

Keywords: Montelukast sodium, Oxidative stressors, Accelerated stability study, Degradation products, LC-HRMS

F-102

Development of Quantitative Method For Determination Of Ezetimibe By NMR

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Abstract:

The chromatographic methods such as HPLC require an authentic reference standard for construction of calibration curve along with a specific method for absolute purity determination. Quantitative proton nuclear magnetic resonance (q^{1}H-NMR) has emerged as a popular non-destructive technique to overcome the limitations of HPLC. To expand the application of nuclear magnetic resonance technology in quantitative analysis of pharmaceuticals, ^{19}F nuclear magnetic resonance (^{19}F-NMR) spectroscopy has been employed as a simple, rapid and reproducible approach. ^{19}F-NMR has several advantages over ^{1}H-NMR like wide chemical shift range (about 400 ppm) and high resolution as the signals don't overlap with each other. This makes the selection of a qualified signal easier for quantitative analysis when compared to q^{1}H-NMR. Fortunately, fluorine is a common atom in the chemical structure of pharmaceuticals, and commercially available fluorine substituted compounds have been estimated to be about 20%. Ezetimibe was selected as a model drug for the quantification by ^{19}F-NMR. To validate the reliability and feasibility of ^{19}F-NMR technology in quantitative analysis of pharmaceutical analytes, the assay result was compared with that of ^{1}H-NMR. Influencing factors, including relaxation delay time, receiver gain, temperature, and data points impacting the accuracy and precision of spectral data was systematically optimized.

Keywords: quantitative ^{19}F-NMR, quantitative ^{1}H-NMR, ezetimibe assay, method validation.

F-103

Optimization of RP-HPLC Method for Estimation of Teneligliptin Hydrobromide Hydrate In Biological Fluid by Using Design Expert

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Abstract:

Teneligliptin hydrobromide hydrate is an extremely effective and long-term DPP-4 inhibitor that improves postprandial hyperglycemia and dyslipidemia. The objective of this present study was to develop and demonstrate an integrated multivariate approach to develop and quantify the constituent concentrations of Teneligliptin hydrobromide hydrate in biological fluid. The method was developed using a mobile phase acetonitrile: water (30:70 v/v) on an Agilent, TC C18 (250 × 4.6 mm) 5µm column and flow rate 1.0 ml/min which was optimized with help of design expert software and validated according to US-FDA guidelines. The detector linearity was established in concentrations ranging from 1-9µg/ml, the r^2 was 0.9995. The method fulfilled validation criteria and was shown to be sensitive.

Keywords: Teneligliptin, QbD, validation

F-104

"Solid as Solvent"- Novel Spectrophotometric Determination of Piroxicam in Solid Dosage Form Using Solids (Eutectic liquid of phenol and paracetamol) as Solubilizing Agents (Mixed solvency concept)

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Abstract:

In proposed research, novel method for spectrophotometric estimation of piroxicam in tablet dosage form was developed and validated as per ICH guidelines. The main objective behind research is to explore applications of mixed solvency concept in analysis of various poorly soluble drugs. Generally in spectrophotometric analysis of poorly water soluble drugs, class II and III organic solvents are used which are very toxic to humans as well as nature. The present study deals with novel spectrophotometric estimation of piroxicam in solid dosage form using eutectic liquid of phenol and paracetamol in 4:1 ratio (PPl41) as solubilising agents. As per the statement of Maheshwari, each substance (gas, liquid or solid) possesses solubilising power. PPl41 possesses significant large solubiliz-

ing power for piroxicam and having solubility more than 110 mg per ml whereas aqueous solubility of piroxicam is 0.4 mg/ml. Calibration curve of piroxicam was plotted by recording the absorbance of standard solutions (5,10,15,20 and 25µg/ml) of piroxicam which were made by diluting the stock solution of piroxicam (50 mg) in PPl41 (10ml) with distilled water. The absorbances were recorded at 358 nm against respective reagent blanks. The percent label claims were found very close to 100 (98.66 ± 1.761 and 99.33 ± 0.904) indicating accuracy of the proposed method. The accuracy and reproducibility of the proposed method was further confirmed by recovery studies. Percent recoveries estimated by the proposed method are close to 100 (99.86 ± 1.878 to 101.65 ± 1.444). The low values of standard deviation, percent coefficient of variation and standard error, validate the method. Thus, it may be concluded that proposed method is simple, safe and precise and exclude use of toxic organic solvents. Phenol does not interfere above 300 nm and paracetamol does not interfere above 315 nm in spectrophotometric analysis.

Keywords: Mixed solvency, spectrophotometric analysis, eutectic liquid, phenol, paracetamol

F-105

Bioanalytical Method Development and Bioequivalence Studies of Tadalafil Tablets by HPLC

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Abstract:

Biopharmaceutical analysis deals with determining trace (microgram or less) levels of organic and selected inorganic medicaments in biologic fluids. Bioequivalence information is required to ensure therapeutic equivalence between a pharmaceutically equivalent test drug product and a reference listed The present method is validated for the estimation of Tadalafil in human plasma over concentration range of 5.0ng/ml to 500.0ng/ml. The precision and accuracy are very much within the prescribed limits in this concentration range. Expected recoveries were observed in the present processing technique for LQC, MQC and HQC. The drug is found to be very stable to the effect of three freeze-thaw cycles and up to 3 hours delay on the bench-top. The values obtained from system suitability studies demonstrated the suitability of the system for the analysis of the Tadalafil in plasma. Limit of detection of the methods is 2.0 ng/ml and Limit of quantitation is 5.0 ng/ml which shows that the developed method has adequate sensitivity and also more than 20 samples can be processed at a time without affecting the assay values. The long-term stability is established for these molecules for the required period of subject samples analysis.

F-106

Stability indicating RP-HPLC Method Development and Validation of Related Substance of Norepinephrine Bitartrate in Norepinephrine Bitartrate Injection

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Abstract:

Impurity profiling of drug involves identification and quantification of related drug substances and impurities. It is an important part of drug development and regulatory assessment as the safety of a drug product is dependent not only on the toxicological properties of the active drug substance but also on the impurities which API contains. Norepinephrine (BP) is α-adrenoceptor agonist and used to treat life-threatening low blood pressure (hypotension). As per British pharmacopoeia, there are seven official impurities (IMP-A, IMP-B, IMP-C, IMP-D, IMP-E, IMP-F and IMP-G) listed amongst them, IMP-A is considered as unknown impurity and if present should be quantified, one degradation impurity (IMP-B) generated in normal storage condition, IMP-C and IMP-E should not be present in final API and IMP-F and IMP-G are routinely removed during manufacturing process. Hence, a stability indicating RP-HPLC method using C18 column was developed where in gradient mobile phase having mixture of buffer (pH 3) and methanol to resolve the impurity A-E peaks from Norepinephrine in bulk and injection. The developed method was validated as per ICH guidelines for specificity, linearity, accuracy, precision, robustness, LOD and LOQ values with reference to IMP-B.Norepinephrine was subjected to acid, base, thermal, photolytic and oxidative stress conditions during stability study. Mass balance 97-103% for Norepinephrine suggested that the developed method can satisfactorily determine the amount of Norepinephrine in the presence of its degradation products/impurities.

Keywords: Impurity profiling, Norepinephrine, stress conditions

F-107

Development and validation of stability indicating planar Chromatographic method for estimation of Azithromycin and Adapalene bulk drug and marketed formulation

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Abstract:

The present work describes simple, rapid, precise and accurate stability indicating HPTLC method for analysis of Azithromycin and Adapalene in their combined dosage form. The combination of these drugs is useful in the treatment of acne. The standard solution of Azithromycin and Adapalene was applied in band width 6mm using Hamilton 100µL syringe on pre coated silica gel aluminum plate 60 F_{254} using Linomat V auto sampler. The development was carried out in 10×10cm twin through glass chamber saturated with the mobile phase in the composition of Toluene: Methanol: Ethyl acetate: Tri ethyl amine (5:2, 5:2, 4:0, 1 v/v/v/v) for 10 min. Rf values of Azithromycin and Adapalene were found to be 0.44 and 0.64 respectively. The detection was carried out at 450nm and 315nm for Azithromycin and Adapalene respectively. Linear responses were observed in the concentration range of 1000-5000 ng/band for Azithromycin and 50-250 ng/band for Adapalene respectively. Developed method was validated according to ICH guidelines. Accuracy of method was determined by recovery studies and was found to be in the range of 98-102%. Intraday and Interday precision were checked and mean %RSD was found to be less than 2. Forced degradation study was performed by using acid, base, hydrogen peroxide and thermal hydrolysis. Both the drugs were successfully analysed by the proposed method in presence of its impurities without any matrix interference. Method was successfully applied for estimation of Azithromycin and Adapalene in marketed formulation.

Keywords: Azithromycin, Adapalene, Stability testing.

F-108

Method Development and Validation for Simultaneous Estimation of Lumacaftor and Ivacaftor by Reversed Phase HPLC Method in Bulk and Tablet Dosage Form

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Abstract:

A method was established for simultaneous estimation of Lumacaftor and Ivacaftor by RP-HPLC method. The chromatographic conditions were successfully developed for the separation of Lumacaftor and Ivacaftor by using Inertsil ODS 3V column, C18 (150 x 4.6 ID) 5 µm, flow rate was 1ml/min, mobile phase was mixed phosphate buffer : ACN, pH 6.5, detection wavelength used by SHIMADZU(LC20ATVP) with UV/PDA detector Auto Sampler. The retention times were found to be 4.003 min and 2.927 mins. The % purity of Ivacaftor and Lumacaftor were found to be 98.92% and 99.5% respectively. The present analytical method was validated according to ICH guidelines (ICH, Q2 (R1)). The linearity study of Ivacaftor and Lumacaftor was found in the concentration range 25µg/ml-200µg/ml and correlation coefficient (R 2) be 0.999 and 0.999, % recovery was found to be 100.13 and 100.53, % RSD for repeatability 0.565 and 0.632, % RSD for intermediate precision was 0.515 and 0.345 respectively. The precision study was precision, robustness and repeatability. It is a convenient, simple and quick method for the determination of Ivacaftor and Lumacaftorin its bulk and pharmaceutical dosage forms.

Keywords: Ivacaftor, Lumacaftor, HPLC, Methanol, CAN

F-109

Development and Validation of Chromatographic Methodfor Simultaneous Estimation of Bromfenac Sodium and Moxifloxacin HCl in Pharmaceutical Dosage Form

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Abstract:

A reserved phase high performance liquid chromatography method was developed and validated for simultaneous estimation of Bromfenac Sodium (BS) and Moxifloxacin HCl (MH).Shimadzu system was used for chromatographic separation by using Kromasil 100-5-C8 column (250 mm X 4.6 mm, 5µm Id) with flow rate 1.0 ml/min & detection was carried out

by UV detector at 280nm at ambient temperature. The mobile phase consistsacetonitrile: potassium dihydrogen orthophosphate buffer with pH 4.3 (60/40 % v/v). The retention time for BS and MH were 5.2 and 2.4 min respectively. The system suitability parameters were calculated and were found within limits. Linear relationships were obtained between response and concentration of drug in the range 4.5-27.0 µg/ml for BS and 2.5-15.0 µg/ml for MH. The LOD and LOQ were 2.32 and 6.91 µg/ml for BS, 2.30 and 6.99 µg/ml for MH respectively. The mean % content of BS and MH were 97.34%and 91.37% respectively in pharmaceutical dosage form. The results of formulation analysis were statistically validated as per ICH guidelines.The procedure is simple, sensitivity and less time consuming compared to other chromatographic procedure. This method can be applied for quantification of different formulations containing Bromfenac Sodium and Moxifloxacin HCl simultaneously.

Keyword: Bromfenac Sodium, Moxifloxacin HCl, RP-HPLC, Validation.

F-110

Spectrophotometric Determination of Tenofovir in Bulk and Tablet dosage form

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Abstract:

A simple new spectrophotometric method has been developed for estimation of Tenofovirdisoproxilfumarate in bulk and tablet dosage form. Tenofovirdisoproxilfumarate is estimated to be 261 nm in double distilled water and methanol (9:1). The Beer's law is obeyed in the concentration range of 10-100 µg/mL of the drug. The slope and intercept values are 0.0178 and 0.0631, respectively. Results of analysis of this method have been validated statically and by recovery studies. The method is applied to the marketed tablet formulation. A result of the analysis of tablet formulation, given as a percentage of label claim ± standard deviation is 92.03 ± 0.44. The precision and accuracy has been examined by performing recovery studies and found to be 97.3±0.66. The developed method is simple, sensitive, and reproducible, and can be used for the routine analysis of Tenofovirdisoproxilfumarate in bulk and tablet dosage form.

Keywords: Tenofovirdisoproxilfumarate, double distilled water, methanol, UV Spectrophotometric method

F-111

Impact of Quality by Design in Analytical Procedures

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Abstract:

The aim of every analytical process is to ensure the quality of the drug product. Therefore to ensure and improve the quality of a pharmaceutical product ICH has launched a very efficient technique termed as Quality by Design (QbD). Implementation of QbD in analysis is termed as AQbD. It is a systematic approach to product development which begins with some predefined objectives, emphasizes product, process understanding and process control which is based upon sound scientific techniques and quality risk management. QbD protocol is based upon some tools like TPP, TPQP, CQA, CPP, DoE and risk management at each step. There is a complete focus on performance during product development through QbD. Therefore chances of errors are minimized. There is a complete check on various quality variables which affect the quality of product. In the presented review authors have summarized the basic concept of QbD, elements of QbD and acquisition process of QbD in various analytical procedures. Due to all these beneficial aspects, maximum industries are adopting QbD technique in product development. In the lateral part of this review, various analytical applications of QbD have been discussed. So, the analysts and manufacturers should explore this approach at research as well as industry levels.

Keywords: QbD, TPP, TPQP, Risk management, Quality variables.

F-112

Process Validation and Risk Assessment Study Of Anti-Migraine Sumatriptan Succinate Tablets 100 mg

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Abstract:

The purpose of research was to study Prospective Process Validation Sumatriptan Succinate Tablets 100mg dosage formulation. Process Validation is the collection and evaluation of data, from the process design stage throughout production, which establishes scientific evidence that a process is capable of consistently delivering Quality products. Three consecutive batches of Sumatriptan Succinate Tablets 100mg manufactured as per the Batch Manufacturing Record. Collected samples at different stages like for sifting, blending, compression as mentioned in the sampling plan for individual process. Then sent for analysis, each parameter was analyzed and tested as per specifications and recorded the results, which were found with in the limits. The results suggest that the all parameters are within the limits. All physical parameters like weight- variation, hardness and thickness, disintegration time, friability were found within the limits. So the manufacturing process intended for further batches. The process is validated as per specifications. Overall manufacturing processing parameters are analyzed and compared with the standard specifications, found within the limit and it was concluded as the parameters mentioned above validated as per BMR and BPR. The process validation data of Sumatriptan Succinate Tablets 100mg reveals that there was no significant variation between batch to batch and all the process variables were studied. Therefore, it can be concluded that the process of Sumatriptan
Succinate Tablets 100mg Validated.

Keywords: Sumatriptan Succinate Tablet, Prospective, Process validation, Risk assessment

F-113

Development and Validation of Chromatographic Method for Estimation of Terizidone in Pharmaceutical Dosage Form

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Abstract:

A high-performance thin-layer chromatographic method was developed and validated for estimation of Terizidone in pharmaceutical dosage form. The proposed method was applied successfully to the pharmaceutical analysis of the recently approved dosage form of Terizidone which is available in market as a brand name of Tericox tablets. The drugs were satisfactorily show peak with RF 0.60 ± 0.03 for Terizidone. Method was validated according to the ICH guidelines. The calibration plot was linear between 50-300ng per band for Terizidone. The LOD and LOQ for Terizidonewas found to be 0.981 and 2.973, respectively. Accuracy and precision of the proposed method was evaluated by Recovery studies (% recovery for Terizidone was 99.88%) and intra-day and inter-day precision studies (standard deviation value for precision studies was found to be 1.24 and 1.00 respectively.) In stability testing, Terizidone were found susceptible to acid hydrolysis and alkaline degradation. Because the method could effectively separate the drugs from their degradation products, it can be used as a stability indicating method. The proposed validated stability indicating assay for the sensitive determination of the mentioned drugs is suitable for Quality control laboratories as a simple fast economic method. Degradation product of Terizidone in alkaline condition was carried out and its degradation product is successfully separated and isolated by HPTLC method. Degradation product was identified by using MS-MS technique.

Keywords: Terizidone, High performance thin layer chromatography, Stability indicating assay, Tericox tablets, Isolation of degradation product, MS-MS identification.

F-114

Analytical Method Development and Validation for Simultaneous Estimation for Metformin HCl, Rosuvastatin Calcium, Telmisartan in bulk drug by UV spectroscopy

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Abstract:

The present study focuses development of UV spectrophotometric method for the simultaneous estimation of Metformin HCl, Rosuvastatin calcium and Telmisartan in bulk drug. The various validation parameters, such as linearity, precision, accuracy, specificity, robustness, limit of detection and limit of quantification were studied according to (ICH) International Conference on Harmonization guidelines (Q2) R1. The first order derivative UV spectrophotometric method was performed at 208nm, 233nm and 221nm for Metformin HCl, Rosuvastatin

Calcium and Telmisartan respectively in 0.1N HCl solution and distilled water (50 : 50). The linearity was found to be in the concentration range of 2-10 µg/ml for Metformin and Telmisartan, 10-50 µg/ml for Rosuvastatin Calcium with correlation coefficient (R^2) 0.994 for Metformin HCl and Rosuvastatin Calcium & 0.998 for Telmisartan. The mean % recoveries were found to be 99.11 ± 0.15, 99.71 ± 0.47 and 98.88 ± 0.66 for Metformin HCl, Rosuvastatin Calcium and Telmisartan respectively. The proposed method is highly sensitive, precise and accurate and therefore can be used for its intended purpose. The suitability of these methods for the quantitative determination of Metformin HCl, Rosuvastatin Calcium and Telmisartan was proved by validation. The proposed method has been validated as per ICH guidelines and successfully applied to the simultaneous estimation of Metformin HCl, Rosuvastatin Calcium and Telmisartan in bulk drug. The results of analysis have been validated statistically and by recovery studies.

Keywords: Metformin HCl, Rosuvastatin Calcium, Telmisartan, UV Spectroscopy and Validation

F-115

Optimization for the Quantification of Markers and Phytochemical Investigation of Thuja by HPTLC

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Abstract:

Background: *Thuja occidentalis* (L) belongs to the family of Cupressaceae. This species is an important herb in medicine as used in treatment of so many diseases. Fresh leaves of *Thuja occidentalis* were collected and subjected to extraction. In this work the markers were determined by HPTLC and phytochemical investigation was also done.

Methods: Markers present were developed by using extracts of the plant *Thuja occidentalis*. The plants contain number of constituents but mainly contain quercetin. Chromatographic separation was performed on aluminium foil plates coated with 200 µm silica gel 60 $_{F254}$ Linear ascending development with methanol: chloroform: toluene 3:4:3 (v/v/v) was performed at room temperature (25 ± 2 °C) in a twin-trough glass chamber saturated with mobile phase vapor. Wavelength was performed in reflectance-absorbance mode at 236 nm. The phytochemical analysis of thuja was also carried out.

Results: The quantification of markers also determined in plants. The phytochemical screening of Thuja occidentalis revealed the presence of alkaloids, flavonoids, phytosterol, tannins, saponins, reducing sugars.

Conclusions: The above method was a rapid and cost effective quality-control tool for routine analysis of markers in thuja occidentalis.

F-116

"Solid as Solvent"- Organic solvent free, eco-friendly, spectrophotometric determination of piroxicam tablets using melted niacinamide as solvent (Mixed solvency concept)

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Abstract:

In this novel research, melted niacinamide (at 135°C) has been used as solvent for distribution of a poorly water soluble drug, piroxicam. This gives an eco-friendly idea as, how to utilize solids in place of toxic type of organic solvents. The main objective is to show "Solids also possess solubilising power". Present research also gives idea as how we can minimize the use of toxic organic solvents in spectrophotometric estimations. Commercial tablets of piroxicam have nicely been analyzed spectrophotometrically without the use of organic solvents. According to the theory proposed byMaheshwari, each& every substance (gas, liquid or solid) possessessolubilising power. Niacinamideimbibes significantly large solubilizing power to piroxicam and having solubility more than 110 mg per ml of melted niacinamide (135°C) whereas aqueous solubility of piroxicam is 0.401mg/ml at room temperature. Calibration curve of piroxicam was plotted by recording the absorbances of standard solutions (5-25µg/ml) of piroxicam which were made by diluting the stock solution of piroxicam (100µg/ml) with distilled water. Using respective reagent blanks, the absorbances of prepared standard solutions were noted at 358nm. The percent label claims were found very close to 100 (99.09 ± 0.877 and 98.39 ± 1.082) indicating accuracy of the proposed method. Percent recoveries estimated by the proposed method are close to 100 (100.33 ± 0.883 to 101.73 ± 0.922). Validation of the analytical method was confirmed by low values of standard error, standard deviation and percent coefficient of variation. Thus, it may be concluded that proposed method is simple, safe and precise

and excludes use of toxic organic solvents.

Keywords: Mixed solvency, solubilizing power, spectrophotometric analysis, niacinamide, piroxicam

F-117

Qualification & Validation – Streamlining the process

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Abstract:

Validation is a documented program that provides a high degree of assurance that a specific process, method, or system will consistently produce same result meeting pre-determined acceptance criteria. Validation has become both a peripheral industry and a career opportunity with adherence to scientific and statistical principles. Validation is a key stage in Product Life Cycle and serious technical exercise in assurance of Quality. Qualification is the proof that a facility/equipment is suited for its intended purpose and in a system, performs reproducibly as required. The qualification process is divided into the following phases: a) Design qualification b) Installation qualification c) Operational qualification d) Performance qualification. With the inclusion of both qualification and validation, comes another part i.e. Process validation. Process validation is the documented evidence that the process, operated within established parameters, can perform effectively and reproducibly to produce a product or an intermediate or API meeting pre-determined specifications and quality attributes. Process validation is of three types a) Prospective b) Concurrent c) Retrospective validation. USFDA in 2011 paved way to a newer approach in process validation by defining process validation as the collection and evaluation of data, from the process design stage through commercial production, which establishes scientific evidence that a process is capable of consistently delivering quality product. Process validation involves a series of activities taking place over the lifecycle of the product and process. For a successful Qualification & validation study, the most important criteria are the front-end study and user requirement specifications (URS),

Keywords: Process validation, Qualification, Front-end study, URS, Consistent

F-118

Method Development and Simultaneous Estimation of Pregabalin and Celecoxib in Pharmaceutical Dosage Form by Using a Developed and Validated RP-HPLC Technique

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Abstract:

A simple, accurate, precise and highly selective reverse phase high performance liquid chromatographic (RP-HPLC) method was developed and validated for Pregabalin and Celecoxib. Chromatographic separation was achieved isocratic ally by using waters alliance 2695 separation module, Hypersil BDS(150 mm x 4.6 mm, 5m) at temperature 30ºC Flow rate selected was 1ml/min. Both changes were identified with 238 nm. Mobile phase employed was potassium di hydrogen orthophosphate buffer of P^H 6.5 and Acetonitrile in the ratio of (70:30) which resulted best resolution and sensitivity. Developed method was validated in terms of linearity, range (37.5 **µg/ml** - 281.25 **µg/ml, for Pregabalin, 100µg/ml -750µg/ml Celecoxib),** precession (correlation coefficient is less than 0.999), robustness, accuracy (recovery of Pregabalin and Celecoxib were 100.3% and 100.13% respectively). The validation of proposed method was verified by recovery studies and can be applicable in routine pharmaceutical analysis.

Keywords: RP-HPLC, Pregabalin, Celecoxib and Potassium di hydrogen orthophosphate buffer.

F-119

Evaluation Of Different Marketed Brands Of Telmisartan Tablets: A Comparative Study

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Abstract:

Quality of any pharmaceutical product is very important because drugs must be marketed as safe and therapeutically activeformulations whose performance is consistent and pre-

dictable. Evaluation of the physiochemical properties of the pharmaceutical products can ensure their quality as well as bioavailability and impart optimum therapeutic activity. Telmisartan tablet was chosen for this comparative study because it is widely used worldwide for treating hypertension. In this present study the weight variation, hardness of five brands of telmisartan tablets marketed were compared. All five brands of telmisartan tested conformed to the IP weight variation test. All the brands had average hardness which was satisfactory for tablet like telmisartan. All the brands had shown their friability variation within ± 1% range specified by IP, and standard deviation of friability was calculated.Among all the marketed brands, the brand-5 is found to be the best brand. All the parameters such as Weight variation, Thickness, Hardness, Friability, Disintegration time, Dissolution Study and Drug content uniformity-were evaluatedwith the other brands.

Keywords: Telmisartan, Weight variation, Hardness, Friability, Drug content, Dissolution.

F-120

Acetone Extraction and Hplc Determination of Acrylamide in Potato Chips

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Abstract:

A new sensitive method using high performance liquid chromatography (HPLC) and liquid extraction for the analysis of acrylamide (AA) in potato chips is reported. The method comprises extraction with acetone using ultrasonic bath and reversed phase C18-AQ (2 × 250 mm) column with water as eluent. Flow rate was 0.15 ml min^{-1} and the column temperature was kept constant at 40 °C. The analysis was performed using a 20 µl injection loop and a UV detector adjusted at 202 nm. In this condition, the retention time for AA was 8 min. A linear calibration curve (regression coefficient = 0.999) in the range of 20-400ng $g^{-1}$was used for quantitative purposes. Limit of detection (LOD) (signal-to-noise ratio of 3:1) and limit of quantification (LOQ) (signal-to-noise ratio of 10:1) for the method was 2.46 and 3.14 ng g^{-1} respectively. Extracted samples and standard solutions with different concentrations of AA were analyzed repeatedly in one day and different days to estimate the repeatability and reproducibility of the method. Analysis of variance on the obtained data showed no significant difference between variances in different days. Using the proposed method, different potato chips samples were analyzed in different days in another laboratory. Paired t-test showed no significant difference between the obtained results from the two laboratories.

Keywords: Acrylamide, HPLC, Determination, Potato chips, Acetone extraction.

F-121

Physico-Chemical and Bacteriological Analyses of Water Used For Drinking and Swimming Purposes in Talcher, Odisha

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Abstract:

Physicochemical and bacteriological analyses were carried out on stream water and river water used for drinking and swimming purposes in Talcher, Odisha. The results obtained were compared with WHO and EPA standards for drinking and recreational water. pH is within the permissible limit &values are close to each other. Conductance & Alkalinity are high value for a water sample which indicate that the presence of Bicarbonate, carbonate, Ca, Mg, Cl-, Na+, K+ ions are in high amount. DO, BOD, and COD show the high values of this parameter indicate heavy bacterial growth. Total Coliform clearly indicates that water from all area is not potable. This water contains bacteria which spread epidemic diseases. TS, TDS, TSS, and Turbidity values from Talcher are more than permissible limit. This indicates heavy pollution in these areas. The presence of pathogens in water for drinking and swimming purposes is considering the possibility of the presence of other bacteria, protozoa and enteric viruses. This worried in gastrointestinal water borne diseases and the low infectious dose for these water borne pathogens.

Keywords: Drinking water, swimming, bacteria, total coliform, pathogen

F-122

Development and Validation of Stability Indicating HPTLC-MS Method for Estimation of Empagliflozin in Pharmaceutical Dosage Form

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Abstract:

A high-performance thin-layer chromatographic method was developed and validated for estimation of Empagliflozin in pharmaceutical dosage form. The proposed method was applied successfully to the pharmaceutical analysis of the recently approved dosage form of Empagliflozin which is available in market as a brand name of Jardiance tablets. The drugs were satisfactorily show peak with RF 0.65 for Empagliflozin. Method was validated according to the ICH guidelines. The calibration plot was linear between 100-1000ng per band for Empagliflozin. The LOD and LOQ for Empagliflozin was found to be 0.171µg per band and 0.521µg per band, respectively. Accuracy and precision of the proposed method was evaluated by recovery studies (% recovery for Empagliflozin was 99.88%) and intra-day and inter-day precision studies (standard deviation value for precision studies was found to be 0.453. In stability testing, Empagliflozin were found susceptible to acid hydrolysis and alkaline degradation. Because the method could effectively separate the drugs from their degradation products, it can be used as a stability indicating method. The proposed validated stability indicating assay for the sensitive determination of the mentioned drugs is suitable for Quality control laboratories as a simple fast economic method. Degradation product of Empagliflozin in alkaline condition was carried out and its degradation product is successfully separated and isolated by HPTLC method. Degradation product was identified by using MS-MS technique.

Keywords: Empagliflozin, High performance thin layer chromatography, Jardiance tablets, MS-MS

F-123

Development of a New Stability Indicating RP-HPLC Method for Simultaneous Estimation of Saxagliptine and Dapagliflozin and Its Validation as Per ICH Guidelines

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Abstract:

A new stability indicating RP HPLC method has been developed and validated for simultaneous estimation of Saxagliptine and Dapagliflozin in bulk and dosage forms. The method involves separation on XTerra C_{18} column (150mm x 4.6mm x5µm particle size). The optimized mobile phase consists of phoaphate buffer (pH 4) and Acetonitrile (50:50v/v) with a flow rate of 1ml/min and UV detection at 225mn. Retention time was 2.1min (Saxagliptine), 2.8min (Dapagliflozin). Linearity range was 20-60ug/ml (Saxagliptine), 40-120ug/ml (Dapagliflozin). Accuracy was in the range of 99.99-100.50% for both drugs. Precision was 0.78% and 0.44% for Saxagliptine and Dapagliflozin. LOD and LOQ are 1.63ug/ml and 5.39ug/ml for Saxagliptine, 1.94ug/ml and 6.50ug/ml for Dapagliflozin. The method developed is more sensitive, accurate and precise than the methods reported earlier. Retention time and run time were also less and hence the method is economical. When applied for tablet assay, drug content was within 100.24-100.43 % of labeled content. Forced degradation studies indicated the suitability of the method for stability studies.

Keywords: Saxagliptine, Dapagliflozin, RP-HPLC Method, Simultaneous estimation, Forced degradation studies

F-124

Magnetic Field Phase Transition Induced Crystallization for Stabilization of Amlodipine Besylate

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Abstract:

The degradation study of pure Amlodipine besylate API (AMB) showed 12.19% of degradation in consecutive 30 days trial. Attempts had been made for stabilization of AMB degradation by polymorphic modification, different systems such as electro (E), magneto(M) and methanol(Me) were used at phase transition of AMB in solution form to obtain the crystals. These customized crystals from different systems and in tablet dosage forms were evaluated for its stability using titrimetric methodology. Study showed that 7%, 2%, 6% degradation observed in E, M and Me respectively. The magnetic field induced phase transition crystallization technique showed significant 2% reduction in pure AMB. This was further confirmed by developing & validating HPLC method for determination of stress degradation of AMB amongst the various systems, M system was found to be more stable. Consequently inter atomic and inter planner distance changes associated with crystallization results in en-

hanced resistance against the all source of degradants.

Keywords: AMB- amlodipine, M system- magnetic crystals of AMB , E- electric crystal of AMB, Meth-methanolic crystal of AMB

F-125

Pyridazinone Derivatives As Potential Inhibitors Against COX-2 Receptor:- Structure Based Designing

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Abstract:

Molecular docking is a computational tool to understand the binding mode of ligands with the Crystal structure of target protein, which is achieved by generatinga number of conformations (or poses) of a ligands within the active site of receptor and scoring them to identify the best binding conformation. An attempt toward designing of some pyridazinone derivatives against inflammation, as inhibitors of Cycloxygenase-2 (COX-2) molecule was carried out using *in silico*approaches of molecular docking studies. Binding conformations were compared with the co-crystallized inhibitor, complexed within the of 3D structure of target protein receptor COX-2 (PBD ID: 6 COX), used in docking simulation. The designed ligands exhibited good binding within the active site of receptor protein. But the Pyridazinone based ligands such as **3l**, **3s**, **3h** and **3p** were screened as the best potent hits, as potential inhibitors of COX-2, on the basis of molecular docking studies.

Keywords: Inflammation, Cyclooxygenase (COX), In Silico Analysis, Binding Affinity, Molecular Docking

F-126

Bio-Analytical Method Development and Its Validation for the Estimation of Lercanidifine in Rat Plasma and Its Application for Pharmacokinetic Studies by RP-HPLC

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Abstract:

A simple, sensitive and rapid reverse phase performance liquid chromatography (RP-HPLC) method was developed and validated for the determination of Lercanidifine from small volumes of rat plasma. The Sample preparation was very simple and it involves protein precipitation method with ACN From the results of all the validation parameters and applicability of the assay. The present method can be useful for pre-clinical pharmacokinetic studies of Lercanidifine with desired precision and accuracy along with high-throughput. The developed analytical method for Lercanidifine in reverse phase chromatographic method utilizing C_{18} column (250 mm × 4.6 mm, 5µ). The peak was detected using a fluorescence detector set at Ex 220 nm and Em 280 nm. The mobile phase used was 1M triethylamine pH-4.0: Acetonitrile in the ratio of 65:35. The retention time of Lercanidifine was found to be 8.25min.The total chromatographic run time was 12.0 min. The flow rate of the mobile phase was 1.0 ml/min at room temperature. Method was found to be linear from 2 to 500ng/ml for Lercanidifine ($r^2 \geq 0.9998$). The results indicate the bio-analytical method is linear, precise and accurate. The developed method was validated and found suitable for application in designing pharmacokinetic studies and simplified solvent system.

Keywords: Lercanidifine, RP-HPLC, Rat Plasma

F-127

Forced Degradation studies to Assess Degradation Behaviour of Chlordiazepoxide and Amitriptyline hydrochloride in Bulk and Pharmaceutical dosage forms by RP-HPLC

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Abstract:

The HPLC is an integral analytical tool to assess drug product stability. Chlordiazepoxide and Amitriptyline hydrochloride as model compounds, attempt was made to develop a specific, precise, accurate, linear, simple, rapid, validated and cost effective RP-HPLC method for the drug stability under forced degradation study. The proposed and developed method, is validated was in accordance with ICH guidelines. The HPLC

method was validated on a LC system µBondapak C18 Column (300 x 3.9 mm,10 µm particle size) with mobile phase of Buffer: Acetonitrile :THF (50:20:30 v/v/v) and UV detection was made at 254 nm. The recoveries were at three concentration levels with an average of 100.65%.

Keywords: RP-HPLC, Forced Degradation Chlordiazepoxide, Amitriptyline HCl

F-128

State Of Art Quantitative Estimation of Efavirenz Using UV-Visible Spectroscopy Method

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Abstract:

Efavirenz is an anti-viral agent of non-nucleoside reverse transcriptase inhibitor category used as a part of highly active retroviral therapy for the treatment of infections of human immune deficiency virus type-1.Efavirenz is partially soluble in water and highly soluble in Methanol. By using simple UV-Visible spectroscopy method a rapid, more sensitive estimation method was done by using various solvents such as Methanol, Acetonitrile (ACN) and water in combination. The specific diluents of two solvents provided 100% accuracy results in the ratio. The present method is simple, rapid, accurate, precise and economical when compared to other methods. The absorption maxima of the drug were found to be 246nm for Efavirenz in solvent system ratio. The method is applied to standard and 3 different dosage forms it gives best results of accuracy, precision & linearity over a range of 2-18µg/ml for Efavirenz. The percentage recovery was found to be 99.85- 101.09% for Efavirenz. Results were analyzed and validated for various parameters as per ICH guidelines.

Keywords: Efavirenz, UV-Visible, Method Development validation, Formulations

F-129

Prospective Process Validation of Antiepileptic Drug: Levetiracetam Tablet USP 500 MG

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Abstract:

The word validation simply means assessment of validity or action of proving effectiveness. Validation in itself does not improve processes but confirms that the processes have been properly developed and are under control. Validation of the individual step is called as Process Validation. In Present research work, Levetiracetam tablet was formulated using direct compression technique, various granulation techniques and using different disintegration agents with Pharmaceutical excipients. Levetiracetam is an antiepileptic drug. These research work concentrates to provide assurance that the manufacturing procedure is suitable for intended purpose and consistently meet predetermined specifications and quality attributes, as per specified master formula record. It also provides a documented evidence for the operation sequence and schedule of manufacturing process and to determine the critical parameters and variables in the process of manufacturing of the tablets. It gives a higher degree of assurance that the manufacturing process consistently meets the pre-determined specifications and quality products output can be used to increase productivity, its consistent quality and decreasing the need for processing/ market complaints.

Keywords: Validation, Process Validation, Levetiracetam, Manufacturing Process.

F-130

A Simple, Precise and Accurate Estimation of Labetalol Using UV-Visible Spectroscopy Method

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Abstract:

A simple, sensitive, accurate, rapid ultraviolet spectrophotometric method was developed for the estimation of Labetalol in its pure form and its bulk formulation. For the estimation of Labetolol the solvent system involved was methanol and water in combination. The absorption maxima (λmax) of the drug were found to be 305nm. The method found very precise with the solvent system ratio was X: Y. Different analytical parameter such as linearity, precision, accuracy, Limit of detection (LOD), Limit of quantification (LOQ) were determined as per ICH guidelines. Calibration curve was found to be linear over concentration range 2-18 µg/ml. The percentage recovery are calculated at 80%,100%,and 120% and were found to be X,Y and Z respectively.RSD of precision was found to be in range of

X and Y. The present method is simple, rapid, accurate, precise and economical as compared to other method.

Keywords: Labetalol, UV-Visible Spectrophotometry, Bulk formulation, Method Validation

F-131

Development and Validation of HPTLC Method for Estimation of Aripiprazole in Tablet Dosage Form

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Abstract:

A specific stability indicating high-performance thin-layer chromatographic method for analysis of Aripiprazole both as a bulk drug and in formulations was developed and validated. The method employed HPTLC aluminium plates precoated with silica gel 60F254 as the stationary phase. The optimized mobile phase system consisted of Toluene: Methanol (8:2v/v) and scanned in Absorbance Reflectance mode at 254nm using Camag TLC scanner 3 with winCATS software. Aripiprazole was subjected to forced degradation studies in order to check the specificity of the method. Densitometric analysis of Aripiprazole was carried out in the absorbance reflectance mode at 254 nm. The Rf value of Aripiprazole was found to be 0.56. The linearity study was carried out and R^2= 0.992. The relative standard deviation for intraday and interday precision was found to be 0.98% and 1.64% respectively. According to validation studies, the developed method was accurate and reproducible and hence can be used for routine analysis of pharmaceutical formulation. Moreover, the method could effectively separate the drug from its degradation products; hence it can be employed as a stability indicating one.

Keywords: Aripiprazole, HPTLC, Forced degradation.

F-132

Formulation and Analytical Method Development for Immediate Release Ziprasidone Hydrochloride for Oral Drug Delivery

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Abstract:

Ziprasidone Hydrochloride (Zip.HCl), an atypical antipsychotic used for the treatment of schizophrenia has poor water solubility. Various hydrophilic polymers were screened for solubility enhancement of Zip.HCl and it was found that **β-cyclodextrin showed maximum solubility enhancement.** Zip.HCl loaded pellets were formulated by extrusion spheronization technique usingZip.HCl**β-cyclodextrin inclusion complex(1:5) with other excipients**.Percent drug release of developed formulation showed enhanced solubility as compared to pure drug and was found to be comparable with marketed tablet formulation.Also, a simple, rapid, and reproducible, stability indicating reverse phase high performance chromatography (RP-HPLC) method for the estimation of Zip.HCl was developed usingC18 column (Kromasil ODS, 5µm, 250mm X 4.6mm) and mobile phase containingPhosphate Buffer (pH 3.0): Methanol (30:70%v/v). The flow rate was 1.0 ml/min and the eluents where detected by UV detector at 317 nm. The retention time for Zip.HCl was found to be 3.6 minutes. Zip.HCl was subjected to stress conditions including acidic, alkaline, oxidation, photolysis and thermal degradation. Whereas it was stable under acidic conditions, neutral hydrolysis, thermal and photo degradation stress conditions. The method was validated as per ICH guidelines and found to be linear within the range of 20-100 µg/ml forzip.HCl.

Keywords: Ziprasidone Hydrochloride, Spheronizer, RP-HPLC, Validation

F-133

Development and Validation Of Novel Spectrophotometric Methods For Simultaneous Estimation Of Pioglitazone And Metformin In Bulk And Fixed Dosage Forms By Area Under Curve And Dual Wavelength Mode

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Abstract:

Two simple, accurate and reproducible spectrophoto-

metric methods have been developed and validated for simultaneous estimation of metformin (MET) and pioglitazone (PIO) in bulk and tablet dosage forms.

(1) Area under curve method: The proposed area under the curve method involves measurement of area at selected wavelength ranges. Two wavelength ranges were selected 228-238 nm and 265-275 nm for estimation of MET and PIO respectively.

(2) Dual wavelength method: In the dual-wavelength method, two wavelengths were selected for each drug in a way so that the difference in absorbance is zero for another drug. PIO shows equal absorbance at 235 and 266 nm, where the difference in absorbance was measured for determination of MET. Similarly, the difference in absorbance at 216 and 241.5 nm was measured for determination of MET.

Linearity range for MET and PIO is 2-10 µg/ml and 10-50 µg/ml at respective selected wavelengths. The proposed methods have been validated and successfully applied to the estimation of MET and PIO in their combined tablet dosage form.

The utility of the methods has been demonstrated by analysis of commercially available formulations.

Keywords: Metformin, Pioglitazone, Area under curve method, Dual wavelength method

F-134

Spectrophotometric Absorbance Correction Method for the Estimation of Tazobactam and Cefepime in Combined Tablet Dosage Forms

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Abstract:

A new, simple, precise, accurate and sensitive UV Spectrophotometric absorption correction method has been developed for simultaneous determination of Tazobactam and Cefepimein combined tablet dosage form using 0.1 N NaOH as solvent. Absorbance correction method was based on the property of additivity of absorbances. The wavelengths selected for the absorption correction method were 259 nm and 306 nm. At 306 nm, Cefepime showed some absorbance while Tazobactam showed zero absorbance. Both the drugs gave absorbance at 259 nm. The method involved solving of an equation based on measurement of absorbance at two wavelengths 259 and 306 nm. The method was validated statistically. The determinations were made at 259 nm for Tazobactam and Cefepime and 306 nm for Cefepime over the concentration range of 3-18 µg/ml for Tazobactam and 10-50µg/ml for Cefepime with mean recovery of 100.34 ± 0.73 % and 99.89 ± 0.52 f or Tazobactam and Cefepime, respectively by absorbance correction method. The precision for intra-day and inter-day of the method were found to be within the limits (RSD<2%). This method was found to be precise, accurate, simple, sensitive, reproducible and economical and can be applicable for the simultaneous determination of Tazobactam and Cefepime in combined dosage form.

Keywords: Cefepime, Tazobactam, Absorbance correction method, Method validation

F-135

Difference Spectrophotometric Method for Simultaneous Estimation of Moxifloxacin and Cefixime Trihydrate in Bulk and Combined Dosage Form

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Abstract:

The objective of present work was to develop rapid, accurate, reproducible, validated and economical difference spectroscopy method for the simultaneous determination of moxifloxacin (MFN) and cefixime (CEF) in tablet dosage forms.The method comprised the measurement of the absorbance of a solution of the tablet extract in 0.1 M NaOH relative to that of an equimolar solution in 0.1 M HC1 at 254 nm for MFN and 292 nm for CEF. The presence of identical isosbestic points for pure drug solutions and tablet extracts indicated the non-interference of excipients in the absorption at these wavelengths. The method was found to be linear over the concentration range of 10-50 µg/ml for CEF and 4-20 µg/ml for MFN. Accuracy was found to be in the range of 99.91-101.18%. Relative standard deviation for precision and intermediate precision was found to be less than 2%. The developed method was successfully applied for the simultaneous estimation of Moxifloxacin and Cefixime in tablet formulation. The results obtained from the validation experiments prove that the developed method is suitable for routine analysis.This method is simple, selective, linear, precise, and accurate and sensitive hence can be successfully employed

for the routine quality control of dosage forms containing both the drugs in pharmaceutical industries.

Keywords: Moxifloxacin, Cefixime, Method validation, Difference Spectrophotometric Method

F-136

Preperation and Analysis of Zidovudine-β-Cyclodextrin Inclusion Complex Using Differential Scanning Calorimetry and Infrared Spectroscopy

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Abstract:

Drug moleculeswith low aqueous solubility havelimited dissolution rate, absorption as well as distribution in the body. Therefore, improvement of aqueous solubility in such a case is a valuable goal to improve therapeutic efficacy of the drug .Inclusion complexes are molecular compounds having the characteristic structure of an adduct, in which one compound spatially encloses another.β-cyclodextrin (CD) in aqueous solutions are able to form inclusion complex with many drugs by taking up a drug molecule or more frequently some lipophilic moiety of the molecule into the central cavity. Cyclodextrins enhance drug aqueous solubilitywhich makes them widely useful in the formulation development.A simple, rapid and economical method for direct determination of Zidovudine(AZT) in inclusion complex form has been developed using infrared spectroscopy. Binary complexes were prepared by mixing AZT and β-CD in 1:1 by physical method or solvent evaporation method. Physical inclusion complexes were characterized by Differential scanning calorimeter (DSC) and Fourier Transform Infrared (FT-IR)spectroscopy. The thermograms of physical mixture and complexes are different from pure drug and β–CD which gives clear evidence that there is formation of the complexes of Zidovudine and β–cyclodextrin at 1:1 molar ratio. The IR spectrum shows shift of the band of carbonyl group from 1685.8 to 1701.9 cm^{-1}which proved the presence of binding interactions and confirmed the formation of solid inclusion complexes.Thus β-CD complexation might be a promising strategy to improve the aqueous solubility and dissolution profile of AZT.

F-137

Method Development and Validation for Simultaneous Estimation of Esmoprazole and Itopride in Combined Pharmaceutical Dosage Form and In Bulk by RP-HPLC

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Abstract:

An accurate and precise RP-HPLC method was developed for the simultaneous estimation of Esmoprazole and Itopride in combined pharmaceutical dosage forms. Separation of the drug was achieved on ACE C_{18} (150×4.6) mm, 5µ using mixture of (A) 6.5 pH di hydrogen ortho phosphate buffer, (B) Acetonitrile and Water in the ratio of 35:65v/v as mobile phase. The flow rate was 1.2 ml/min and the detection wavelength was 272 nm. The proposed method was validated for various parameters according to ICH guidelines. This method can be employed for routine quality control simultaneous analysis of Esmoprazole and Itopride in combined pharmaceutical dosage forms.

Keywords: simultaneous estimation; RP-HPLC; Esmoprazole; Itopride.

F-138

Development and Validation of Analytical Method for Anticancer Drug Erlotinb in Bulk Drug and in Tablet Dosage Form Based on HPLC

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Abstract:

In the present work, a novel reversed phase-high performance liquid chromatographic (RP-HPLC) method for the estimation of Erlotinib in bulk and tablet dosage form has been developed and validated. The selected mobile phase was methanol (A) and water with triethyl amine (TEA 0.1%) (B). The injection volume of sample was 20 µl. The gradient program was employed at flow rate of 1 ml/min on the Eclipse plus C_{18} (250 × 4.6 mm; 5 µm particle size) column was used and maintained at 30 °C and PDA detection (at 240 nm) was performed. The retention time of the Erlotinib was found 5.43 minute in the

mobile phase A: B (50:50 v/v). The developed method showed linear ($r^2 > 0.999$), precise (%RSD < 1), accurate (recovery 99.26 to 99.50%), specific and robust. The Erlocip tablet was assayed by validation. The Erlotinib content in the tablet varied from 98.65 to 99.80.

F-139

Bio-Analytical Method for the Estimation of Cilnidipine and Olmesartan Medoxomil in Human Plasma

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Abstract:

The main aim of the present study was to develop and validate a simple, rapid and sensitive assay method for simultaneous extraction and quantification of clinidipine and Olmesartan medoxomil. Here at first standard and stock solution were prepared and bioanalytical method validation is performed and different stability tests such as thaw stability test, bench top stability tests etc. were performed. Though LC-MS/MS method is more sensitive than HPLC method, the method is simple, accurate and sensitive with an LLOQ 100.000 ng/mL for CILNIDIPINE and 5.000 ng/mL for OLMESARTAN MEDOXOMIL, when 200 µl of plasma was used for the assay of Cilnidipine and Olmesartan medoxomil. The chromatographic analysis time/sample was less than 3min as compared to HPLC methods, generally several times longer (>15 min) and therefore the method is useful for high turn around sample analysis and has sufficient sensitivity for pharmacokinetic studies. These methods applied for determination of pharmacokinetic parameters, which is useful for pharmaceutical industry. The method is currently being used for the plasma level determination of Cilnidipine and Olmesartan medoxomil in human plasma in BA/BE Studies.

Keywords: Bio analytical, LC-MS/MS, HPLC, human plasma

F-140

Development of Stability indicating RP-HPLC method for simultaneous estimation of Teneligliptin Hydrobromide and Metformin hydrochloride in pure and dosage forms

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Abstract:

A stability indicating RP HPLC method has been developed and validated for simultaneous estimation of Metformin HCl and TeneligliptinHBr in bulk and dosage forms. The method involves separation on C8 column (250mm x 4.6mm x 5µm particle size). The optimized mobile phase consists of Phosphate buffer (pH 5) and Acetonitrile (70:30v/v) with a flow rate of 1.0 ml/min and UV detection at 246nm. . The stock solution was made in mobile phase. Retention time was 3.153 min (Metformin HCl), 6.330 min (Teneligliptin HBr). Linearity range was 250-1250ug/ml (Metformin HCl), 10-50 ug/ml (TeneligliptinHBr). LOD and LOQ are 0.72 ug/ml and 2.40 ug/ml for Metformin HCl, 0.15ug/ml and 0.51ug/ml for Teneligliptin. The precision, ruggedness and robustness values were also within the prescribed limits (<1% for system precision and <2% for other parameters). When applied for tablet assay, drug content was within 98.89-103.74 % of labelled content. Stress degradation studies performed using acid, base, peroxide & photolytic methods, Thermal and Humidity condition (40°c/ 75%RH). The degraded products were identified using FT-IR and Mass Spectroscopy. The method developed was found to be sensitive, accurate and precise.

Keywords: Teneligliptin HBr, Metformin HCl, Degradation, Degradation products, Mass Spectroscopy.

F-141

Dissolution Test Method for Teneligliptin Using UV and RP-HPLC

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Abstract:

The aim of proposed work was todevelop and validated a dissolution test method for Teneligliptin hydrobromide hydrate tablets using UV Spectrophotometer and RP-HPLC. The optimized dissolution parameter includes 900mL of Phosphate buffer pH 7.5 as dissolution medium and paddle (type II) appa-

ratus at a stirring rate of 50rpm. The drug release was evaluated by UV spectroscopic and RP-HPLC methodusing 245.6nm as detection wavelength. The developed selective LC method for the quantitative estimation of TENEfrom bulk and tablets shows sharp resolved peak with good run time.The chromatographic separation achieved on Shodex C-18-4E (250×4.6 mm, 5m) with Methanol (70%): Phosphate buffer pH 7.2(30%) at flow rate of 1 mL/min.The method was validated to meet requirement for a global regulatory filing as per ICH guidelineswhich includes accuracy, linearity, precision and robustness. The results obtained by UV and RP-HPLC method were found to be reliable, accurate, precise and can be employed for routine dissolution analysis of Teneligliptin hydrobromide hydrate tablets.

Keywords: Teneligliptin (TENE), Reverse Phase HPLC, Validation

F-142

Process Validation for Development of Antitubercular Tablet Dosage Forms

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Abstract:

Process validation could be a created of documented evidence that provides a high degree of assurance that a selected method can consistently produce a product meets its pre-determined specifications and quality standards. In the present study, the process validation of solid dosage forms was carried out through protocol preparation and regulatory basis with special emphasis on tablets in industry. The study enlightened that process validation is to create a robust formulation and to validate all the critical parameters challenged in manufacturing process like dry mixing, blending, lubrication, compression, coating and packing. The results obtained during the different processing steps to evaluate and qualify the acceptability of the manufacturing process of rifampin USP 150 mg, isoniazid USP 75 mg and ethambutol hydrochloride USP 275 mg tablets. By comparing the results of above challenged parameters, it was found that all the results of three batches had met the pre determine specification and FDA requirement. Thus, it can be concluded this study can be beneficial for the formulation of antitubercular tablets dosage form by wet granulation through correct process followed as per cGMP requirements.

Keywords: Process validation, Antitubercular tablet dosage forms, cGMP

F-143

Design, Development and Standardization of Anti-aging Polyherbal Formulation

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Abstract:

Title: Design, Development and Standardization of Anti-aging Polyherbal Formulation.

Aim: To Design and Standardization of polyherbal Anti-aging Formulation.

Need: Due to the current status of environment condition and day to day life style human skin become more prone to aging. Now a days the healthy lifestyle and nutrition intake are also lacking and these reasonsleads towards the dullness and fasten the aging of skin. Conventional treatment may available but givesserious side effects on long term uses. Hence there is pressing need of alternative medicine to the said problem. In this regards, the attempt has been made is present research to develop and standardized polyherbalformulation which will produce equal effects in every batches i.e. batch to batch consistency.

Material and Methods:*Rosemary extract, Salix alba, Purnica gravitum*(pomegranate) are used in formulation to arrest the skin aging and it also standardized by HPLC Method.

As per ICH guidelines, the simple, specific, reproducible, precise and robust HPLC method have been developed and validated for the quantification of Rosmarinic acid and Salicin in formulation. Waters HPLC system (quaternary gradient) coupled with a PDA detector with the column Inertsil ODS 5µ (4.6 x 250mm) was used for the HPLC analysis. Mobile phase consisting of 0.1% Formic Acid and 100% Acetonitrile at flow rate 1ml/min was used for simultaneous method.

Results: The formulation was tested for its all physical and chemical parameters and found to be passed as per specification.Retention time for Salicin was found to be around 6.00 minutes and for Rosmarinic acid was around 13.00 minutes. System suitability parameters were calculated and found to be within limits. The linear relationship was obtained between response and concentration with correlation coefficient (r2) in the range 50-150 ppm for Salicin (r2= 0.999) and 50-150ppm for Rosmarinic Acid (r2= 0.999). The HPLC simultaneous method

for Rosmarinic acid and salicinvalidated for Accuracy, Recovery, Specificity, Method Precision, and Intermediate Precision and found to be accurate to analyzed Rosmarinic acid and salicin from Formulation.

Conclusion: The Formulation containing Rosmarinic acid, Salix alba and pomegranate extractsis used as Anti-aging which may prove fruitful to prevent aging due to harmful environment and other culprit.

Future Scope: Clinical trials can be planned.

F-144

Simultaneous Estimation of Metaxalone and Diclofenac Sodium in Combined Dosage Forms by RP-HPLC method

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Abstract:

A simple, sensitive, rapid and reproducible RP-HPLC chromatographic method has been developed for the estimation of Diclofenac and Methaxalone in pharmaceutical formulation. The chromatography was carried out on gradient system C_{18}(250×4.6mm,5µ) using a mixture of buffer acetonitrile and methanol as a mobile phase in the ratio (45:27.5:27.5 % v/v) at flow rate 1ml/min and detection was done 276nm.The retention time for Metaxalone and Diclofenac sodium was found to be 11.732 and 14.001 min respectively.The results obtained in proposed method are in good agreement with labelled amounts, when marketed pharmaceutical preparation were analysed.The method was validated for parameters like accuracy,precision, ruggedness,specificity, linearity and range according to ICH guidelines. The mean recoveries from tablet formulation were between 98-102%. The detector response was found to be linear is the concentration range of 80-120 % test concentration of each drug.

Keyword: RP-HPLC, Validation, Metaxalone and Diclofenac.

F-146

Design, Development and Standardization of Laxative Polyherbal Formulation

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Abstract:

Title: Design, Development and Standardization of Laxative Polyherbal Formulation.

Aim: To Design and Standardization of PolyherbalLaxative Formulation.

Need: Due to sedentary life style and less fibrous food like fast food, the metabolism become slower and it leads to problem of indigestion and constipation. Many conventional treatments may available for the same however they may cause habit-forming trends and loss of strength of the intestine hence the alternative therapy which may give improvement in metabolism and relief in constipation, should be developed. In the present research the attempt has been made to develop the formulation which gives beneficial effect to digestion and constipation as well.

Material and Methods:*Cassia angustifolia* and *Terminalia belerica* are used in formulation as active ingredient to get relief from constipation and it also standardized by HPLC Method to get batch to batch consistency during manufacturing.

As per ICH guidelines, the simple, reproducible, precise and robust HPLC method have been developed and validated for the quantification of Sennosidesfrom formulation. Waters HPLC system (quaternary gradient) coupled with a PDA detector with the column Inertsil ODS 5µ (4.6 x 250mm) was used for the HPLC analysis. Mobile phase consisting of Buffer solution and 100% Acetonitrile at flow rate 0.5 ml/min was used for HPLC simultaneous method.

Results: The formulation was tested for its all physical and chemical parameters and found to be passed as per specification. Retention time for Sennosides A was found to be around 28.00 minutes and for Sennoside B was around 29.00 minutes. System suitability parameters were calculated and found to be within limits. The linear relationship was obtained between response and concentration with correlation coefficient (r^2) in the range 100-300 ppm for Sennoside A (r^2= 0.999) and 120-360 ppm for Sennoside B(r^2= 0.999). The simultaneous HPLC method for Sennoside A and Sennoside B was validated for Recovery, Specificity, Method Precision and Intermediate Precision which was found to be accurate to analyzedSennoside A and Bfrom Formulation.

Conclusion: The Formulation containing *Cassia angustifolia* and *Terminalia belerica* are used in effective management of indigestion and constipation. **Future Scope:** Clinical trials can be planned.

F-147

Determination of Equilibrium Bile Acid Binding Capacity of Colesevelam Hydrochloride tablets

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Abstract:

A liquid chromatography method with UV detection was developed for determination of bile acid binding capacity of ColesevelamHCl in pharmaceutical formulations. Colesevelam HCL is a polymer in nature. Colessevelam Hydrochloride is the polyallylamine Hydrochloride cross linked with epichlorhydrine and alkylated with 1-bromodecane and (6-bromohexyl)-trimethylammonium bromide. Being a polymer compound it lacks a UV chromophore. In the absence of a UV absorbing chromophore and highly non polar of compound, the direct quantitation of Colesevelam is become a major challenge. . The pharmacological activity of ColesevelamHCl is all about binding to bile acids like Glycocholic acid sodium, Glycochenodeoxycholic acid sodium and Taurodoxycholic acid sodium. The activity of the drug is depends on the bile acid binding capacity. The novel method for determination of bile acid binding capacity was developed and validated for the purpose of in vitro bio equivalence study based on high performance liquid chromatography (HPLC) with UV detection. An isocratic mobile phase containing 0.04 M potassium dihydrogen phosphate, methanol and acetonitrile in the ratio of 32:34:34 V/V/V. Chromatography was carried out using 35°C on a Grace Alltima C18, 250 x 4.6 mm, 5.0 µm column. The detection was carried outusing UV detector set at 210 nm. The compounds were eluted isocratically at a steady flow rate 1.0 mL/min. The retention time of Glycocholic acid sodium, Glycochenodeoxycholic acid sodium and Taurodoxycholic acid sodium are corresponding as 3.8, 5.0 and 5.7 min respectively. The asymmetry factor of all three peaks are 1.0 and theoretical plates are in the range of 8000 to 10000. A calibration curve was obtained from 0.05 mM to 45 mM total bile acid concentration (r>0.99 for all the three bile acids). Within day and between the day % RSD was below 20.0 for Glycocholic acid sodium, and below 10 for Glycochenodeoxycholic acid sodium and Taurodoxycholic acid sodium. Specificity experiments revealed the absence of interference from excipients.Recovery from the spiked sample withGlycocholic acid sodium, Glycochenodeoxycholic acid sodium and Taurodoxycholic acid sodium was between 99 and 101 % for both with and without acid pre-treatment. The analytical solutions are stable for 24 hours in ambient temperature (25°C). The method is found robust in small and deliberate change in wavelength, flow rate, column oven temperature and organic content in the mobile phase.

Keywords: Colesevelam HCl, Bileacid binding capacity, UV detector, HPLC.

F-149

Analytical Method Development and Validation for Estimation of Zaleplon in API and Pharmaceutical Dosage Forms by RP-HPLC

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Abstract:

A rapid and precise Reverse Phase High Performance Liquid Chromatographic method has been developed for the validated of Zaleplon in its pure form as well as in tablet dosage form. Chromatography was carried out on Apollo C18 (4.6×150mm, 5µ) column using a mixture of Acetonitrile and water (80:20 v/v) as the mobile phase at a flow rate of 1.0ml/min, the detection was carried out at 253nm. The retention time of the Zaleplon was 2.6 ±0.02min respectively. The method produce linear responses in the concentration range of 20-100µg/ml of Zaleplon. The method precision for the determination of assay was below 2.0% RSD. The method is useful in the quality control of bulk and pharmaceutical formulations.

Keywords: Zaleplon, RP-HPLC, Validation.

F-150

Development Of Quantitative Method For Determination Of Artesunate Sodium In Pharmaceutical Formulation Using Proton Nuclear Magnetic Resonance Spectroscopy

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Abstract:

A rapid, specific and accurate proton nuclear magnetic resonance spectroscopy (^{1}H NMR) method for the determination of artesunate sodium in formulation has been developed without involvement of pre-column or post-column derivatization, any sample pretreatment, as is the requirement in HPLC

studies. The method was developed on a JNM-ECA 500 series spectrometer using caffeine as an internal standard and deuterated methanol as NMR solvent. For the quantitation of the drug, ^{1}H NMR signals at 5.51 ppm (singlet) and 3.5 ppm (singlet) corresponding to the methine proton of artesunate sodium and internal standard caffeine were used, respectively. The method was duly validated for the parameters of specificity, linearity, range, limit of detection (LOD), limit of quantitation (LOQ), accuracy, precision, solution stability and robustness, as suggested in ICH Q2(R1). The advantages of the method are that no reference standard of the analyte is required for quantification and the analysis is non-destructive in nature.

Keywords: Artesunate, quantitative proton NMR, validation, tablet, caffeine

F-151

Development of new analytical method for the quantitative determination of Tofacitinib

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Abstract:

Rheumatoid arthritis is a chronic autoimmune disease which involves joint inflammation, synovial proliferation and destruction of articular cartilage. The primary symptom of rheumatoid arthritis is joint pain and dysfunction of immune system but it also affects the blood vessels, heart, brain and skin. The most common drugs used to treat rheumatoid arthritis are Methotrexate, Sulfasalazine, and Leflunomide etc. U.S. FDA currently approved drug tofacitinib in a new class of Janus kinase (JAK) inhibitors for the treatment of rheumatoid arthritis. JAKs have a pivotal role in triggering cytokine-induced signal transduction pathways that influence normal and pathological cellular processes of haematopoiesis and immune cell function, including pathogenic mechanisms which are involved in rheumatoid arthritis. Selective inhibition of JAKs by tofacitinib potentially modulates inflammatory processes and provides a novel approach for the treatment of rheumatoid arthritis. Tofacitinib is indicated for the treatment of adult patients with active rheumatoid arthritis who have an inadequate response to methotrexate and other DMARDs (disease modifying antirheumatic drugs disease modulatory anti rhumatoid drugs). Quantitative estimation of drug analysis plays an important role in the development of drug. Pharmaceutical industries rely upon quantitative chemical analysis to ensure that the raw material used and the final products obtained meet the required specification. Here we are presanting a new simple, sensitive and cheap method for quantitative determination for tofacitinib.

Keywords: Tofacitinib, Rheumatoid arthritis, method developmen

F-152

Method development and validation for the simultaneous estimation of terbinafine and desloratadine using UV-visible spectrophotometer

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Abstract:

Fungal infection is a disease of tropical and subtropical region associated with itching and rashes. Different type of fungal infection occurs in human and various studies shows presence of mast cells at the site of fungal infection. Desloratadine is a drug having mast cell stabilizing property and terbinafine is an allylamine derivative antifungal agent prescribed to patients to treat fungal disease. A new method for estimation of terbinafine and desloratadine was developed on UV-visible spectrophotometer. The solvent system used was methanol: water (50: 50 v/v). The developed method was validated according to the guidelines of ICH. The developed method showed linearity, accuracy, precision and the method was found to be robust and specific. The % RSD for various parameters was found to be less than 1.

Keywords: Terbinafine, desloratadine, combination, simultaneous estimation, UV-visible

Spectrophotometer

F-153

Preparation and UV Spectrophotometric Determination of Hydrotropic Solid Dispersions of Quercetin

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Abstract:

The present work describes the preparation of hydrotropic solid dispersions of quercetin and uv-spectrophotometric method for its content evaluation. The proposed solid dispersions are non-toxic and safe.Various hydrotropes like sodium citrate, sodium bicarbonate and sodium acetate were tried alone and in combination to prepare the dispersion. The Sodium bicarbonate (2N) was found to be better hydrotrope compared to the other selected, enhancing the solubility almost 15 times than the original quercetin. The prepared dispersions were evaluated for its melting point, microscopy, pH and content evaluation. Drug content was found to be 101.5±1.7 The UV method developed was validated for accuracy and precision. DL and QL were also estimated.

F-154

Bioanalytical Method Development and Validation of Ribavirin in Rat Plasma by RP-HPLC Method

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Abstract:

A simple, rapid, selective, sensitive, accurate and precise High Performance Liquid Chromatography (HPLC) with UV detection method has been developed and validated for determination of Ribavirin in rat plasma. The mobile phase containing a mixture of Acetonitrile: Water (60:40v/v) was used with C18 (250x4.6mm) column. The flow rate was 1ml/min and Ribavirin was monitored at 218 nm. Plasma samples were processed using acetonitrile as precipitating agent to extract drug. The linearity for Ribavirin was found to be 0.5 to 12 µg/ml with regression coefficient (r2) 0.9990. The recovery was found to be 88.09%.The proposed method was also applied for the estimation of bioavailability, bioequivalence, pharmacokinetic & toxicokinetic data of Tablet formualtion.

Keywords: Ribavirin, RP- HPLC, Accuracy, Precision, Robustness, LOD, LOQ, and Specificity

F-155

Qualification of HPHV Steam Sterilizer

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Abstract:

The primary objective of proper sterilization of material is to ensure that particle and microbiological levels are kept below the limits for the chosen grade of area, as set in the GMP for various regulatory guidelines. Since it has direct impact on both contamination control and productivity of a sterile manufacturing process, so sterilization of materials is most important in pharmaceutical industries. For sterilization of Non-porous load i.e, Standard process has been developed.The purpose of this study is to initially develop the sterilization process parameter for the articles, followed by implementation of the sterilization process for the articles. The process development included qualification of equipment and the articles.The result of the tests during the process development found to be complying with the acceptance criteria for the test performed. Hence, it can be concluded that the method employed for the development of sterilization process for Non-porous load is qualified.

Keywords: Sterilization process development, Non-Porous load qualification, Cycle development.

F-156

Development and validation of RP-HPLC Method for Simultaneous Determination of Candesartan cilexetil and Hydrochlorothiazide in Bulk and Tablet Dosage Form

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Abstract:

A simple, accurate and sensitive RP-HPLC method was developed and validated for the simultaneous determination of candesartan cilexetil and hydrochlorothiazide in bulk as well as pharmaceutical dosage Form. The separation of two components was achieved on Analytical Technologies Ltd. Grace C_{18}(250mm x4.6ID, 5µm) with UV-3000M detection at 267nm. Isocratic elution with a mobile phase consisting of Methanol: water (80:20) at flow rate 0.8mL/min was employed. Linearity was observed in concentration range 16µg/ml-80µg/ml and 13µg/ml – 65µg/ml for candesartan cilexetil and hydrochlo-

rothiazide respectively. The linear regression equation was found to be Y=33039x+29439 for candesartan cilexetil and Y=47508x+38728 for hydrochlorothiazide with correlation coefficient 0.997. The LOD was found to be 0.005µg/ml and 0.007µg/ml for candesartan cilexetil and hydrochlorothiazide respectively were as LOQ was found to be 0.01µg/ml and 0.02µg/ml for candesartan cilexetil and hydrochlorothiazide respectively. The mean analytical recovery in determination of candesartan cilexetil 99.28-99.23% and 98.91-98.41% for Hydrochlorothiazide tablet respectively. Thus, the proposed method is applicable for routine determination of candesartan cilexetil and hydrochlorothiazide in bulk and pharmaceutical formulation.

Keywords: Candesartan Cilexetil, Hydrochlorthiazide, RP-HPLC, Validation

F-157

Corrective Action and Preventive Actions and its Importance and Process in Quality Management System

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Abstract:

A well-designed and implemented corrective and preventive action (CAPA) offers a mechanism for obtaining critical quality data in a timely manner to enable early warning of potential failures and redeployment of resources to problematic areas. Every organization should have a written standard operating procedure (SOP) establishing the provisions for corrective and preventive actions. Instructions for how they should be handled within the organization in case of potential product problems, customer complaints or action to eliminate the cause of a detected Nonconformities or incident. Effective corrective action and preventive action (CAPA) systems are a key component to continuous improvement. This review provides a comprehensive view on steps involved in corrective action and preventive action, mechanism of taking CAPA enabling to improve the system of quality management and Application of CAPA System throughout the Product Lifecycle in pharmaceutical industry, and it is importance to establish change management system after CAPA which provide a high degree of assurance there are no unintended consequences of the change.

Keywords: Corrective and preventive action, Quality management system, Change management system.

F-158

Method Development and Validation of High Performance Liquid Chromatographic Method for Salbutamol in Rat plasma

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Abstract:

A simple and sensitive high performance liquid chromatographic (HPLC) method was developed for quantification of salbutamol in rat plasma. Terbutaline was used as an internal standard (IS). The present method used Solid phase extraction of salbutamol from rat plasma. Separation was carried out on reversed-phase C_{18} column (250 × 4.6 mm, 5µ) and the column effluent was monitored by UV detector at 276 nm. The mobile phase used was acetonitrile: 50mM ammonium acetate (pH 7.0), (80: 20 % v/v) at a flow rate of 1.0 mL min^{-1}. This method was linear over the range of 50.0– 1000.0 ng mL^{-1} with regression coefficient greater than 0.99. The method was found to be precise, accurate and specific during the study. The method was successfully applied for pharmacokinetic study of salbutamol in rats.

Keywords: High performance liquid chromatography; Salbutamol.

F-159

Analytical Method Development and Validation for the Simultaneous Estimation of Cinitapride Hydrogen Tartrate and Pantoprazole Sodium in Bulk and Pharmaceutical Dosage Form

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Abstract:

A simple, rapid, precise and selective UV spectropho-

tometric method was developed for simultaneous estimation of Cinitapride Hydrogen Tartrate and Pantoprazole Sodium in combined capsule dosage form. This method involves the measurement of absorbances of Cinitapride and Pantoprazole at the wavelengths of 262 nm (λ_{max} of Cinitapride) and 281 nm (λ_{max} of Pantoprazole) using methanol as solvent. Linearity was observed in the concentration range of 4-30 µg/mL for both the drugs. The accuracy of the method was confirmed by recovery studies of capsule dosage form and was found to be 100.3% and 99.9% for Cinitapride and Pantoprazole respectively. The LOD of Cinitapride and Pantoprazole was found to be 0.259µg/ml and 0.367 µg/ml and LOQ of Cinitapride and Pantoprazole were found to be 0.865µg/ml and 1.224µg/ml respectively. The method showed good precision and reproducibility with % RSD less than 2. Thus the proposed method was found to be rapid, precise, accurate and cost effective quality control tool for the routine analysis of Cinitapride and Pantoprazole in bulk and combined dosage form.

Keywords: Cinitapride Hydrogen Tartrate, Pantoprazole Sodium, UV spectrophotometric Method.

F-160

Sensitive Liquid Chromatography–Mass Spectrometry Method For the determination of Ranolazine Tablets from Rat plasma: Application to Pharmacokinetic study

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Abstract:

A simple, fast and sensitive high-performance liquid chromatography (HPLC)–mass spectrometric (MS) method has been developed for the determination of Ranolazine in rat plasma is described. After protein precipitation, chromatographic separation of Ranolazine in plasma was achieved at 30° C with a C_{18} with a mobile phase containing Acetonitrile and 0.5% Formic acid – (95:5 % v/v) at a flow rate of 0.2 mL/min and detected using Electro Spray Ionization (ESI) mass spectrometry in positive selected ion monitoring (SIM) mode. This method was linear over the range of 1.0– 120 ng / mL with regression coefficient greater than 0.99. The validated method was accurate, precise, selective, and sensitive. It's applicable in pharmacokinetic, bioavailability or bioequivalence studies.

Keywords: Ranolazine; LC/MS; bioavailability, pharmacokinetics

F-161

Development and Validation of RP HPLC Method for Quantitative Estimation of Lenvatinib in Capsule Dosage Form

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Abstract:

A simple, accurate, precise and reproducible Reverse Phase High Performance Liquid Chromatography (RP-HPLC) method was developed for the determination of Lenvatinib in capsule dosage form. The chromatographic separation was achieved on Inert sustain C18 column (250 mm × 4.6 mm × 5 µ). The mobile phase used was Water: Acetonitrile: Trifluoroacetic acid in the ratio of 60: 40: 0.1 %v/v. The influence of mobile phase composition, injection volume, mobile phase pH, flow rate, temperature and detector wavelength was investigated. Retention time was found to be 4.15 min. Method was linear over the range of 10-80 µg/ml with regression coefficient 0.999. The method was validated for system suitability, accuracy, precision, linearity and specificity. Validation study reveals that the developed method is specific, rapid, reliable and reproducible hence it can be applied for routine quality control analysis of Lenvatinib in capsule dosage forms. The method was validated as per ICH guideline ICH, Q2 (R1).

Keywords: Lenvatinib, validation, dosage form.

F-162

UV-Spectrophotometric Method for the Determination of Rosiglitazone Maleate in Pharmaceutical Dosage Forms

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Abstract:

The objective of the proposed method is to develop sim-

ple & accurate method for the determination of Rosiglitazone maleate by UV spectrophotometric method in pharmaceutical dosage forms. Stock solution of Rosiglitazone was prepared & the calibration curve was drawn by suitable dilution of the standard solution. Commercially available Rosiglitazone tablet was taken & analysed. And the validation of the adopted method was ascertained by Precision & Accuracy. From the studies, it was found that, Rosiglitazone obeys linearity within the concentration range of 1-80µg/ml. From the results of precision study, it was found that the % R.S.D is less than 2%, which indicates that the method has good reproducibility. From the results of accuarcy study, it was found that the % recovery values of pure drug from the pre-analyzed solution of formulation were in between 97.5-98.12%, which indicates that the proposed method is accurate. The proposed method is specific while estimating the commercial formulations without interference of excipients and other additives.

Keywords: Rosiglitazone, Methanol, Precision, Accuracy, Validation

F-163

Analytical Method Validation by UV Spectrophotometry and

HPLC: Emphasizing on UV-Spectroscopy

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Abstract:

Validation refers to establishing documented evidence that a process or system, when operated within established parameters, can perform effectively and reproducibly to produce a medicinal product meeting its pre-determined specifications and quality attributes. Objective of this research was, to compare the method validation by UV- spectroscopy and HPLC. HPLC and UV both are used for analytical quantification. But HPLC is highly sophisticated instrument and we need highly skilled personnel for operating and the method used is very laborious and time consuming and lastly the HPLC grade chemicals are expansive so why can't we perform analysis by UV- spectrophotometer as it is easy, quick, accurate, cost effective than HPLC. Method validation parameters were performed according to ICH Guidelines of paracetamol, & caffeine by UV – Spectrophotometer and HPLC The parameters which was analysed were accuracy, range, specificity, LOQ, LOD, precision, robustness and assay%, and the data is presented in the above table. After analysing the data we can say that, methods can be developed and validated with the help of UV-Spectrophotometer .The advantage of UV method over HPLC method is that the proposed UV method does not require the elaborate treatment and procedures usually associated with chromatographic method. It is less time consuming and economical. A statistical comparison of the quantitative determination of paracetamol, caffeine and ciprofloxacin shows that HPLC method as more accurate and precise than UV method. The results indicate HPLC and UV spectrotometry methods are adequate methods to quantify paracetamol & Caffeine in bulk dosage form.

Keywords: - HPLC, Method Validation, UV-Spectrophotometry, RP-HPLC, Comparison

F-164

Development and Validation of Spectrophotometric Method for the Determination of Dolutegravir in Bulk and Pharmaceutical Formulations

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Abstract:

In the present work, a simple and sensitive spectrophotometric method wasdeveloped for the quantitative estimation of Dolutegravir in bulk and pharmaceuticalformulations and was validated as per ICH guidelines.A simple, cost effective colorimetric method was developed andvalidated for the determination of Dolutegravir in bulk and its pharmaceutical formulations.The method relay on the reaction of the drug with 3-methyl-2-benzothiazoline hydrazine(MBTH) to get light green colour and resulting solution absorbance was measured at its absorption maximum (λmax) 630 nm. The Beer's law has been obeyed in the concentrationrange of 100-600 µg/ml. The analytical parameters of interest LOD and LOQ of the proposedmethod were calculated as 65.45 and 198.33µg/mL respectively. All the variables wereexamined to optimize the reaction condition. There was no interference observed in thepresence of common pharmaceutical excipients.

Key words: Dolutegravir, MBTH reagent, Validation, ICH guidelines

F-165

Development of Stability Indicating Assay Method for Estimation of Trapidil Using *RP-HPLC*

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Abstract:

The proposed work describes development of RP-HPLC stability indicating assay method for estimation of Trapidil in bulk and formulation. The method development was carried out on Princeton SPHR-100 C_{18} (250×4.6 mm, 5µ) column using mobile phase comprises of Acetonitrile: Phosphate buffer pH 3.0 in ratio 50:50 that at flow rate 1mL/min using 221nm as detection wavelength. The retention time of Trapidil was found to be 4.178 min. The linearity was found to be in the concentration ranging 10-70µg/mL. The percent mean estimation of drug was nearly equal to 100%. The described validated RP-HPLC method is sensitive, accurate, precise and robust. The force degradation studies were conducted to know the stability of drug samples under various stress conditions via solution and solid state analysis and % of undegraded drug was calculated. The method was found suitable for routine analysis of Trapidil in dosage form.

Keywords: Trapidil, RP-HPLC, Stability indicating method, Stress degradation study.

F-166

Standardization of Gangadhar Churna (Brihat)

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Abstract:

Standardization of herbal formulations is essential to assess the quality of drugs, in order to ensure their purity and efficacy based on the concentration of their active principles, as herbals are trending on vast basis due to the huge amount of benefits they offer as compared to chemical based preparations. This article reports on the standardization of Gangadhar churna, an ayurvedic medicine in powdered form used in the treatment of various gastro intestinal complications as dysentery, diarrhea, malabsorption syndrome and ulcerative colitis. As significant work has not been done yet on the standardization of Gangadhar churna, therefore an attempt has been made on it in this research article. Gangadhar churna was prepared as per the Ayurvedic Formulary of India. In-house preparation and the marketed formulation have been standardized on the basis of organoleptic characters, physical characteristics, and physico-chemical aspects. The set parameters were found to be sufficient to evaluate the churna and can be used as reference standards for the quality control/quality assurance laboratory of a Pharmaceutical house.

Keyword: Gangadhar churna, physico-chemical properties, herbal formulation, standardization

F-167

Isolation and Characterization of Chemical Compounds by Flash Chromatography Technique

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Abstract:

The main purpose of this work is to isolate and characterized the chemical compounds from Nortriptyline API Flash chromatography is basically an air pressure driven hybrid of medium pressure and shorter column chromatography which has been optimized for particularly rapid separation. Flash chromatography is a technique used to separate mixtures of molecules into their individual constituents, frequently used in the drug discovery process. 100 mg of bulk drug was weighed accurately and transfer in 10 ml of volumetric flask. Drug was dissolve in methanol and volume was made up to 10 ml with same solvent. So as to get the conc. of 10,000 µg/ml and it treat as degradation technique. Degradant solution was adsorbed over silica gel (# 60 – 120) in the ratio 1:4 (drug to silica gel) and finally dried under vacuum below 600 C. A column of 5 litres capacity was first loaded with 1 to 2 g of silica gel (# 60-120) with chloroform as solvent (dry packing). The adsorbed material (200 mg) was charged and eluted with chloroform: methanol gradient (100:0---90:10---80:20---70:30---60:40---50:50---40:60---30:70---20:80---0:100). The fractions were collected, concentrated, weighed and characterized by UV, IR, LC-MS, and NMR techniques.

F-168

Chemometric Assisted Optimization of RP-HPLC Technique in the Simultaneous

Estimation of Guaifenesin and its Impurity Guaiacol in Bulk and Tablet Dosage Form

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Abstract:

A simple, rapid and precise RP-HPLC method was designed and optimized chemometrically for the simultaneous determination of Guaifenesin and impurity guaiacol in bulk and tablet dosage form. The designed method was optimized by Central Composite Design under response surface methodology. By trial and error method, MeCN concentration, buffer pH and flow rate of mobile phase was selected as factors for optimization. As response variables, the capacity factor for the 1st retention time of the eluted peak guaifenesin (tR_1), the resolution between two peaks guaifenesin and its impurity guaiacol ($Rs_{1,2}$), the capacity factor of the last peak guaiacol (k_1) were selected and observed. The optimized condition in the separation of guaifenesin and its impurity guaiacol was carried out in Waters Column C_{18} (4.6 x 150mm) using the mobile phase containing phosphate buffer pH-6.4: Acetonitrile in the ratio of 72.52:27.48%v/v at a flow rate of 1.4 ml /min. and detected at a wavelength of 275 nm. The comparison of experimental and predictive values (applying CCD) of different functions under optimal conditions was found to be within the allowable error limit and gave a high desirability value (D) of 0.772. Retention time was found to be 5.180 minutes for guiafenesin (GF) and 9.990 minutes for guaiacol (GC). The calibration curves were found to be linear from 6 – 36 µg/ml for GF and 3-18 µg/ml for GC with correlation coefficient values 0.9995 and 0.9997 for GF and GC respectively.

Keywords: Guaifenesin, Guiacol, CCD, retention time, resolution.

F-169

Stability Indicating Forced Degradation Studies to Assess Degradation Behaviour of Chlordiazepoxide and Amitriptyline Hydrochloride in Bulk and Pharmaceutical Dosage Form by RP-HPLC

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Abstract:

A stability-indicating RP-HPLC method was developed and validated for the determination of chlordiazepoxide and amitriptyline hydrochloride in tablet dosage forms using C18 column(300 x 3.9 mm,10 µm particle size) with mobile phase consisting of Buffer: Acetonitrile :THF (50:20:30 v/v/v)) with a flow rate of 0.1 mL/min (UV detection 254 nm). Linearity was observed over the concentration range 50–200 mg/mL (R2=0.9999 and 0.9998).Chlordiazepoxide and amitriptyline hydrochloridewas subjected to stress conditions including acidic, alkaline, oxidation, photolysis and thermal degradation. Chlordiazepoxide and amitriptyline hydrochloride is more sensitive towards acidic degradation. The method was validated as per ICH guidelines.

Keywords: Chlordiazepoxide and amitriptyline hydrochloride, RP-HPLC, Forced degradation studies.

F-170

Development and Validation of a HPLC and a UV Spectrophotometric Method for determination of Valsartan in Pharmaceutical Preparations

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Abstract:

A high performance liquid chromatographic (HPLC) and ultraviolet (UV) methods were developed and validated for the quantitative determination of Valsartan in Pharmaceutical Dosage form. HPLC was carried out by reversed phase technique on a RP-18 column with a mobile phase composed of Acetonitrile and 0.5 % triethylamine (pH 7.5 adjusted with orthophosphoric acid (30:70, v/v). UV method was performed with the λ max at 222.0 nm. No spectral or chromatographic interferences from the tablet excipients were found in UV and HPLC. Validation parameters such as linearity, precision, accuracy, and specificity were determined.

Keywords: HPLC; UV; Valsartan; Tablets

F-171

Evaluation of Intrinsic Stability and Development of RP-HPLC Method for Simultaneous Estimation of Drugs

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Abstract:

The simultaneous estimation of Dapoxetine Hydrochloride (DAP) and Vardenafil Hydrochloride (VAD) in tablet dosage form were carried out using RP-HPLC. The chromatographic separation and resolution of drugs from the generated impurities in stress conditions was achieved on Inertsil ODS C18 (150 × 4.6 mm, 5µ) column and Acetonitrile: 0.02 M Phosphate buffer (pH 3.0) as a mobile phase in ratio 50:50v/v. The flow rate was 0.5 mL/min and 278 nm as wavelength of estimation. The retention time of DAP and VAD was found to be 4.198 min and 2.858 min respectively in selected optimized chromatographic conditions. The method was validated as per ICH guidelines, showed linearity in between 15-75 µg/mL for DAP and 5-25µg/mL for VAD. The drugs and drug product were exposed to thermal, photolytic, hydrolytic and oxidative stress conditions and the % estimation of undegraded drugs were carried out. The developed RP-HPLC method was found to be simple, reliable, accurate and precise, can be applied for simultaneous estimation of the drugs in tablet dosage form effectively.

Keywords: Dapoxetine Hydrochloride (DAP), Vardenafil Hydrochloride (VAD), RP-HPLC, Stability indicating method, Stress degradation study.

F-172

Application of Quality by Design Approach for Development and Validation of Analytical RP-HPLC Method for Sertraline Hydrochloride

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Abstract:

QbD is a systematic risk based proactive approach to pharmaceutical development that begins with predefined objectives and emphasizes product and process understanding. Quality by design (QbD) refers to the achievement of certain predictable quality with desired and predetermined specifications.The present study describes application of Quality by Design approach to the development and validation of analytical RPHPLC method for Sertraline HCL. Optimization was done by response surface methodology, applying a three level Box-Behnken design. Three factors selected were flow rate, pH, and methanol concentration in mobile phase. The optimized chromatographic method was validated according to the ICH Q2 (R1) guidelines for linearity, precision, range, accuracy and robustness. Detection was done using UV detector at 226 nm. The developed method employed mobile phase methanol: water (pH 6.4) (87:13), and flow rate 0.8 ml/min, which was optimized with the help of design expert software. High linearity of the developed method was confirmed over concentration range of 10-50 µg/mL for Sertraline HCl with correlation coefficient of 0.9993. The percentage RSD for precision and accuracy of the method was found to be less than 2%. The proposed method can be successfully used to determine the drug contents of marketed formulation.

Keywords: Quality by Design, Sertraline HCl, Box-Benhken Design

F-173

Spectrophotometric Determination of Tizanidine and Orphenadrine via Ion Pair Complex Formation Using Eosin Y

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Abstract:

A simple, sensitive and rapid spectrophotometric method was developed and validated for the determination of two skeletal muscle relaxants namely, tizanidine hydrochloride (I) and orphenadrine citrate (II) in pharmaceutical formulations. The proposed method is based on the formation of a binary complex between the studied drugs and eosin Y in aqueous buffered medium (pH 3.5). Under the optimum conditions, the binary complex showed absorption maxima at 545 nm for tizanidine and 542 nm for orphenadrine. The calibration plots were rectilinear over concentration range of 0.5-8 µg/mL and 1-12 µg/mL with limits of detection of 0.1 µg/mL and 0.3 µg/mL for

tizanidine and orphenadrine respectively. The different experimental parameters affecting the development and stability of the complex were studied and optimized. The method was successfully applied for determination of the studied drugs in their dosage forms; and to the content uniformity test of tizanidine in tablets.

F-174

Biomarker Quantification: Development of Fit for Purpose LC-MS/MS Method for Determination of Methyl Guanidine in Mice Urine

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Abstract:

Accurate quantitation of biomarkers is always challenging, when biomarker has poor retention on chromatographic column and/or possess a chemical structure resistant for derivatization. Methyl Guanidine (MG) a product of protein catabolism normally gets excreted in urine. Endogenous MG concentration in urine increases if there is reduced urine production or there is conversion of creatinine to MG is also an important read out biomarker for kidney fibrosis model. The objective was to develop LC-MS/MS based quantitative method, which can accurately determine MG level modulation in mice urine for an in vivo efficacy model.For quantification of MG in mice urine sample artificial urine was used as surrogate matrix for preparation of calibration standard while quality control standard were prepared in authentic mice urine diluted 50 folds with artificial urine prior to extraction. Mobile phase consist of 10 mM ammonium fornate and acetonitrile at flow rate of 0.5 ml/min. The retention time for MG and dextromethorphan was being 2.3 and 2.0 respectively. The calibration curve for MG was linear over concentration range 2-1000 ng/mL. The calibration model selected on based on the analysis of the data by linear regression (r^2) 0.9968. The mean % recovery for LOQ, MQC, HQC samples of methyl quinidine were 95.36 %, 94.23% and 92.5% and 97.43%. The mean recovery of % CV recovery of methyl quinidine across QC levels is 2.9%.Hence this LC-MS/MS method is very precise, accurate, sensitive and robust for determination of MG in mice urine.

Keywords: Methyl guanidine, Biomarker quantification, LC-MS/MS

F-175

Method Development and Validation for Dissolution by Using HPLC Method

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Abstract:

The transfer of molecules of loins form solute state in a solution is known as dissolution. Dissolution test is required to study the drug release from the dosage form and it is in vivo performance. Dissolution test is applied to evaluate the lot to lot quality of drug product and development of new formulation and in quality control. The purpose of this paper is to review the method development for dissolution procedure(s) and to provide practical approaches for determining specificity, linearity, range, accuracy, precision, limit of detection, limit of the dissolution test procedure itself, but also for any assay used to evaluate the test results. So HPLC is the most analytical method for drug identification, Qualitative and quantitative method.

Keywords: Dissolution method development, Method development, HPLC, Analytical method development, Method validation.

F-176

Establishment and Validation of TLC Method for the Simultaneous Estimation of Gallic and Ascorbic acid in Amla Juice Preparation

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Abstract:

A simple, selective, precise, and reproduciblethin-layer chromatography (TLC) method for the simultaneous estimation analysis of ascorbic and gallic acid in amla juice preparation. The TLC study has been developed was performed on aluminium-based pre-coated TLC plates (Silica gel G $60F_{254}$). The chromatograms of samples were developed in twin through glass chamber pre-saturated with mobile phase (toluene: ethyl

acetate: methanol: formic acid; 3:3:2:1, v/v/v/v) at room temperature (25 ± 2°C). The densitometric analysis was carried out in absorbance mode at 254 nm. The optimized mobile phase showed compact spots of AA and GA at 0.59 and 0.86 R_f respectively, from the other constituents present in the samples. The linear regression analysis data for the calibration plots showed good linearity (r^2= 0.992 and 0.996) with respect to peak area in the range of 200-1400 ng $spot^{-1}$ for both the chemicals. The method was validated as per International Conference on Harmonization (ICH) guidelines. The limits of detection and quantification (40 and 140 ng $spot^{-1}$, respectively) were also established. The proposed method has shown the excellent recovery (98.97–99.89%), which supports the suitability of the method for the analysis of ascorbic acid and gallic acid in theamla juice and other preparations containing these ingredients.

Keywords: Amla juice, Validation, Ascorbic acid, Gallic acid

F-177

Development and Validation of Ahighly Sensitive LC-MS/MS Method for the Estimation of Dexlansoprazole in Commercial Formulations

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Abstract:

Our objective is to develop and validate ahighly sensitive LC-MS/MS method for the estimation of Dexlansoprazole in its formulations. Dexlansoprazoleis a proton pump inhibitor that is marketed under the brand name Dexilant. Chemically, it is an enantiomer of lansoprazole.It is available commercially as delayed release capsules (30 and 60 mg). It is used for the treatment of heartburn associated with symptomatic non-erosive gastro-esophageal reflux disease (GERD); the healing of erosive esophagitis (EE) and in maintaining healed EE. Chromatographic separation was carried out on a Zorbax SB-C18 (150 x 4.6 mm, 3.5µ particle size) column using 0.5 mM ammonium acetate and acetonitrile in the ratio of (30:70, v/v) with a flow rate of 0.8 ml/min. Detection was carried out by triple quadrupole mass spectrometry with electro spray ionization (ESI) in positive mode with proton adducts at m/z 198.05>136.05and retention time of drug was found to be 2.00 min respectively. The method was linear in the concentration range of 0.7-2794 ng/ml. The r^2 value was found to be 0.999. The proposed method was validated by performing linearity, recovery, specificity, robustness, LOD/LOQ and interday /intraday precision. The LOD and LOQ values were found to be 0.3 ng/ml and 0.2 ng/ml respectively.

Keywords: Dexlansoprazole, Formulation, LC-MS/MS

F-178

RP-HPLC Method Development and Validation for Estimation of Alogliptin Benzoate in Rat Plasma

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Abstract:

Alogliptin Benzoate is the benzoate salt form of alogliptin, a selective, orally bioavailable, pyrimidinedione-based inhibitor of dipeptidyl peptidase 4 (DPP-4), with hypoglycaemic activity. The objective of the study was to develop a simple, accurate, precise and rapid RP-HPLC method with subsequently validate as per ICH guidelines for the determination of Alogliptin using mobile phase water: acetonitrile (60:40% v/v) on an Agilent TC C18 Reversed-Phase column with the specification (250×4.6mm I.d.), 5µm particle size of column. The flow rate was kept 1.0ml/min and temperature at 23˚C and chromatogram were recorded at λ_{max} 277nm. The retention time of alogliptin was found to be 3.08±0.02min. The linearity of the proposed method was investigated in the range of 5-50µg/ml (r^2 = 0.9997) for alogliptin. The method was statistically validated for its linearity, accuracy and precision.

Keywords: HPLC Method, Alogliptin, Validation

F-179

Development and Validation of a HPLC method for the determination of Ranolazine Residues on Pharmaceutical Manufacturing Equipment Surface by Swab Sampling Method

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Abstract:

A High-performance liquid chromatography method for the determination of Ranolazine residues on equipment surfaces was developed and validated in order to control a cleaning procedure. Recovery study was conducted for the API and tablet. The HPLC method was validated on a LC system Shimadzu using Phenomenex C_{18} (250 mm×4.6 mm×5 µm) at 25°C in the presence of a mobile phase composed of 25 mM phosphate buffer (pH 4.5): Acetonitrile 60:40 % v/v at flow rate of 1.0 ml/min and an injection volume of 20 µl and UV detection was made at 248 nm. Linearity of the method ranging from 50 to 250 µg/ml. The detection limit (DL) and quantification limit (QL) were 5 and 7 µg/ml, respectively. The intra-day and inter-day precisions, were below 2.00%. The recoveries were 98.68, 101 and 102.28% for three concentration levels with an average recovery of 100.65%.

Keywords: HPLC, Cleaning validation, Swab analysis, Ranolazine

F-180

Development and Validation of Spectrophotometric Methods for Simultaneous Estimation of Cefuroxime Axetil and Linezolid in Pharmaceutical Dosage Form

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Abstract:

Two simple, accurate, sensitive, precise and economical UV spectrophotometric methods Simultaneous Equation Method, Q – Absorbance Ratio Method (Method-I, Method- II) have been developed for simultaneous estimation of Cefuroxime axetil and Linezolid in pharmaceutical dosage forms. Method-I employs solving of simultaneous equations based on the measurement of absorbance at two wavelengths, 282.0 nm and 243.2 nm which are the λmax values of cefuroxime axetil and linezolid, respectively in 0.1 MHCl.Method- II is based on the principle of Q- absorbance ratio where in the absorbance was measured at 254.0 nm (iso-absorptive point) and 243.2 nm (λ max of linezolid) in 0.1 M Hydrochloric Acid. The linearity was obtained in the concentration ranges of 5 - 25µg/mL and 6 - 30 µg/ml, respectively.The accuracy and precision of the methods were determined and validated statistically. Both the methods showed good reproducibility and recovery with % RSD less than 2. Both methods were found to be rapid, specific, precise, less expensive and accurate and these methods require no preliminary separation and found no interferences from the tablet excipients so it can be used for routine analysis of both drugs in quality control laboratories.

Keywords: Cefuroxime axetil (CEF), Linezolid (LIN), Simultaneous Equation Method, Q – Absorbance Ratio Method.

F-181

Formulation and Evaluation of Effervescent Tablets of Diclofenac

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Abstract:

Recently fast dissolving the drug delivery systems have started gaining popularity and acceptance as new drug delivery systems, because they are easy to administer and lead to better patient compliance. Usually elderly people experience difficulty in swallowing the tablet. Diclofenac is an NSAID which has greater inhibitory action against the inducible form of cyclooxygenase which is implicated in the inflammatory response against the sensitive form of this enzymes inhibition. The aim of this study was to formulate effervescent tablet with sufficient mechanical integrity and to achieve faster disintegration in the water. Effervescent tablets are uncoated tablets that generally contain acid substance and carbonates or bicarbonate and which react rapidly in the presence of water by releasing carbon dioxide. They are intended to be dissolved in water before use effervescent composition in the form of tablets comprising a therapeutics agent, a granulating agent, a micro particulate effervescent and an effervescent system which dissolve rapidly in water to yield an effervescent solution containing a completely dissolved therapeutic agent and a process for their preparation.

Keywords: Effervescent tablet, COX-1, COX-2, Diclofenac

F-182

Simultaneous estimation of Metformin

Hydrochloride and Nateglinide in tablets using validated gradient HPLC method

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Abstract:

The present work describes a validated reverse phase ion-pair high performance liquid chromatographic method for simultaneous estimation of Metformin Hydrochloride (MET) and Nateglinide (NTG) in tablet formulation. Chromatography was performed on an Discovery ODS C_{18} (50 × 4.6 mm I.D, 5µm particle size) column in gradient mode with mobile phase containing acetonitrile: 0.01 M KH_2PO_4 and 0.01 M octane sulphonic acid (pH 7.0 with NaOH). The flow rate was 1.0 ml/min and the eluent was monitored at 218 nm. The selected chromatographic conditions were found to effectively separate MET and NTG. Plasma protein precipitation technique was employed for extraction of MET and NTG from plasma. Linearity for MET and NTG were accessed in the range of 25-10000 ng/ml and 10-10000 ng/ml, respectively. The proposed method was found to be accurate, precise, reproducible and specific and can be used for simultaneous analysis of these drugs in bulk drug and in tablet formulation.

Keywords: Metformin; Nateglinide; Simultaneous; Tablet; HPLC

F-183

Development and Validation of a Sensitive Method for Ciprofloxacin in Gingival Crevicular Fluid by HPLC using UV - Visible detection

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Abstract:

Increased interest in the clinical use of antibiotics for periodontal therapy required the development of a sensitive assay for the quantitation of Ciprofloxacin in gingival crevicular fluid (GCF). The HPLC assay employs a C18 reversed-phase Hypersil BDS column with a mobile phase composed of methanol and phosphate buffer (pH 3.5). The chromatographic separation was monitored by a UV- Visible detector with an excitation wavelength of 290nm. The retention time of Levofloxacin (IS) and Ciprofloxacin were 5.55 min and 6.52 min respectively. Ciprofloxacin was extracted from GCF collected on capillary tubes by addition of a Acetonitrile containing the internal standard Levofloxacin, and phosphate buffer. The percentage mean extraction recovery of low, mid and high quality control samples was 89.53 ± 0.91 % (Mean ± SD) for Levofloxacin and it was 91.2 ± 2.2 % for Ciprofloxacin. The lowest limit of quantitation was 50 ng/ml, with a relative standard deviation of 2.56%. The inter-day and intraday precision at LLOQ was 3.20 ± 0.80 (mean±SD) and 3.505± 0.84 (mean±SD). The typical GCF volumes collected were 0.1-1 µl. The method was validated for the linear concentration range 50-1300 ng/ml of levofloxacin on the capillary tubes. This assay for Ciprofloxacin was shown to be an accurate, precise and rugged method. The proposed method can be used for the estimation of Ciprofloxacin which was administered as in situ gels in periodontitis.

Keywords: Ciprofloxacin; Gingival crevicular fluid (GCF); UV- Visible detector; HPLC.

F-184

Development and Validation of a New Chromatographic Method for the Simultaneous Estimation of Serratiopeptidase, Aceclofenac and Paracetamol by RP-HPLC

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Abstract:

Method development, validation is an important parameter for the simultaneous estimation of Serratiopeptidase (SERA), Aceclofenac (ACE) and Paracetamol (PCM) by RP-HPLC, is supposed to be a costly and tedious process. The present study revealed using cheap and cost effective solvent system for the simultaneous estimation of Serratiopeptidase, Aceclofenac and Paracetamol. Development and validation of a new chromatographic method for the simultaneous estimation of Serratiopeptidase, Aceclofenac and Paracetamol by RP-HPLC of marketed formulations. Simultaneous determination of SERA, ACE and PCM were carried out by RP-HPLC at the wavelength 327 nm, flow rate 0.4 mL/min, and the mobile phase used was water: methanol. Further validation parameters such as system suitability, linearity, accuracy, precision, specificity, LOD, LOQ and robustness were taken into account to carry out the validation of the method. Absorbance maxima for the simultaneous determination were selected by the UV spectrophotometer and that was found to be 327 nm in methanol and water. During the

process of RP-HPLC, the linearity was obtained in the concentration range of 2-10 µg/mL for SERA, 100-500 µg/mL for ACE and 20-100 µg/mL for PCM. Correlation coefficient (r) for SERA, ACE and PCM in methanol and water was found to be 0.9817, 0.991 and 0.9949.

Keywords: Aceclofenac; Paracetamol; RP-HPLC; Serratiopeptidase.

F-185

Spectrophotometric Determination of Sitagliptin and Metformin in Their Pharmaceutical Formulation

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Abstract:

Two simple, accurate and precise spectrophotometric methods were developed and validated for the determination of sitagliptin phosphate monohydrate (STA) and metformin hydrochloride (MTF). The first method was based on measuring the absorbance of STA at 268 nm in the range of 25-500 µg mL^{-1}. The second method was the isosbestic point method. The total mixture concentration was calculated by measuring the absorbance at 257 nm. The proposed methods used to determine each drug in binary mixture. The results were statistically compared using one-way analysis of variance (ANOVA). The developed methods were satisfactory applied to the analysis of the pharmaceutical formulation and proved to be selective and accurate for the quality control of the cited drugs in their pharmaceutical formulation.

Keywords: metformin; sitagliptin phosphate; spectrophotometry.

F-186

Identification of Flavonoid Glycosides from Methanol Extract of fruit (*Cucumis Dipsaceus* Ehrenb.) by Spectroscopic Methods

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Abstract:

The prime objective of this research work was to isolation and identification of flavonoid glycosides from methanol extract from fruit (*Cucumis dipsaceus* Ehrenb.). The dried and powdered fruit was first defatted by n – Hexane solvent and then methanol extract was obtained using methanol solvent on water bath maintaining temperature approximately 35 - 38°C of polyphenolic contents in soxhlet apparatus. Isolation was done by column chromatographic method on methanol extract by attractive advantage of escalating polarity starting non polar to polar solvents (Petroleum ether, Chloroform, Ethyl acetate and Methanol). The elution of 20ml was collected and then pooled similar fractions after analyzing TLC profiling according to the ratios of different solvents used. All collected fractions were concentrated by using vacuum distillation rotary apparatus and then stored in desiccators to keep fractions free from moisture. Chloroform: Ethyl acetate fraction was again repeated for column chromatographic method for purity using increasing polarity of Chloroform (100%), Chloroform, Ethyl acetate (95:5) …… Ethyl acetate (100%) and Chloroform, Ethyl acetate fractions were obtained. These fractions were analyzed and compared with standard marker by compounds for TLC profiling, then all spots on precoated TLC of Merck F_{254} were visualized under UV light (254nm and 366nm before and after derivatized with 0.5% Anisaldehyde with H_2SO_4. The Chloroform, Ethyl acetate fraction was analyzed and the flavonoid glycoside structure was elucidated / identified by using spectroscopic methods (UV, IR, NMR and Mass). It was concluded that the structure of flavonoid glycoside was Quercetin – 3 – rutinose – 7 – rhamnose (M. Wt. 756.663g/mol).

Keywords: *Cucumis dipsaceus* **Ehrenb., Methanol extract (Fruit), isolation, characterization, Spectroscopic methods.**

F-187

Process Validation of Diclofenac Sodium Granules

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Abstract:

The main aim of pharmaceutical industry today is to manufacture products of the right quality at the lowest possible cost and to provide quality merchandise to the clients. Evaluation or validation of the manufacturing process is distinguished from those validation data which more properly fall

under the remit of GMP Inspection. The purpose of this study is to initially carry out process validation at all stages from initial development to production of Diclofenac Sodium granules (100mg).The granules thus produced were validated to assure that the critical parameters like dry mixing, granulation, drying and blending are within predetermined specifications meeting all quality attributes. During the study the critical process variables of Diclofenac Sodium granules (100mg) were validated to demonstrate the consistency of the manufacturing processes to produce the products of desired quality. The validation studies were conducted on 3 consecutive batches, which were intended for the use of commercial purposes of this validation study is concurrent type. All the in-process variables and finished product characteristics were monitored. Further from the results, it is inferred that the manufacturing processes of Diclofenac Sodium granules (100mg) are valid.

Keywords: Critical process parameters, Concurrent validation, Diclofenac Sodium granules (100mg), GMP

F-188

Development of Spectrophotometic Methods for the Estimation of Water Insoluble Calcium Channel Blockers Using Hydrotopic Solubilization

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Abstract:

The present study deals with a rapid, simple, accurate, and rugged UV Spectrophotometric methods have been developed for the estimation of some water insoluble calcium channel blockers using hydrotropic solubilization phenomenon in pure and as well as in dosage forms. The calibration graphs were linear in the 2-20µg/ml concentration range (r>0.999) for Nimodipine. The detection was made on 346nm. The method was validated according to ICH guidelines by performing linearity, accuracy, precision, limits of quantitation and selectivity. The results show the method is suitable for its intended use.

Keywords: Nimodipine, method validation, simultaneous spectrometric analysis

F-189

Inhibition Study of Enzyme Aldehyde Oxidase by Chemical Inhibitor- A Drug Discovery Prospective

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Abstract:

Aldehyde oxidase (AO)are molybdoflavo enzymes present in cytosolic compartment with broad substrate specificity, oxidizing different types of aldehydes, and heterocyclic rings has attracted increased interest in recent years. The physiological function of aldehyde oxidase is largely unknown, although the enzymes play an important role in metabolism of numerous compounds of medicinal and toxicological interest, as they oxidize a wide range of aldehyde and heterocyclic compounds aldehyde oxidase. This unit provides methods for identification and confirmation of AO as metabolic pathways as well as a method for estimating clearance of Zoniporide that are AO substrate. Determination of incubation time for AO inhibition assay is 90 min. The saturation parameters of Zoniporide is Km, Vmax found 2.887 and 19.87 respectively. With help of AO inhibition assay determine the absolute IC 50 value of inhibitor Raloxifene hydrochloride is 0.118 µM.

Keywords: Aldehyde oxidase (AO), metabolism, inhibition, molybdoflavoenzymes, clearance.

F-190

Process Validation of Ciprofloxacin 500 MG Tablets

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Abstract:

Establishing documented evidence which provides a high degree of assurance that a specific process for manufacturing of Ciprofloxacin 500 mg tablets will consistently produce a product meeting its pre-determined specifications and quality attributes.It mainly involves the steps to be followed to evaluate and qualify the acceptability of the manufacturing process of Ciprofloxacin 500 mg tablets. The process is limited to the three batches manufactured of specific batch size with specified equipments and control parameters for Tablets. It

involves sequential arrangements of all process for manufacturing of Ciprofloxacin 500 mg tablets like sifting, premixing, compaction, milling, blending, compression, coating and packing operations. The results suggest providing documentary evidence that all the manufactured ciprofloxacin 500 mg tablets were evaluated as per specifications. The steps involved such as Blend uniformity results and compression assay results were found within acceptable limits. Other tests related to compression such as hardness, thickness, disintegration, and for coating such as weight gain, disintegration were found within acceptable limit. The process validation data of Ciprofloxacin 500 mg tablets reveals that there was no significant variation between batch to batch and all the process variables were studied. Therefore it can be concluded that the process of Ciprofloxacin 500 mg tablets for three batches stands Validated

Keywords: Ciprofloxacin 500 mg, Blend uniformity, Validation

F-192

Simultaneous Estimation of Guaifenesin, Levocetrizine and Ambroxol HCl by RP-HPLC

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Abstract:

The present investigation was aimed to establish a liquid chromatographic method for simultaneous estimation of guaifenesin, levocetrizine and ambroxolHCl in ternary fixed dosage form. The three drugs were well resolved using ODS C_{18} reverse phase column with mobile phase consisting of ammonium phosphate buffer, pH 4.5: acetonitrile (60:40, v/v) at a flow rate of 1.0 mL/min and UV detection at 236 nm. The response was a linear function of analyte over the concentration range of 12.5-75 µg/mL for guaifenesin, 0.625-3.750 µg/mL for levocetrizine and 3.75-22.5 µg/mL for ambroxolHCl with correlation co-efficient value of 0.999. The retention time values were found to be 2.231, 2.772 and 6.309 min respectively for guaifenesin, levocetrizine and ambroxolHCl with rapid analysis time. Maximum recovery (99.12-101.2%) was obtained in ternary liquid oral formulation (Leoriv plus syrup). A satisfactory separation of three drugs from the degradation products was achieved. The net degradation of guaifenesin, levocetrizine and ambroxol HCl in acid hydrolysis, base hydrolysis, oxidation, thermal and UV conditions was calculated.

Keywords: Guaifenesin, Levocetirizine, Ambroxol HCl, RP-HPLC, stability studies.

F-193

Exploration of Advanced Technique in Field Ofseparation: HILIC

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Abstract:

Hydrophilic interaction liquid chromatography (HILIC) is a modern and sophisticated technique. It has been applied for analysis of many hydrophilic compounds. Hydrophilic stationary phase along with an organic solvent widely used for separation of amide, diol, polyol, bare silica, ion exchange and zwitter ion phases have been used as a rich mobile phase for HILIC. HILIC separation is achieved by partition between a mobile phase and a water rich layer on the stationary phase. Therefore, it is important for HILIC that a stable water rich layer can be formed on the stationary phase. Mobile phase for HILIC chromatography includes water-miscible polar organic solvents with a small amount of water. Some example of frequently used solvent in their increasingly strength used in HILIC mode: Acetone, acetonitrile, isopropanol, ethanol, methanol and water. Applications of HILIC for analysis of carbohydrates, peptides, aminoglycosides, β-lactams, tetracycline and other antibiotics are reviewed.The main potential application areas of HILIC cover proteomic, glycomic and metabolomic research, drug and natural products analysis. Development and research into new materials for stationary phases is expected to expand the applications of HILIC.The number of HILIC applications steadily increases and even though off-line or heart-cutting setups are more frequent and comprehensive.

Keywords: HILIC, zwitter ions, Metabolomics, applications

F-194

Modified HPLC Method Development and Its Validation for Simultaneous Estimation of Telmisartan and Hydrochlorothiazide in Combined Tablet Dosage Form

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Abstract:

Multi-ingredient formulation is regularly used in the management of various ailments in order to avoid the intake of large number of doses. Hydrochlorothiazide and Telmisartan is one of such combination useful in the treatment of Hypertension. In the proposed project, an attempt has been made to develop and validate a HPLC method and to apply the method for determination of Hydrochlorothiazide and Telmisartanin tablet dosage form. A HPLC method was developed and validated successfully for simultaneous estimation of Hydrochlorothiazide and Telmisartan. The method utilizes aBDS hypersil C_{18}, 250mm × 4.6mm, 5µ(particle size), Thermo scientific with mobile phase of 0.05 M KH_2PO_4Buffer : Methanol: TEA (80: 20: 0.1) (%v/v) (pH 4.0 by o-phosphoric acid) with the flow rate of 1 ml/min and UV detection at 231nm. The method was validated as per ICH guidelines. Linearity was observed over concentration range of 6.25-18.75 ppm for HCTZ and 20- 60 ppm for TEL respectively. The accuracy of the proposed method was determined by recovery studies and found to be 99.48- 99.94% and 99.57-99.98% for HCTZ and TELrespectively. The proposed method was extended for estimation of HCTZ and TEL in tablet formulation and it was found to be well within the acceptance limit. This RP-HPLC method for simultaneous estimation of HCTZ and TEL was found to be linear, accurate, precise, robust and rugged. Hence it can be used for routine analysis of HCTZ and TEL in tablets.

Keywords: Hydrochlorothiazide, Telmisartan, RP-HPLC, Method development and Validation.

F-195

Estimation of Iron Content in Folic Acid Tablets by AAS

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Abstract:

A novel method was standardized for quantification of elemental Iron in chemically synthesized Folic acid (API) by Atomic Absorption Spectroscopy for inline quality control. This investigation of the proposed AAS method proved that this procedure is not affected by high concentrations of other metals. Calibration graph for iron was linear at levels near the detection limit upto at least 0.0148 µg/ml. The optimal conditions for determination of elemental Iron were determined and the developed method was evaluated in comparison with validation parameters. The obtained results demonstrated that the procedure could be successfully applied for estimation of elemental in folic acid.

Keywords: Folic acid, atomic absorption spectroscopy.

F-196

Quality Control Studies of Cetrizine Hydrochoride Tablets

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Abstract:

Cetrizine is a widely used anti histaminic and anti allergic drug worldwide. The present study was conducted to analyze the quality of three marketed brands of Cetrizine tablet formulation manufactured by different multinational and national companies. The tablet formulations of different brands were tested for various parameters like weight variation, hardness, friability, and disintegration time and dissolution profile using standard techniques to evaluate their quality. The values were compared with the standards. Weight variation value requirement was complied by all brands. The hardness of all the brands was found to be in the range of 4.2-4.4kg while friability was less than 1 %. Friability results were under the recommended limit of 1%. Even the disintegration test results fell within the set limits of pharmacopoeia of not more than 30 minutes. The result indicate the differences for release profiles, all the brand products released 80% of drug labeled amount according to USP, so they can satisfy patient needs. Therefore, it can be concluded that almost all the brands of Cetrizine that are available in India meet the USP specification for quality control analysis, which have compared.

F-197

Bioassay guided and UPLC-QT of MS/MS characterization of antioxidant molecules from *Emblica officinalis*

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Abstract:

Objective: Extraction isolation Characterization bioassay guided antioxidant fraction from *Emblica officinalis*.

Method: *Emblica* powdered material was extracted with methanol and aqueous methanol and both extracts were further fractionated with solvents of varying polarity (non polar to polar) such as *n*-hexane, chloroform, ethyl acetate, and *n*-butanol. All extracts were checked for *in vitro* antioxidant activities by DPPH, ABTS and ferric reducing methods. In between methanolic and aqueous methanolic extracts the EtOAc extracts were found most active amongst fractions. From ethyl acetate fraction gallic acid was isolated and eleven other consistuents were identified using UPLC-QTOF-MS/MS. UPLC method developed for gallic acid, ascorbic acid, caffeic acid, quercetin, and myricetin in quantified by UPLC and gallic acid and ascorbic acid were also quantified by HPLC.

Result: The results of this study indicated that extracts and fractions of *E. officinalis* are rich in antioxidants and can be used as a suitable source of natural antioxidants in the food and pharmaceutical industries.

Conculsion: Isolation of gallic acid from ethylacetate fraction form *Emblica officnalis.* identification of 11 active consistuents using UPLC-QTOF-MS/MS.Quantification of active consistuents by HPLC (gallic acid, ascorbic acid) and UPLC (gallic acid, ascorbic acid, caffeic acid, quercetin, myricetin).The results of this study indicate that the extracts and fractions rich in antioxidants can be used as alternative source of natural antioxidants for use in food and pharmaceutical industries. Further research on isolation and identification of individual molecules including new molecule should be carried out to understand antioxidant mechanism clearly.

Keywords: Emblica officinalis, Gallic acid, Quercetin, Myricetin and Caffeic acid.

F-198

Biosensor: An Analytical Approach for Detection of Residual Drug Contaminants

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Abstract:

With the increasing incidences and high prevalence of hazards to human health has stipulated the both opportunity and challenges for regular monitoring of food and environmental contaminants. The food borne illness is usually infectious or toxic in nature caused by pharmaceuticals, mycotoxins, microorganism and chemicals (heavy metals and dye). According to World Health Organization (WHO), the increased mortality of foodborne diseases has resulted in 2.2 million deaths per annum. In the recent years, the stubbornly increasing human health problems due to intake of contaminated food and exposure to environmental pollutants has increased the demands of designing and fabricating the more reliable and field suitable technologies for cost effective and on-site analysis. With the advancements in sensor technology, biosensors have become more and more indispensable tools in human safety, clinical diagnostic and food safety. As per IUPAC definition "biosensor is a device that uses specific biochemical reactions mediated by isolated enzymes, immunosystems, tissues, organelles or whole cells to detect chemical compounds usually by electrical, thermal or optical signals". In a typical design of biosensor, transducer converts the signal of specific biochemical reaction into a quantifiable and measurable signal, which is proportional to the concentration of cognate molecule or group of analyte present. Biosensors are characterized by a high level of specificity and selectivity of bio-recognition elements, which specifically reacts with a given target molecule. Recently, the abuse use of antibiotics in the food industry attracted a significant attention based on their residual presence in foodstuffs. Thus, there is an immense need to undertake the present problem and finding out the optimal solution for the regular monitoring of the antimicrobial residues even been low leveled (ppb or ppt). In the last decades, various biosensing platforms have been successfully demonstrated for detection of residual antibiotic or their metabolite.

Keywords: Biosensors; Antibiotics; Food contamination; Transducer

F-199

Analytical Method Development and Validation of Simultanious Estimation of Paracetamol, Caffeine and Ibuprofe in Capsule Dosage Form by RP-HPLC

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Abstract:

A chromatographic method has been developed as per ICH norms for the simultaneous estimation of paracetamol, caffeine and ibuprofen from pharmaceutical formulation. The methods was carried out on a column C18 (250 × 4.6, 5mc) with a mobile phase consisting of buffer (adjusted to pH 2.5 with 1 % w/w orthophosphoric acid) acetonitrile in 85:15 ratio and filtered through 0.45mc cellulose nitrate filters. The flow rate 1.5 mL /min. Detection was carried out at 230nm. The retention time of Paracetamol 3.434, Caffeine 4.484 and Ibuprofen 16.292 min respectively. The developed method was validated in terms of accuracy, precision, linearity, limit of detection, limit of quantification and solution stability. The proposed method can be used for the estimation of thease drug is combined dosage forms.

Keywords: RP-HPLC, Paracetamol, Caffeine, Ibuprofen, Validation

F-200

Development and Validation of Novel Analytical Method for the Estimation of Glimeperide, Pioglitazone and Nitrofurantoin

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Abstract:

An easy, perfect, specific and exact process has been studied for the simultaneous estimation of Glimepiride pure drug form as well as tablet dosage forms. As there are not reported the UV methods for Quantitative evaluation of first order peak detect method for Glimepiride in bulk as well as tablet dosage form, so there is a need to expand novel methods to analyze the drugs using Methanol as a solvent. Glimepiride has absorbance maxima at 225 nm. Equally this drug act upon Beer's law in concentration range of 5-25µg/ml. The consequences of the study were validated statistically and recovery studies were adequate as per ICH guide lines. Thus the projected method can be professionally useful for the simultaneous estimation of Glimepiride in regular analysis effort. An easy, original, and exact evaluation of first order valley detect method was developed for the assay of Pioglitazone in pure drug form and its tablet dosage form. The drug was estimated by using Methanol as solvent for study, which is determined by spectrophotometrically at 234 nm. This drug follows Beer's law in the concentration range of 15-75µg/ml. The recovery studies determine the accuracy of the projected process and the outcome is as per ICH guidelines. For the evaluation of Nitrofurantoin in bulk as well as tablet dosage form, first order peak detect method was developed, which is based on absorption at maximum wavelength 333 nm using acetone as a solvent. This drug follows the Beer's law in the concentration range of 5-25µg/ml. The recovery studies establish the accuracy of the projected process plus outcome were confirm as per ICH guidelines. This process was useful for the assessment of Nitrofurantoin in pure drug form as well as in tablet dosage form.

Keywords: Glimepiride, Pioglitazone, Nitrofurantoin, First order derivative, peak & valley detect method.

F-201

Estimation of Torsemide and Spironolactone in Tablet Dosage Form by U.V Spectroscopy

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Abstract:

There are three simple, accurate, and reproducible spectrophotometric methods have been developed for the simultaneous estimation of Torsemide (TOR) and spironolactone (SPI) in combined tablet dosage form. These methods employed were absorbance ratio; (I) first order derivative spectroscopy method, (II) and area under curve (AUC) method, (III). Torsemide showed absorbance maxima at 288 nm and spironolactone showed at 238 nm in methanol as solvent. Beer's law was obeyed in concentration range of 0-25 mcg ml-1 for both drugs for all proposed three methods. The first developed method makes use absorbance ratio method using 255 nm as isobestic point. The second method is based on first order derivative spectroscopy to overcome spectral interference from other drug, wavelengths 315 nm and 225 nm were selected for the determination of the TOR and SPI respectively. Third method is area under curve method, the sampling wavelengths range selected are 294-290 nm and 240-236 nm with linearity for TOR and SPI respectively. The results of the analysis were validated statistically and recovery studies were carried out as per ICH guidelines.

Keywords: Torsemide (TOR) and Spironolactone

(SPI), Absorbance ratio method, first order derivative spectroscopy method, Area under curve method (AUC).

F-202

GC-NMR: A Modern Hyphenated Approach in Analysis

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Abstract:

Hyphenation technique is a combination of separation technique such as chromatography with some online spectral analysis technique. GC-NMR is the latest and prominent approach in the field of analysis. The Gas chromatography (GC) and nuclear magnetic resonance (NMR) hyphenation technique has become an effective technique in various research fields of pharmaceutical industries such as volatile compounds analysis, identification of volatile oils (essential oil and crude oil), alkaloids identification, metabolites analysis, food analysis, analysis of isomers (enantiomers), analysis of hydrocarbons, determination of chiral compounds and drug impurity profiling. Only NMR technique provides truly comprehensive structural information needed for a definitive identification of organic compounds, especially in the case of new compounds. The online GC-NMR is a special processing technique in handling and recording NMR spectra in the gas phase with very low sample amounts with improved sensitivity and prediction of 2D spectra of peaks. It is a new technique and progress towards its application is continued. In the present review authors have made an attempt to describe various components of the technique as well its applications in pharmaceutical field. Further developments in this field are desirable.

Keywords: Hyphenation, GC-NMR, 2D spectra, Impurity profiling.

F-203

Spectrophotometric Determination of Lisinopril in Pharmaceuticals Using Ninhydrin

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Abstract:

An accurate and precise spectrophotometric method is presented for the determination of lisinopril based on the formation of a yellow colour product with ninhydrin in the presence of bicarbonate with an absorption maximum at 420 nm. The reaction proceeds quantitatively at 97 ± 1°C in 10 min. The calibration curve is linear over the range of 5.0-50.0 µg/mL and is described by the regression equation A = (-) 0.0175 + 0.0079 C with a regression coefficient (r) of 0.9979 (n = 6). The calculated molar absorptivity and Sandell sensitivity values are 2.02×10^3 L/mol/cm and 0.219 µg/cm^2, respectively. The limits of detection (LOD) and quantification (LOQ) calculated as per ICH guidelines are 0.68 and 2.07 µg/mL, respectively. The within-day accuracy expressed as relative error was better than 2.5% with precision (RSD) ranging from 1.02 to 1.93%. The between-day accuracy ranged from 1.5-3.0% with a precision less than 4%. The method was successfully applied to the analysis of three brands of tablets containing lisinopril. The results obtained were in agreement with those obtained by the BP method. Accuracy was also checked by placebo blank and synthetic mixture analyses besides a recovery study *via* standard addition procedure. The method was also used to check the stability of lisinopril in solution.

Keywords: lisinopril, ninhydrin, spectrophotometry, pharmaceuticals

F-204

Total Dissolved Salts-Permissible Range for Drinking Water

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Abstract:

TDS are naturally present in water or are the result of mining or some industrial treatment of water. TDS contain minerals and organic molecules that benefits such as nutrients like Ca, Mg, Na and K cation and carbonate, hydrogencarbonate, chloride, sulphate and nitrate anions or may contain toxic metals and organic pollutants. The palatability of drinking water in relation to its TDS level are as follows: Excellent-less then 300mg/L, Good between 300mg/L and 600mg/L, Fair between 600mg/L and 900mg/L, Poor between 900mg/L and 1200mg/L; and unacceptable, greater then 1200mg/L. Water with extremely low concentrations of TDS may also be unacceptable because of its flat, insipidtaste.RO purifiers are nowadays very common in every house. The main functions of these RO's are

to divide the input water into two parts and force the dissolved solids out from one in to other. But most buyers do not know that these RO's also separates the essential salts required by our body and the shortage of which leads to many problems such as a negative effect on homeostasis mechanism, compromising the mineral and water metabolism in body. In early studies, inverse relationships were reported between TDS concentration in drinking water and the incidence of cancer, Coronary heart disease, Arteriosclerotic heart disease and cardiovascular disease. Total mortality rates were inversely correlated with TDS levels in drinking water. Water containing TDS concentration below 1000mg/L is usually acceptable to consumers, although acceptability may vary according to circumstances. However, presence of high levels of TDS in water may be objectionable to consumers owing to the resulting taste and to excessive scaling in water pipes, heaters, boilers and household appliances.

Keywords: Palatability, Insipid, TDS, RO

F-205

Developed RP-HPLC Methods for the Estimation of Bioactive Marker Compounds in Astangavaleha: An Ayurvedic Polyherbal Formulation

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Abstract:

Astangavaleha is official in The Ayurvedic formulary of India. It is most common formulation used in respiratory disorders. This formulation containing biologically active markers in many Ayurvedic medicines play a significant role. The objective of this present research work was to developed and validates RP-HPLC method for quantification of tannic acid, gallic acid, piperine and 6- gingerol in commercially available and in-house prepared formulations of Astangavaleha. The fingerprint method for quality control of Astangavaleha was developed by using RP- HPLC method. Selected mobile phases were optimized to obtain a reasonable run time, suitable retention time and the sharpness of the peak. The chromatogram of tannic acid, gallic acid, piperine and 6-gingerol under experimental condition showed a single peak of the marker at 25.980 min, 3.150 min, 2.543 min and 21.670 min respectively. The developed HPLC method were having excellent linearity over the concentration range of 2–20 µg/ml of tannic acid, 2–20 µg/ml of gallic acid, 2-20 µg/ml of piperine and 10-70 µg/ml of 6-gingerol respectively. Method were validated in terms of linearity, limit of quantification (LOQ), limit of detection (LOD), precision, repeatability & recovery study. The results indicate that the developed RP-HPLC method can be used for the routine estimation of tannic acid, gallic acid, piperine and 6-gingerol in Astangavaleha as well as Ayurvedic formulations congaing these marker componds.

Keywords: Astangavaleha, quantification, retention time, chromatogram

F-206

Analysis of Extractable and Leachable Phthalates in Pharmaceutical Products by High Performance Thin Layer Chromatography

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Abstract:

A simple and rapid method for simultaneous estimation of four phthalates, namely dimethyl phthalates (DMP), diethyl phthalates (DEP), dibutyl phthalates (DBP) and di-(2-ethylhexyl) phthalates (DEHP) in pharmaceutical products by high performance thin layer chromatography (HPTLC) was developed. The plastic pharmaceutical packaging material and content were extracted with mixture of saline solution as buffer and n-hexane by liquid-liquid extraction. The chromatographic separation was carried out on the precoated silica gel aluminium plate with carbon tetrachloride: ethyl acetate (9.4: 0.6, v/v) used as developing system. The filtered organic liquid was spotted on the TLC plates and densitometric detection was performed at scanning wavelength of 240 nm. The linear regression analysis data for the calibration plots showed good linear relationship with r = 0.9980, 0.9981, 0.9965 and 0.9962 in the same concentration range 10 – 140 ng/band of DMP, DEP, DBP and DEHP respectively. The method was validated with respect to linearity, accuracy, precision and specificity. The seventeen different pharmaceutical products were processed for the extractable and leachable study using the new method, which is shown to be the suitable for routine use for quality control and regulatory purpose.

Keywords: Extractable, Leachable, Phthalates, Pharmaceutical packaging, High performance thin layer chromatography.

G-2

Prevalence and Incidence of Alzheimer's Disease in India: A Meta-Analysis

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Abstract:

A disease of unknown aetiology, Alzheimer's disease (AD) is the most common type of dementia. As the elderly population grows worldwide, the number of patients with AD also increases rapidly. The aim of this meta-analysis is to evaluate the prevalence and incidence of AD in India. We conducted a literature search on Medline, Scopus, and CINAHL. A Bayesian random effects model with 95% credible intervals was used. The I^2 statistic was applied to assess heterogeneity.A total of 3.7 million people in India are suffering from Alzheimer's disease, the most common form of dementia, and related disorders, and the figure is likely to double by 2030, according to health experts. People over the age of 60 are becoming victim of Alzheimer's, with women constituting 70% (2.59 million) of the total burden of the disorder.The prevalence of Alzheimer's disease in India was estimated at 12.64 % (95% CI, 4.73-5.39). The prevalence in men was 30% and in women, 70% and increased with age.The incidence of Alzheimer's disease in India per 1000 person-years for AD was 11.67 (95% CI: 10.9–12.4) for those aged ≥ 55 years andhigher for those aged ≥ 65 years15.54 (95% CI: 14.6–16.5). Incidence rate of AD increased significantly and proportionately with increasing age.

Keywords:Alzheimer, Alzheimer'sDisease, AD, Prevalence, Incidence.

G-4

Methodologic Considerations of Methicillin-Resistant Staphylococcus Aureus Decolonization among Persons Living with HIV

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Abstract:

People living with HIV(PLWH) have a higher prevalence of methicillin-resistant *Staphylococcus aureus* (MRSA) colonization and likelihood of recurrent infection than the general population.Simultaneously treating MRSA-colonized household members may improve success with MRSA decolonization strategies. This article describes a pilot trial testing household-level MRSA decolonization and documents methodologic and pragmatic challenges of this approach. We conducted a randomized controlled trial of individual versus individual-plus-household MRSA decolonization to reduce recurrent MRSA. PLWH with a history of MRSA who are patients of an urban HIV clinic received a standard MRSA decolonization regimen. MRSA colonization at 6 months was the primary outcome. One hundred sixty-six patients were referred for MRSA screening; 77 (46%) enrolled. Of those, 28 (36%) were colonized with MRSA and identified risk factors consistent with the published literature. Eighteen were randomized and 13 households completed the study. This is the first study to report on a household-level MRSA decolonization among PLWH. Challenges included provider referral, HIV stigma, confidentiality concerns over enrolling households, and dynamic living situations. Although simultaneous household MRSA decolonization may reduce recolonization, and retention challenges specific to PLWH limit the ability to conduct household level research. Efforts to minimize these barriers are needed to inform evidence-based practice.

Keywords: Methicillin Resistant Staphylococcus Aureus(MRSA), Randomized Controlled Trail, People Living with HIV(PLWH), MRSA Decolonisation.

G – 5

Thermodynamic Studies of Quercetin with Sodium Dodecyl Sulphate, Tween 20 and Tween 80 in Ethanol-Water Solvent Systems

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Abstract:

The research work represents the conductance and thermodynamicstudies for well-known flavonoid; quercetin, anionic surfactant; sodium dodecyl sulphate (SDS) and non-ionic surfactants; Tween 20 and Tween 80. The specific conductance studies were determined in four different concentrations of ethanol and water i.e. 100% water, 30% v/v ethanol (water rich), 70% ethanol (ethanol rich) and 100% ethanol at five different temperatures (20°C, 25°C, 30°C, 35°C and 40°C). From the conductance studies, the CMC and X_{cmc} values were determined as a function of temperature. From these values, various ther-

modynamic parameters were evaluated, namely, the standard enthalpy change (DH°_{m}), standard entropy change (DS°_{m}) and standard Gibbs energy change (DG°_{m}). The thermodynamic parameters along with other acoustical studies will be utilized in determining the thermodynamically stable concentration which will be helpful for designing pharmaceutical formulations.

Keywords: Flavonoids, Surfactants, Thermodynamics, Specific Conductance, Formulations.

G – 6

Small Interfering RNAwith an Anticancer Drug to Silenc Beta Catenin Expression for Effective Cancer Chemotherapy

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Abstract:

Cancer is a disease in which a set of cells display incursion, metastasis and uncontrolled growth. Cancer afflicts people of all age with a high risk in the elderly population. Worldwide, the death toll in the year 2015 due to breast cancer was reported to be 8.2 million and about 14.1 million new cases were diagnosed.Among all cancers, breast cancer is the second most prevalent one. About 27.1 million cases are expected to be diagnosed by 2030 with 13 million deaths. In WNT signalling pathway, the mutation of β-catenin and APC genes leads to an increase in the level of β -catenin protein. Furthermore, by enhancing the cellular proliferation and development of breast cancer. The expression of cellular genes after transfection with annealed small interfering 21-mer RNAs can be regulated by RNA interference in mammalian cells. In the current study, we envisaged the effect of small interfering RNA (siRNA) on decreasing the high constitutive levels of beta catenin protein in breast cancer cell lines with mutations in either β -catenin or APC genes. These results indicate that siRNA can target specific factors whose expression was altered in malignancy and may have the potential as a therapeutic modality to treat human cancer.We have developed a siRNA which blocks Beta catenin expression with adjuvant treatment of Tamoxifen which is Estragon inhibitor. Various studies were done to show knockdown efficiency of formulated siRAN and Tamoxifen combination. Studies like gene knockdown studies, cytotoxic studies, Formulation development, serum stability.

Keywords: Cancer, Tamoxifen, siRNA.

G – 7

Isolation and Screening of Pterin Deaminase Producing Fungi from Soil Samples

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Abstract:

Pterin deaminase is a folate deaminating enzyme has been reported to have antitumor activity against leukemic cell line and melanoma induced in mice. In the present study, a total of twenty-five fungal cultures were isolated from soil sample collected in and around the city of Coimbatore district. The diversity of fungal isolates was found to be higher in the cultivated land soil compared to unattended barren land and coconut plantation soils. A rapid plate assay method was used for the first time to screen the pterin deaminase producing fungus using folate as a substrate in modified czapek Dox agar medium. The strain CLS-6 was selected based on the zone of clearance and pink coloration around the zone with a maximum enzyme activity of 40.2 IU/ml and 36.5 mg/ml of protein for further purification and characterization.

Keywords: Pterin Deaminase, Lumazine, Folate, Substrate, Cancer.

G-8

Production of Ethanol from Rice Bran using *Saccharomyces Cerevisiae*

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Abstract:

Bioethanol offers great benefits for safeguarding the environment, boosting the rural economy, and ensuring fuel security. Interestingly, the world's focus is switching over from corn and sugarcane to cellulosic or plant biomass as renewable raw material for production of bioethanol. The major factor affecting the efficiency of the conversion of lignocellulosic materials into energy products is the hydrolysis/saccharification of lignocellulose. The key to a successful cellulosic ethanol production is to develop effective pretreatment technology leading to

rapid and high yield hydrolysis of lignocellulose; converting it to fermentable sugars for subsequent fermentative production of ethanol. Rice bran is an attractive lignocellulosic material for bioethanol production since it is one of the most abundant renewable resources. It has several characteristics, such as high cellulose and hemicelluloses content that can be readily hydrolyzed into fermentable sugars. This research work was aimed to study the production ability of *Saccharomyces cerevisiae* after treatment of rice bran with acid and alkali. From the present study, it was recognized that the lignocellulosic waste, like rice bran can be used as raw material for ethanol production. The acid and alkali substrate saccharification followed by fermentation could increase the yield ethanol. The yield of alcohol was high after 0.4M sulphuricacid hydrolysis (96.88%), when compared with other concentration. The highest yield by alkali hydrolysis was 67.48% by 0.4M Sodium hydroxide. The results obtained from this study showed that the rice bran possessed an excellent potential for agro-residue based ethanol production and the maximum yield can be obtained after acid hydrolysis.

Keywords: Fermentation, Alcohol, Hydrolysis, Rice Bran, *Saccharomyces Cerevisiae.*

G-9

Production of Fungal Keratinase and Its Therapeutic Application

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Abstract:

Keratinasesare a type of serine proteases which hydrolyse keratin and find use in detergent, cosmetic and pharmaceutical industries. The therapeuticapplication of these enzymes has gained importance in the recent years in treatment of onycomycosis and acne. Work was carried out on production of this enzyme using a fungal isolate belonging to *Aspergillus* species. The organism was cultivated on basal salt medium containing 1% keratin for 9 days at 28°C with 150 rpm. The activity of enzyme was measured in terms of tyrosine produced. The enzyme was extracted with 80% ammonium sulfate precipitation and the molecular weight of enzyme was determined using SDS-PAGE. The enzyme activity was found to be3.54U/ml. This enzyme shows 13.33% nail degradation depicting its application in soil waste management. The strain was irradiated with UV light for strain improvement. Further studies on enzyme purification using sephadexand the anticancer application of the enzyme are in progress.

G–10

Histopathological Study of Cardiac Lesions in Methamphetamine Poisoning-Related Deaths

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Abstract:

The purpose of the present study was to determine cardiac pathology in methamphetamine poisoning-related deaths. The study included 100 cases of methamphetamine poisoning-related deaths and 100 cases as control group. Toxicology analysis of liver, gastric content, bile, urine and blood were conducted to detect drugs, poisons and alcohols using thin layer chromatography, gas chromatography/mass spectrometry, and high-performance liquid chromatography. Positive toxicology analysis results except for amphetamine and methamphetamine were excluded from the study in order to omit interfering factors. The most striking features of cardiac damage were observed by light microscopy.Methamphetamine and amphetamine were detected in either urine or gastric content samples. In all of the cases methamphetamine toxicity was determined to be a direct cause of death by forensic medicine practitioner. Cardiovascular pathology was noted in 68% of studied cases. The most common histopathologic features were myocardial fiber hypertrophy, mild, moderate to severe atherosclerosis and focal degeneration/necrosis.The results of the current study highlight the fact that cardiotoxic effects of methamphetamine can explain increasing reports of heart failure and consequently death in young abusers.

Keywords:Cardiac Histopathology, Forensic Medicine, Forensic Pathology, Forensic Toxicology, Methamphetamine Poisoning-Related Death.

G – 11

Antimicrobial Efficacy of *Alternanthera philoxeroides* Mart (Griseb.) against Clinical Isolates of Urinary Tract Infections

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Abstract:

Urinary tract infection (UTI) has become a more grievous problem and affects millions of people worldwide each year. The increase in bacterial resistance has created the necessity for studies directed towards the development of new antimicrobials. The present study was undertaken to evaluate the phytoconstituents of leafy vegetable *Alternanthera philoxeroides* Mart (Griseb.) and their potential in treating urinary tract infections. In this study the *A.philoxeroides*methanolic extract(APME) was prepared by cold maceration. The preliminary phytochemical screening revealed the presence of alkaloids, glycosides, flavonoids, phenolics compounds and tannins. The quantitative determination of tannin and flavonoid contents was performed spectrophotometrically. The susceptibility towards various antibiotics against *Staphylococcus aureus*, *Staphylococcus saprophyticus, Enterococcus faecalis, Escherichia coli, Pseudomonas aeruginosa, Klebsiella pneumoniae, Proteus mirabilis* and *Proteus vulgaris* of clinical isolates were determined by micro-titre plate assay using resazurin. The antibacterial efficacy of APME was studied by agar well diffusion method and they exhibited good inhibitory effect that is comparable with standard nitrofurantoin (300µg). The results indicated that the bioactive compounds from leaves of *Amaranthus tricolor* has a notable antibacterial activity against tested microorganisms. The isolated bioactive compounds are further studied for their structural elucidation.

Keywords: *Alternanthera philoxeroides,* **Urinary Tract Infections (UTI), Antibacterial Activity.**

G – 12

Isolation, Structural Elucidation and Antimicrobial activity of 24-Methylene Cycloartenol and Methyl 3,4,5-trihydroxybenzoate from *Amaranthus tricolor (L)*

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Abstract:

The leaves of Amaranthus tricolor (L) were collected, dried and pulverized. The methanolic extract of powder was prepared by cold maceration process (ATME). 2gm of ATME was dissolved by adding 100ml of chloroform. To this 150 ml of distilled water was added. The mixture was separated into two phases non-polar (chloroform) and polar (aqueous) was separated. The polar fraction was dried and purified by adding methanol and acetonitrile till colorless crystals obtained. Further this compound was characterized for structural elucidation and it was identified as methyl 3,4,5-trihydroxybenzoate. The non-polar fraction was evaporated and subjected to HPTLC to optimize mobile phase. The fingerprint analysis of extract by HPTLC optimized a mobile phase N-hexane: ethyl acetate (6:4% v/v). This produced 11 fractions. The antibacterial agents of these fractions were identified by bioautography and fraction-III (compound-III) was separated by column chromatography. Further this compound was characterized for structural elucidation and it was identified as 24-methylene cycloartenol.The *in-vitro* evaluation of antimicrobial efficacy of methyl 3,4,5-trihydroxybenzoate and 24-methylene cycloartenol was determined by measuring the minimum inhibitory concentration (MIC) using microtiter plate assay against clinical isolates of multi drug resistant UTI pathogens. The MIC values were ranged from 6.25 to 12.5 µg/ml. The findings of the above study suggest that 3,4,5-trihydroxybenzoate and 24-methylene cycloartenol from *Amaranthus tricolor* possess multiple biological activities. These compounds need to be studied in *in-vivo* system to improve its bio efficacy mode and thus in future this can serve as a lead for antimicrobial agent.

Keywords: 3,4,5-Trihydroxybenzoate, 24-Methylene Cycloartenol, *AmaranthusTricolor,* **Antimicrobial.**

G-13

Recent Advancement in Gene Delivery Systems into Tumors: New Avenues for Cancer Therapy

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Abstract:

Enormous research in the area of gene delivery has been conducted worldwide, in particular for cancer gene therapy application for nearly past two decades. Numerous novel therapies are in development for targeting tumors cells but cancer gene therapy has not yet been indicated in clinical practice. The focus of present review is on recent developments highlighting the advantages and the limitations of various types of gene delivery systems (viral & non-viral vectors) used in cancer gene therapy. Amongst the non-viral systems, Rexin-G (Epeius Biotechnologies), recently approved by the U.S. FDA, for the treatment of all solid chemo-resistant malignancies, and n granted Orphan Drug Status for pancreas cancer, osteosarcoma, and soft

tissue sarcoma, as well as fast track status for pancreas cancer is a landmark technology for targeted delivery. Other recent additions to gene delivery systems have been discussed at length.

Keywords: Rexin-G, gene delivery, Solid Dispersion, Carriers, Solubility, Dissolution, Bioavailability, Permeability.

G – 14

Role of Nanorobots in the Field of Pharmacy

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Abstract:

With the current rate of advancement in scientific technologies, medical science is growing at exponential rate. The future is all about Nanotechnology, Automated robots have already started making their way into medical science which comes handy especially in critical situation where doctor is not available. In the near future, we can even evision millions of these automated nanorobots that would float around in your body. As stated earlier these could perform the required operation at molecular level i.e. carrying and delivering drugs to specific defected cell, repairing tissues, cleaning blood vessels & airways. We could even find a potential counter for ageing process to an extent. Many scientists are working on the bright side of nanorobots, especially on cancer treatments. General applications of nanotechnology in pharmacy include treatment of chemotherapy, avoidance of multi-drug resistance, treatment of leprosy, ocular drug delivery, DNA2 delivery, also they can be used as biosensors, biomarkers etc. In this review, we will summarize briefly about nanorobots and its tools, mechanism, approaches and main futuristic applications of the same which mainly useful for medicinal and to develop new formulations related to nanotechnology to cure the major diseases.

Keywords:Virtual 3D Nanorobots, Biosensors, DNA Joints, Brain Aneurysm.

G – 15

The Combined Effect of Amprenavir and Ritonavir on Visceral Leishmaniasis for the Treatment of HIV-Vl Co-Infection

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Abstract:

Among the various species of *Leishmania*; *L. donovani,* and *L. infantum* are found to be the prime causes of visceral leishmaniasis mainly in tropical countries like India. As leishmaniasis is treated by drugs like pentavalent antimonials, meglumine antimoniate and sodium stibogluconate etc. But earlier reports show that these drugs are lesser efficacious and have dose dependent side effects. Also, previous studies showed that the HIV patients often get co-infected with visceral leishmaniasissincetheir immune system is already compromised.It was reported previously that leishmanial DNA topoisomerase I (LdTOPILS) has emerged as an important therapeutic agent and HIV-1 Protease Inhibitors (PIs) are widely used as anti-HIV drugs. There has been reports that some of the HIV-1 PIs like Saquinavir, Nelfinavir and Ritonavir have inhibitory effects on *Leishmania* parasites.Hence, use of combination of PIs with ritonavir can produce enhanced effect on catalytic activity of topoisomerse. Therefore, the present study will investigate an intensive study of treatment with combination of amprinavir and ritonavir. The present study might develop a newer platform for the treatment of HIV-VL co-infection with this combination therapy which might exploit the therapeutic development for treatment of HIV-VL co-infection in future.

Keywords: Amprenavir, Ritonavir, Visceral Leishmaniasis, HIV-Vl Co-Infection.

G – 17

Comparative In-Vitro Antibacterial Efficacy of Alternanthera Philoxeroides and Amaranthus Viridis

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Abstract:

The two plants presented in this study are *Alternanthera philoxeroides* and *Amaranthus viridis* L. belong to the family Amaranthaceae traditionally used as leafy vegetables. The aim of the present study was to investigate antibacterial activity of leaves of two plants against various Gram positive and Gram-negative bacteria *in-vitro*. Susceptibility of Gram positive (*Staphylococcus aureus, Bacillus subtilis, Bacillus megaterium, Enterococcus faecalis, Streptococcus mutans*) and Gram negative

(*Escherichia coli, Klebsiella pneumoniae, Pseudomonas aeruginosa* and *Proteus vulgaris*) were tested. The ethanol extracts of the leaves were prepared by cold maceration. The qualitative screening of phytochemical compounds showed the presence of steroids, glycosides, alkaloids, tannins and phenolic compounds.

The ethanolic extracts of *A.philoxeroides* (APEE) and *A.viridis*(AVEE) exhibited remarkable antimicrobial property against tested microorganisms. The APEE exhibited higher antibacterial activity compared to AVEE. The activity of these extracts was comparable with the reference standard tetracycline. MIC and MBC were performed by agar dilution method and the range was found to be 0.97 mg/ml to 250 mg/ml. The current result supports the medicinal use of the leaves which acts as an antibacterial agent. However further studies needed to isolate the active constituents from the leaves and to study the antibacterial activity in cellular level.

Keywords:*Alternanthera Philoxeroides, Amaranthus Viridis,***Antimicrobial, Agar Well Diffusion.**

G – 18

Role of Pharmacist in a Biotechnology

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Abstract:

The pharmacist is the backbone of the medical field. Pharmacist plays a vital role in the health care system through the production of medicines and provides detailed information related to their rational use and their safety parameters. Pharmacist responsibilities include a range of care for patient's health and progress to optimize patient's response to the medication therapies. This review article is undertaken to highlight common errands of the pharmacist in the field of biotechnology. Role of pharmacist in biotechnology includes theproduction of commercial products, drug information on biotechnology-derived drugs, newer drug delivery systems, plant tissue culture and plant biotechnology,DNA profiling and fingerprinting, and pollution control. Besides above-mentioned duties, the pharmacist can also contribute much more to the society and there is a wide scope to search new endeavours.

Keywords: Pharmacist, DNA, Biotechnology.

G – 19

Amphotericin B Emulsomes against Leishmania Donovani infected Macrophage cells and experimental hamsters

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Abstract:

The control of visceral leishmaniasis or kala-azar (VL), a major tropical parasitic disease caused by *Leishmania donovani*, remains a challenging problem because the available chemotherapeutics such as amphotericin B (AmB) have serious side effects and require long-term treatment. Therefore, AmB was formulated in tristearin-based emulsomes (nanosize lipid particles) stabilized by soya phosphatidylcholine (PC), as a new delivery system for macrophage targeting for the treatment of VL. Emulsomes were modified by coating them with macrophage-specific ligand (*O*-palmitoyl mannan, OPM).The surface modified emulsomes and their plain counterparts were characterized for size, shape and entrapment efficiency. The antileishmanial activity of AmB-deoxycholate (AmB-Doc) and emulsome entrapped AmB was tested *in vitro* in *Leishmania donovani* infected macrophage-amastigote system (J774A.1 cells), which showed higher efficacy of OPM grafted AmB emulsomes (TSEs-OPM) over plain AmB emulsomes (TSEs) and AmB-Doc. Fluorescence microscopy study showed significant localization of fluorescein loaded TSEs and TSEs-OPM inside the liver and spleen cells of golden hamsters. The *in vivo* antileishmanial activity of the AmB (0.5mg/kg) was tested in AmB-Doc, TSEs and TSEs-OPM forms against VL in *L. donovani* infected hamsters. Formulation TSEs-OPM eliminated intracellular amastigotes of *L. donovani* within splenic macrophages more efficiently (70.1 ± 4.8% parasite inhibition) than the formulation TSEs (47.4 ± 3.4% parasite inhibition) or AmB-Doc (33.6 ± 2.9% parasite inhibition). The proposed formulations, TSEs and TSEs-OPM showed excellent potential for passive and active intramacrophage targeting respectively and the approach could be a successful alternative to the currently available drug regimens of VL and systemic fungal infections.

Keywords: Emulsomes, Visceral Leishmaniasis, Macrophage, Targeting, Hamster

G – 20

Plant Microbiome –Genegraphics

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Abstract:

The plant-based-sea water culture medium is introduced to in vitro cultivation and in situ recovery of the microbiome of halophytes. The ice plant (Mesembryanthemum crystallinum) was used, in the form of juice and/or dehydrated plant powder packed in teabags, to supplement the natural sea water. The resulting culture medium enjoys the combinations of plant materials as rich source of nutrients and sea water exercising the required salt stress. As such without any supplements, the culture medium was sufficient and efficient to support very good in vitro growth of halotolerant bacteria. It was also capable to recover they're in situ culturable populations in the phyllosphere, ecto-rhizosphere and endo-rhizosphere of halo^{o} phytes prevailing in Lake Mariout, Egypt. When related to the total bacterial numbers measured for Suaedapruinosa roots by quantitative-PCR, the proposed culture medium increased culturability (15.3– 19.5%) compared to the conventional chemically-synthetic culture medium supplemented with (11.2%) or without (3.8%) NaCl. Based on 16S rRNA gene sequencing, representative isolates of halotolerant bacteria prevailed on such culture mediumwere closely related to Bacillus spp., Halomonas spp., and Kocuria.

Keywords: Microbiome, rRNA.

G – 21

Gene Therapy Approach in HIV Combat

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Abstract:

Acquired immunodeficiency syndrome (AIDS) is a life-threatening disorder caused by infection of individuals with the human immunodeficiency virus (HIV). Entry of HIV-1 into target cells depends on the presence of two surface proteins on the cell membrane: CD4, which serves as the main receptor, and either CCR5 or CXCR4 as a co-receptor. A limited number of people harbour a genomic 32-bp deletion in the CCR5 gene (CCR5Δ32), leading to expression of a truncated gene product that provides resistance to HIV-1 infection in individuals homozygous for this mutation. Moreover, allogeneic hematopoietic stem cell (HSC) transplantation with CCR5Δ32 donor cells seems to confer HIV-1 resistance to the recipient as well. Genome editing is the most precise form of gene therapy, able to achieve permanent genetic disruption, modification, or insertion at a predesignated genetic locus. The most well-studied candidate for anti-HIV genome editing is CCR5, an essential co-receptor for the majority of HIV strains, and the lack of which confers HIV resistance in naturally occurring homozygous individuals. Genetic disruption of CCR5 to treat HIV has undergone clinical testing, with seven completed or ongoing trials in T cells and hematopoietic stem and progenitor cells, and has shown promising safety and potential efficacy profiles.

Keywords: CCR5, HIV, Genome Editing.

G – 22

Immobilization and Estimation of Activity of Yeast Cells

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Abstract:

It became clear that living processes were based on the action of enzymes. Cell immobilization serves as a useful tool for the immobilization of intracellular enzymes. The purpose of study is to improve economically important processes by attaching the yeast cells to matrices.In this analytical study by using mixed models of matrices to determine the effective combination for immobilizing cells without any damage.It was noted that the glucose content in both cells increased which indicates the production of carbon dioxide and alcohol and then the values started falling down this is because the osmotic concentration of the sugar gets so great that the yeast is unable to get enough water for growth. Use of mixed matrices enhanced the biological activity of cells thus improved their performance. Immobilization of yeast cell showed technical and economic advantages over free cell system.

Keywords: Free Yeast Cell, Immobilized Yeast Cell, Sodium Alginate, Gelatin.

G – 23

DNA Profiling: An Era of Forensic Research

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Abstract:

The DNA profiling (DNA fingerprint, DNA testing, DNA typing) is a forensic technique used to identify individuals by characteristics of their DNA. The DNA profiling is used in parentage testing and criminal investigation to identify individualand to trap criminals. Although 99.9% of women DNA sequences are same but remaining of 0.01% of DNA is enough to distinguish one individual from another, unless they are monozygotic (identical) twins. The specific regions of DNA vary highly between different individuals called polymorphic.The DNA polymorphisms can be analysed to give a DNA profile.Human DNA profiles can be used to identify the origin of a DNA sample at a crimescene and also toidentify parentage. One of the current techniques for DNA profiling uses polymorphisms called short tandem repeats (STRs). STRs are regions of non-coding DNA that contain repeats of the same nucleotide sequence.STRs are present at different places or genetic loci in a person's DNA. The DNA profile is usually generated by examining STRs at 10 or more genetic loci thatare usually on different chromosomes. Hence, the review is scripted to highlight a wide range of applications of DNA profiling in forensic implementations.

Keywords: DNA, STR.

G – 24

Applications of Optogenetics in Modern Medication

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Abstract:

The review is undertaken to highlight modern technique Optogenetics and its applications in the medical treatments. Optogenetics is a method that combines genetic and optic approaches to control the electrical activity of excitable cells. This method is based on the implementation of specific light-sensitive proteins which are called opsins. These transmembrane proteins change their conformation under light with a specific wavelength (390-700nm) and as a result, ionic currents flow across the cell membrane. The area of optogenetics can be subdivided into optogenetic sensors and effectors. The former is used to monitor neural circuits and the latter is used to directly manipulate neural circuits. The green fluorescent protein (GFP) revolutionized large areas of scientific research. Presently, commonly used GFP techniques fall under the umbrella term of optogenetics. Likewise, multi-component devices involving multiple genes having used to create light-sensitive action potentials and would also be categorized as optogenetics. Optogenetic effectors have increased our ability to manipulate neural circuits while optogenetic sensors are increasing our ability to observe such circuits. Further development in this area can accelerate the pace of neural research.

Keywords: Optogenetics, Green Fluorescent Protein.

G – 26

Bioelectronic Medicine

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Abstract:

The field of bioelectronic medicine combines molecular medicine, bioengineering, and neuroscience to discover and develop nerve stimulating and sensing technologies to regulate biological processes and treat disease.The nervous system uses electrical signals to communicate information throughout the body. Virtually every cell and organ of the body is directly or indirectly controlled by these neural signals. Researchers are learning the language of these neural signals so that we can listen for signals of disease or injury. We are also using bioelectronic medicine technologies to record, stimulate, and block neural signals, which is essentially teaching the body how to heal itself. Bioelectronic medicine will change the way we treat diseases, injuries and conditions such as rheumatoid arthritis, diabetes, paralysis, bleeding, and even cancer.Bioelectronic medicine hasthe potential to be superior to drugs interms of efficacy, cost and safety becauseit directly modulates the natural language of the body's nervous systems. This technology is already highly advanced, at least in some medical applications such as implantable cardiostimulators and various other implantableprosthetic devices includingvagus nerve stimulators to treatrheumatoid arthritis.

Keywords:Bioelectronic Medicine, Rheumatoid Arthritis, Diabetes, Paralysis.

G – 27

Clinical Significance of Glycosylated Heamoglobin Over Diabetes Mellitus

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Abstract:

In a current research, Diabetes mellitus is a chronic metabolic disorder characterised by hyperglycaemia and altered metabolism of carbohydrates, lipids and proteins. Haemoglobin is the substance which is present inside the cells that carries oxygen to the cells of the body and glucose molecules in the blood normally become stuck to haemoglobin molecules with covalent bonding, these is known as glycosylated haemoglobin HbA1c or HbA1c. When blood glucose levels are high, glucose molecules attach to the haemoglobin. The longer hyperglycaemia occurs in the blood, the more glucose binds to haemoglobin& the higher the glycosyltedhaemoglobin in the red blood cells. A common problem is fasting blood sugar test is that the glucose levels tends to alter quickly with changes in exercise pattern, food intake etc. These can often misleading to the doctor. The HbA1c calculator monitoring blood glucose over a period of time its help the doctor understands the actual improvement. The normal procedure involes in these test.A blood test can ensure that which amount of glycosylated haemoglobin is present in the blood. The glycosylated haemoglobin test is a blood test that reflecs average blood sugar levels over the preceding 2-3 months by measuring the amount of glucose adhering to haemoglobin, a protein in red blood cells. The product formed by the attachment of glucose to heamoglobin.The research is recommended for ensuring blood sugar control in the pre-diabetic patient and monitoring blood sugar control in diabetes mellitus patients.

Keywords:Glycosylated Haemoglobin, HbA1c.

G – 28

Evaluation of the Therapeutic Efficacy of Nanoparticulated Myricetin in Combating Oxidative Hepatocellular Degeneration by Non-InvasiveNuclear Imaging Technology Using ^{99m}Tc Radiopharmaceuticals.

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Abstract:

The theme of work was to evaluate the therapeutic effectiveness of oral administration of polylactide co-glycolide (PLGA) Nanocapsulated myricetin (Nano-Myr) against diethylnitrosamine (DEN) induced hepatocellular carcinoma (HCC) in rat model. Nano-Myr of average diameter 100-200 nm and encapsulation efficiency of 70% was prepared. FESEM, FTIR, DSC, XRPD analysis revealed that there is no chemical interaction between drug and the polymer and in-vitro release studies showed drug release for over 7 days. The in evaluation of the formulation was done in HepG2 (Human hepatocellular carcinoma) cell line by conducting cytotoxicity assay, nanoparticle uptake studies using Flow cytometry and Confocal microscopy. Three i.p. injections of the chemical hepatocarcinogen DEN at 15 days interval causes hepatotoxicity with the generation of reactive oxygen species (ROS), lipid peroxidation and depletion of antioxidant enzyme levels in liver (verified by biochemical assay and scintigraphy studies). Nano-Myr in DEN induced HCC rats exerted significant protection against HCC and restored redox homeostasis in liver cells. Nanocapsulated Myr caused significant increase in liver enzymes and decreased elevated level of conjugated diene. Histopathological analysis confirmed the pathological improvement in the liver which was corroborated by scintigraphic imaging of liverusing 99m-Tc labeled sulphur colloid. Nano Api was found to be a potential formulation in oral route in combating the oxidative damage of hepatic cells and eliminating DEN induced hepatocellular cancer cells in rat whereas identical amount of free Myr treatment was found almost ineffective.

Keywords: Myricetin, PLGA Nanoparticles, Hepatocellular Carcinoma (HCC), Scintigraphic Imaging.

G – 29

Biotransformation of Isoeugenol to Ferulic acid through Microbes

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Abstract:

In the current research, a Phenylpropanoid compound was biotransformed using microbes. The objective behind the

research was to increase the yield of ferulic acid through microorganisms. In this regard, novel strain was isolated from cow dung bacterium capable of converting isoeugenol to ferulic acid. Bacterium strain CF, was found to produce higher yield of ferulic acid when grown in the presence of isoeugenol, which is used as a sole carbon source. This strain degrades isoeugenol to ferulic acid *via* coniferyl alcohol and coniferyl aldehyde. Lignin related phenylpropanoids like isoeugenol is the component of essential oil, clove; serve as a potential substrate for production of ferulic acid. Resting cells of identified bacterial strain was screened using conventional enrichment process. Biotransformation operation was carried out in incubator shaker at 180 rpm for 72h at pH 7. Ferulic acid formation was analysed by TLC, developing HPLC method and confirmed by GC-MS. The novel bacterium cells produced 0.36 mg/l ferulic acid from 0.0132 mM isoeugenol, with a molar conversion yield of 16.7% at 37 $\pm 2^0$C after 36-h incubation in the presence of 0.25% of dimethyl sulfoxide. Growth kinetic study of screened bacteria was also studied.Thus, it can be concluded that this study can be beneficial for biotransformation of isoeugenol to ferulic acid using micro-organism.

Keywords: Ferulic Acid, Micro-organism, Isoeugenol, Biotransformation.

G – 30

Biotechnology for Sustainable Development

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Abstract:

Biotechnology contributes a significant role to fulfill the desired nutritional requirements of blasting population of the world. Sustainable development involves diverse and complex approaches. Among the broad range of technologies with the potential to reach the goal of sustainability biotechnology take an important place especially in the fields of food production, renewable raw materials and energy, pollution prevention and bioremediation. Resources, environment, food and sustainable development (REFS) are the topic of world. There are three super challenges of the 21st century: (1) climate change, (2) food security, (3) dependence on imported petroleum, and I think techniques of biotechnology are efficient enough in meeting out these challenges. Plants can provide human beings with renewable energy, food and materials and are base for sustainable development in different form around the worlds. Plant genetic engineering has made significant contribution to production of biotech crops for food, feed, valuable recombinant proteins.

Keywords: Biotechnology, Sustainable Development.

G – 31

Impact of Bioinformatics in Vaccine Discovery

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Abstract:

Bioinformatics has recently become a common laboratory name for groups studying genomic sequences. It is composed of many different, yet interconnected scientific fields such as genomics, proteomics, and transcriptional profile. On the other hand, systems biology utilizes the persisting information on functioning of signaling pathways, metabolic networks and genetic sequences for the furtherance of scientific research and application. Bioinformatics incorporates and applies the theoretical and practical knowledge of statistics, mathematics, computer science, engineering and biology and allows in silico analysis of biological data and computerized interpretation of that data for future applications. This study will focus on different genomic mining tools/algorithms available for predicting unlock reading frames and their associated explanation, physical and functional characterization, and cellular localization. It helps analyze and catalogue the biological pathways and networks that are an important part of systems biology.

Keywords: Drug Discovery, Bioinformatics.

G – 32

Isolation of Lab and Production of Lactic Acid by Optimizing Carbon and Nitrogen Sources

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Abstract:

Probiotics are probably one of the most widely used products now a day in the field of nutrition. Lactic acid which is given in the form of probiotics acts as best nourishing agent in their deficiency people. The present study determines the best source of lactic acid bacteria to optimize and the cost-effective media for production of lactic acid by following strict vegetarian rule. As this media is prepared completely by eliminating animal products and replacing them with waste, cheap plant products. In this work, we conducted comparative analytical study for isolation of best bacteria from 6 different sources and for determination of best carbon sources and nitrogen sources among the different sources available to constitute a best media which is cost effective for the production of lactic acid. From the results it is stated that the whey water which is a waste product of dairy industry acts a best source for the organism. In case of optimization of the media it is observed that molasses a byproduct of sugar industry incorporated as a carbon source, lentils as nitrogen source in the media showed best results in terms of lactic acid production. By this we can conclude that the low-cost media is obtained by using the fruits waste and the animal products can be replaced with the plant seeds for the production of probiotic lactobacilli and lactic acid.

Keywords: Probiotics, Molasses, Lactobacilli, Lactic Acid.

G – 33

In-Silico Docking Studies on Isoflavones Targeting BCL-2- an Antiapoptotic Protein

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Abstract:

Flavonoids are a group of more than 4000 polyphenolic compounds that occur naturally in plant origin. These polyphenolic compounds display a remarkable spectrum of biological activities including those that might be able to influence processes that are dysregulated during cancer development. Isoflavones are one among these flavonoids reported especially in legumes. B Cell Lymphoma-2 (Bcl-2) protein is a survival protein very well expressed in breast cancer which confers resistance to apoptosis and thereby reducing the effectiveness of chemotherapy. Molecular docking studies facilitate the drug discovery process in preliminary screening. Hence, in this study Bcl-2 is docked with isoflavones, Genistein and Daidzein using *Auto dock tool 1.5.6.*Structure for Daidzein (CID 5280961; IUPAC name: 5,7-dihydroxy-3-(4-hydrooxyphenyl) chomen-4-one)) and Genistein (CID 5281708; IUPAC name: 7-hydroxy-3-(4-hydrooxyphenyl) chomen-4-one)) were retrieved from NCBI Pubchem compound database. The structure of anti-apoptotic protein Bcl-2 was taken from Protein Data bank (PDB ID- 1G5M). Binding ability of Genistein and Daidzein with Bcl-2 was evaluated in this study by *in-silico* technique which indicates that these compounds occupy positions in binding pocket with low energy of °5.33 and °5.66 respectively. Ligand binding site was discovered and closely interacting aminoacids in the binding site were identified as GLU 200, ASN 192, TRP 144 for Genistein with Bcl-2 and ASP 171 for Daidzein. The intermolecular energy between Bcl-2 and isoflavones were found to be -6.53 and -6.55 for Genistein and Daidzein, respectively. This study substantiates the effectiveness of Genistein and Daidzein to bind with Bcl-2 protein.

Keywords: Flavonoids, Genistein, Daidzein, Chemotherapy.

G – 34

Determination of Bacterial Resistance by Efflux Pump Assay

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Abstract:

Increased resistance of bacteria towards antibiotics posed risk in treating dreadful infections. Definitely an alternative drug or determination of resistance to overcome the issue is a paramount importance. In view of this clinical bacterial isolates *Klebseilla pneumonia,Pseudomonas aeuroginosa*and *Bacillus subtilis* were subjected to study for their resistant pattern towards selected antibiotics (Ampicillin, Chloromphenicol, Ceftriaxone and Roxithromycin). Preliminary susceptibility analysis for the selected microbe with antibiotics were screened using disc diffusion method. Minimum inhibitory concentration's (MIC) were determined by Rezasurin dye method. Efflux pump method was also done to understand the ability of microbe to resist antibiotic through efflux mediators. Ampicillin is resisted by *P.aeuroginosa* but intermediate to Chloramphenicol and Chloramphenicol is resisted by *S.aureus* but intermediate to Ampicillin. *P.aeuroginosa*and*S.aureus* were sensitive to both the Ceftriaxone and Roxithromycin. Resazurin dye method re-

veals the MIC of antibiotics and it is for *P.aeuroginosa* which is highly sensitive to Ceftriaoxne (7.81 µg/ml), chloramphenicol (7.81 µg/ml) and roxithromycin (16.62 µg/ml) while *S.aureus* is sensitive to ampicillin (7.81 µg/ml) alone. The accumulation assay was performed to determine the activity of efflux pumps in the bacterial cells.*P.aeuroginosa and S.aureus* has shown high efflux activity at 45th and 60 min respectively, of Ethidium bromide at 1000mM (glucose containing PBS) followed by 100, 50 and 10mM compared to control (glucose free PBS). Ethidium bromide accumulation and efflux activity in bacterial isolates divulged the critical importance of efflux pump in the extrusion of harmful compounds for the survival of bacteria under stressful environment.

Keywords:Bacterial Resistance, Efflux Pump Assay.

H-1

A Prospective Survey of Prescription Practice of Inotropic Drugs in ICU Patients in a Tertiary Care Hospital at Delhi

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Abstract:

Patients admitted to the intensive care unit of study has received multiple medications for cardiac diseases. Case study was conducted with a variety of age group in 101 patients to assess the cardiac disease patients on the bases of their gender, age group, diagnosed, pattern of Inotropic drugs and to suggest necessary modifications in the treatment and diagnosis to achieve rational therapeutic practices. Maximum patients have the following co morbidities i.e. Diabetes, Hypertension, Sepsis, COPD etc. Various diagnosis was reported in the patients like Coronary Artery Disease (28 Patients were Diagnosed), Tricuspid Valve Dysplasia (18 patients), Acute Coronary Syndrome (7 Patients), Chronic Kidney Disease (3 patients) and 12 were suffering from sepsis etc. The average number of positive inotropic drug, negative inotropic drug and dose dependent drugs were found to be 85%, 10% and 5% respectively. Norepinephrine was observed to be most common inotropic drug in prescriptions (approx 60%). All patients treated with Inotropes were having their Cardiac output within 50-60 %. A wide spectrum of cardiac disorder was noticed in age group of 61-80 years. Inotropic agent especially positive Inotropes were utilized in the recent treatment strategy.

H-2

A Survey of Overweight and Obesity in Adolescents of Semi-Urban, Rural Area of Gondia District, Maharashtra

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Abstract:

In present study the overweight and obesity among semi-urban & rural adolescents in Gondia District, Maharashtra. The data were collected under the PHC centre with cross-sectional sampling of children, 186 in rural and 223 in semi-urban, aged 14–16 years doing study in schools in year of 2016. Studied the factors i.e., overeating, quitting smoking, lack of sleep, junk foods, gadgets gaming, age, gender and body mass index (BMI) were used to define overweight and obesity. The prevalence of obesity increased significantly from 13.7% in rural to 15.4% in urban ($p<0.01$), whereas underweight decreased from 12.7% to 3.4% ($p<0.001$). There was a significantly higher risk of being overweight and obese in urban than rural, after adjusting for age, gender, over eating junk foods, gadgets gaming (inactivity) and body mass index (BMI) were used to define overweight and obesity. Semi-urban Males had significantly higher increase in prevalence and risk of being overweight and obese. Male gender and higher socio-economic status is associated with a significant risk of being both overweight and obese. The study showed an increasing overweight and obesity in semi-urban adolescents especially with male gender, calling for an urgent need for immediate and targeted preventive measures.

Keywords: Body Mass Index (BMI), Overweight, Obesity

H-3

A Pattern of Self-medication Practices: Rural Area of Dawaniwada, Gondia District

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Abstract:

The use of self-medication is highly prevalent in the community. Self-medication can be defined as obtaining and consuming one (or more) drug(s) without the advice of a physician either for diagnosis, prescription or surveillance of treatment. In practice, it also includes use of the medication of family members, especially where the treatment of children or the elderly is involved. Pharmacists and pharmacy attendants play an important role in fostering self-medication among the public. Aim of present study is the awareness of self-medication practices in rural area of Dawaniwada. A cross-sectional study was carried out in rural area of Dawaniwada, to assess the knowledge, awareness and perception of self-medication practices by house-to house survey during the period of June 2016 to March 2017. A self-developed, pre-validated questionnaire consisting of both open-ended and closed-ended items

was used. The study population comprised of inhabitants of rural area of Dawaniwada, Gondia Dist. All participants who were willing to participate in the study were enrolled. The survey was descriptive and data was summarized as counts and percentages of 245 participants enrolled, 178 responded (72.6%). A total of 67 (27.34%) participants were excluded in accordance with the exclusion criteria like incomplete information and not using self-medication. Out of 168 respondents, 127 (75.5%) reported self-medication within 1 year of recall period. Most common conditions/symptoms for self-medication in students were fever (72.6%), pain (64.3%) and respiratory symptoms (57.1%), followed by infections, headache and diarrhea, etc. A Self-medication is an alarming sign for society. Self medication with OTC drugs may lead to adverse drug reactions, drug-drug interactions, skin problems, hypersensitivity reactions, allergy and even death. Several studies show that self-medication is a global phenomenon. Self-medication can be prevented or minimized by increased awareness and education in society.

H-4

Case Studies on Rabies and Hydrophobia in aTertiary Care Hospital

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Abstract:

Hydrophobia means fear of water. Actually, it is not the disease but it is one of the predominant symptom of disease called "Rabies". Rabies is the type of viral infection which infect all mammals including humans. Eventually, it occurs due to the bite of rabid animals like dogs, cat, monkey etc. but it is noted that in 90% cases the cause is bite of stray dog which produce symptoms like insomnia, fever, hydrophobia, aerophagia, photophobia, dysroxia, paralysis, hallucinations, restlessness, anxiety, hypersalivation and sometimes it may lead to death because of number of reasons but on the top the people are not much aware about post exposure treatment or anti- rabies vaccines, the patients who die due to rabies are those who don't seek the treatment timely, some rabid animals are not fully vaccinated which is not known to all. The reported case study of hydrophobia or rabies in 33yrs old male patient who was admitted to the tertiary care hospital of Dehradun with the chief complaints of fever, hypersalivation, photophobia, hydrophobia. His past history reveals that about 8weeks ago the patient was bitten by street dog but only the scratches was there so the patient didn't receive any medication for that before getting admitted to the hospital. Based on signs and symptoms , with causality assessment diagnosis rabies was confirmed. For effective treatment, patient was managed with symptomatic therapy and supportive care.

Keywords: Rabies, Dog Bite, Hydrophobia, Photophobia, Post Exposure Treatment

H-5

A Bacteriological Pattern of Late Onset of Neonatal Sepsis at Tertiary Care Hospital

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Abstract:

Neonatal sepsis may be defined as a clinical condition identified by signs and symptoms of infection with or without bacteria in first month of life. The various factors of neonatal mortality is sepsis, which is about 30-50% of neonatal deaths in developing countries. The aim of the study is to determine bacteriological profile of neonatal sepsis including common bacterial organisms, risk factors and antibiotic sensitivity pattern of organisms in neonatal sepsis. In this study, the numbers of male neonates (38.66%) are less prone to sepsis than female (61.33%) neonates. The proportion of gram negative organisms were higher than the gram positive organisms, which showed that (72%) were gram negative organisms and (28%) were gram positive organisms in late onset of sepsis. The most common organisms causing late onset of neonatal sepsis is Klebsiellae pneumonia (50.66%) followed by Pseudomonas Aeruginosa (32%), E.coli (22.66%), and CONS (4%). The presence of clinical symptoms leading to diagnosis of late onset of sepsis are poor feeding, jaundice, vomiting, diarrhoea, apnoea, excessive crying, breathlessness, meningitis and pallor. The study concluded that the most common neonatal risk factor that increase rate of late onset neonatal sepsis are low birth weight, premature rupture of membrane, prematurity, maternal urinary tract infection, lack of breastfeeding, maternal fever, difficult in delivery, bleeding problem.

Keywords: Neonatal Sepsis, Late Onset of Sepsis, Clinical Symptoms, Risk Factor

H-6

Assessment of Serum Vitamin D3 and Calcium level in Thyroid Dysfunction

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Abstract:

Vitamin D serve as an immunomodulator in reducing the incidence of autoimmune diseases. It is unique among hormones because it can made in the skin from exposure to sunlight. Vitamin D is recognized to be an essential element for bone metabolism and skeletal health; its deficiency can cause rickets in children as well as an increased prospenity for osteoporosis. The objective behind this study was to examine the relationship between hypothyroidism and vitamin D deficiency and to evaluate the relationship between serum calcium levels with hypothyroid disease state. This was a prospective study conducted in 30 patients and serum vitamin D levels were measured among them by using spectrophotometric method. Data was collected using self designed questionnaire. Serum 25(OH) Vitamin D was significantly lower in hypothyroidism patients than in controls (t=11.6,p=0.0001). Its level was insignificantly decreased in females than male patients. Moreover, serum calcium levels recorded a significant decreased in hypothyroid patients when compared to controls (t=2.423, P =0.0384). Hence, it was concluded that patients with hypothyroidism suffered from hypovitaminosis D with hypocalcaemia that is significantly associated with the degree and severity of the hypothyroidism. This encourages the advisability of Vitamin D supplementation and recommends the screening for Vitamin D deficiency and serum calcium levels for all hypothyroid patients.

Keywords: Vitamin D, Hormones, Hypothyroidism, Hypocalcaemia, Spectrophotometry.

H-7

Impact and Assessment of Dot TB Programme on the People of Rural Areas of Patna District of Bihar

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Abstract:

Tuberculosis(TB) is a highly infectious bacterial disease caused by Mycobacterium Tuberculosis. India accounts for 26% of the total global TB burden of 2.0-2.5 million new cases annually. The commonest from of TB in India is pulmonary TB which affects the lungs. The main objective of this survey was to study the effect of Directly Observed Treatment (DOT) provision for TB patients in controlling non adherence, incomplete, inadequate treatment of Tuberculosis and also preventing the emergence of drug resistance TB in rural areas of Patna district. A questionnaire was prepared covering the objective of the survey. The study received 100% response and there was no dropdown of respondent. About 39% of the respondent were affected by TB. Out of which 18% are cured from TB, rest are under treatment. Among those who are under treatment, 56% are under DOT and 44% preferred private or others. About 45% of those under treatment, are likely to have Drug Resistance TB due to incomplete or inadequate treatment. Cases of drug resistance TB are on a steep rise. On an average patients visits three providers, qualified and unqualified practitioners, AYUSH providers and chemists for nearly two month before he/she is diagnosed with TB. Unfortunately, unqualified practitioners and chemist sold cough syrups, antibiotics to ease symptoms not referred them to TB Centres Pharmacists are the first point of medical care. Drug- resistant TB can be reduced if trained them towards screening and referral to classic TB symptoms adults to the designated TB centres.

Keywords: DOT, Pulmonary TB, Drug Resistance TB, Pharmacist

H-8

Assessment of Off-Label Drug Use in a Tertiary Care Hospital

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Abstract:

According to WHO, Off-label use is defined as the use of pharmaceutical drugs for an unapproved indication or in an unapproved age group, dose, dosage or route of administration. This was an observational study conducted in 11 departments of PSG hospitals for 6 months which included patients who

were prescribed at least one drug for their medical condition. The total off-label drug use in the hospital was 10.40%. Of the total 1646 prescriptions, 54.7% were off-label. Pantoprazole, enoxaparin and folic acid were the highest used off-label drugs. A total of 108 adverse drug reactions were reported for the off-label drugs. In this study, there was a correlation between multiple disease conditions of the patient and number of off-label drugs, number of off-label drugs and number of ADRs, age and off-label drugs, evidence for off-label drugs and ADRs. The prescriber's knowledge of off-label use was relatively high compared to other studies. Thus it can be concluded that assessment of prescribers' knowledge and frequent audits of off-label prescriptions by regulatory authorities may decrease the problems arising from its use.

Keywords: Off-Label Use, Type, Adrs, Evidence

H-9

Antibiotics Drug Utilization Research in a Secondary Referral Healthcare Setting of South India

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Abstract:

Antibiotics are one of the most commonly used medicines in hospitals and have substantial share from the hospitals budget. As their inappropriate use has both medical (increased risk of side-effects, therapeutic failure), economic (financial burden) and public health consequences (selection of resistance), substantial efforts are needed to rationalise their use for which drug utilization studies will be a tool for determining the effectiveness of drug use. The current six months prospective study was performed to assess antibiotics utilization through drug utilization metrics, in patients for whom at least one antibiotic is prescribed, in a secondary care referral healthcare setting of south India. Out of 300 patient's prescription, 120 from pediatrics, 100 from general medicine, and 80 from surgical departments, 57% were male and 43% were female. The total number of antibiotics utilized were 452, 20.4% from pediatrics, 23.8% from general medicine and 42.6% from general surgery respectively. Metronidazole was majorly prescribed in surgery and ceftriaxone were majorly prescribed in pediatrics and general medicine. Average number of antibiotics were 1.12, 1.62 and 1.21 in departments of pediatrics, general medicine and surgery respectively. The ratio of PDD: DDD of antibiotics was lesser than 1 in all departments. In conclusion, the drug utilization research on antibiotics showed no discrepancies, and as per drug utilization metrics calculated as 100 bed days, and PDD: DDD ratio encountered no over or under utilization of antibiotics.

Keywords: Antibiotics, Defined Daily Dose, Drug Utilization Research, INRUD Indicators, Prescribed Daily Dose

H-10

A Case Report on Allergic Bronchopulmonary Aspergillosis with Pulmonary Arterial Hypertension and Chronic Obstructive Pulmonary Disease

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Abstract:

Allergic bronchopulmonary aspergillosis (ABPA) is a condition characterised by an exaggerated response of the immune system (a hypersensitivity response) to the fungus Aspergillus (most commonly Aspergillus fumigatus). It occurs most often in patients with asthma or cystic fibrosis but an association of ABPA with chronic obstructive pulmonary disease (COPD) has also been found lately. ABPA is still under recognized and under diagnosed in India, inspite of its relatively high prevalence. Here in we present a case of 47 year old man with complaint of gradually progressing breathlessness since 10 months, bilateral lower limbs swelling, abdominal pain while coughing, excess sweating, edema since 6 days. He had a history of pulmonary tuberculosis 12 year back, treated with anti-tubercular treatment. He was diagnosed as a case of COPD, Pulmonary Arterial Hypertension and ABPA. Chest X- ray revealed cavitary lesions in the upper lobe of left lung. High resolution computed tomography was done depicting round solid mass surrounded by gas indicating aspergilloma. Echocardiography revealed pulmonary arterial hypertension (Pulmonary artery systolic pressure of 74 mmHg). During the 20 days of hospital stay the patient was managed with Ramipril, Amphotericin B, Dexamethasone, Nebulize Salbutamol. Amphotericin B showed adverse reactions resulting in skin rashes and pain in lower limbs, although

it was resolved by lowering the dose of Amphotericin B from 150 mg to 100 mg and oral fexofenadine.

Keywords: Allergic, Aspergillosis, Bronchopulmonary, COPD, Pulmonary Arterial Hypertension

H-11

Assessment of Prescribing Pattern of Antiepileptics Drugs in Epileptic Patients at Tertiary Care Hospital, Bhimavaram

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Abstract:

Epilepsy is the second most common neurological condition characterized by recurrent and unprovoked seizures. Epilepsy is a second common neurological disorder affecting the well being of patients so we conducted prospective observational study in Epileptic patients to assess prescribing pattern of Antiepileptics. To assess the prescribing pattern of Antiepileptic drugs in treatment of epileptic patients at tertiary care hospital, Bhimavaram. A 6-month prospective observational clinical study was carried. The study enrolled a total of 100 cases to investigate the prescribing pattern of Antiepileptic drugs in Epileptic patients using predesigned format. In our study it was observed that male patients (60%) were mostly effected with epileptic disease and patients above 51 (44%) years were mostly effected. GTCS (52%) was most common type of epilepsy encountered and conventional AEDs (49.5%) were commonly prescribed. Most of patients were treated with dual therapy (41.8%) coming to overall AED utilization most of patients with epileptic disorder was mostly prescribed with Levetiracetam (38%) followed by Clobazam (28%) and Phenytoin (12.5%), Sodium valproate (12.5%) with equal ratios. Hypertension (28%) was the most common co-morbidity among epileptic patients compared to Diabetes (23%) and Stroke (14%) and Proton pump inhibitors (28%) were most common co-prescribed drug compared to Antibiotics (14%) and Statins (8%). So it was concluded that prescription pattern of drugs in this study is relevant with current trend of prescribing pattern of drugs in epilepsy.

Keywords: Epilepsy, Anti-epileptics, Levitiracetam, Clobazam

H-12

A Pilot Study on Various Nosocomial Infections in a Tertiary Care Hospital

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Abstract:

Nosocomial infections are those infections acquired as a result of treatment in a hospital or health care service providing center. Nosocomial infections usually encountered include urinary tract infection, respiratory tract infection, Enterococci and Enterobacter spp.To determine the various nosocomial infection occurring in tertiary care hospital. This was an observational and prospective study conducted in a different wards and departments of a tertiary care hospital Shri Mahant Indresh Hospital, Patel Nagar, Dehradun for a duration of three months. Study includes inpatients in different wards of the hospital. The patient treated on outpatient basis, patients refuses to take part in the study was excluded from the study. The inpatient profile form, patient history records, laboratory data of different departments of hospital was evaluated. A total number of 50 subjects were included to evaluate the study. In the study, maximum number of cases were found infected with urinary tract infection(52%), followed by surgical site infection(43%), neonatal infection(3%) and respiratory tract infection(2%). On the bases of above results and discussion we can conclude that gram-negative and gram-positive pathogens were responsible for majority of nosocomial infections occurring in a tertiary care hospital. Urinary tract infection, surgical site infection were commonly occurring nosocomial infection.

Keywords: Nosocomial Infection, Urinary Tract Infection, Enterococci, Enterobacter Spp

H-13

Assesment of Incidences of Dermatological Diseases and Prescription Pattern in Dermatology Department of a Tertiary Care Hospital in Dehradun

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Abstract:

The objectives of this study was to evaluate the common dermatological diseases and to assess the prescription pattern in terms of WHO core prescribing indicators among the patients attending the outpatient dermatological department of Tertiary Care Hospital, Dehradun. The prospective, cross-sectional study was conducted on 200 patients visiting dermatology outpatient department of Shri Mahant Indiresh Hospital (SMIH), Patel Nagar, Dehradun, for the period of 3 months. Patients equal to or greater than 18 years of age were included in the study. Data was obtained by using prescriptions of patients attending outpatient department after taking informed consent. Rationality of drug usage was evaluated by analysing the drug prescriptions. Out of 200 patients, 117 (59%) and 83 (42%) were males and females, respectively. Majority of the patients (29%) were in age group of 29-38 years. The common disease among study population was fungal infection. Tinea capitis (29.17%) being most common followed by other fungal infection (20.84%). A total of 906 drugs were prescribed with an average of 4.53 drugs per prescription. Only 1.96% drugs were prescribed by their generic name which is drastically low and 11.70% drugs were prescribed from WHO EML. 35.33% of drugs were prescribed in FDC's. Among therapeutic class of drugs, Corticosteroids 266 (29.36%), followed by Antifungals 174 (19.21%) and Antihistamines 164 (18.11%) was most frequently prescribed drugs. More than 3 drugs were prescribed in 45.50% prescriptions which clearly indicate high prevalence of Polypharmacy. Among individual drugs Levocetirizine 103 (11.36%) followed by Tolterodine 101 (11.14%) were prescribed.

Keywords: Dermatology, Prescription Pattern, WHO Core Prescribing Indicators, FDC's (Fixed Dose Drug Combinations), Corticosteroids

H-14

Cost Effective Analysis Between Glimipiride and Gliptin Used in Diabetic Patients n Tertiary Care Hospital

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Abstract:

Diabetes mellitus is a spectrum of common metabolic disorders arising from various mechanisms all resulting in hyperglycemia. It is a disorder which can lead to coronary artery disease, cerebro- vascular disease, Nephropathy, Diabetic retinopathy, Neuropathy. So, early treatment is necessary to prevent these complications. In this regard, Oral Hypoglycemic drugs are most common type of treatment given for patient .A better cost effective drug can minimize the economic burden on the patients as it is a chronic disease. The present study is aimed to asses cost effectiveness between glimepiride and gliptin that may improve the clinical and economical aspect of patient and increase quality of health in patient.

Keywords: Diabetes Mellitus, Pharmacoeconomics, Cost Effectiveness, Glycaemic Control, Optimal Therapy

H-15

Implementation Strategies in Prevention and Management of Osteoporosis

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Abstract:

Osteoporosis is a major public health problem characterized by low bone mass and micro architectural deterioration(MAD) of bone tissue. It may result in high risk of bone fractures with impaired quality of life. Risks factor may include previous fractures, family history of fractures, early menopause and diseases known to effect bone (rehumathoid arthritis). The diagnosis of osteoporosis can be made if the bone density T-score is less than or equal to 2.5 or below this information can be used with other risk factors to estimate the 10year risk of fractures. Patients at the highest risk for fractures can be treated from many approved treatments this can be given orally (calcitriol;hormone replacement therapy) subcutaneously (parathyroid hormone) or intravenously (zoledronic acid) and a results in reduction in fracture risk, osteoporosis can be prevented by carefull attention to exercise and diet.

Keywords: Osteoporosis, MAD, Prevention, Diet

H-16

A Retrospective Study on The Incidence of Sternal and Donor Site Wound Infections Following Cardiac Surgery

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Abstract:

Sternal wound infections (SWI) and donor site infections (DSI) are the potentially life-threatening complications of cardiac surgery. The objectives are to study the incidence of sternal and donor site wound infections post cardiac surgery, to review the pathogens isolated from wounds and to review the antibiotic sensitivity of these isolated pathogens and any changes in the sensitivity pattern over time. The study was done in patients with sternal/donor site infections post cardiac surgery whose cultures have been isolated. The organisms isolated from the infections were assessed. Staphylococcus aureus, Klebsiella pneumoniae, E.Coli and Pseudomonas aeruginosa were the common pathogens isolated. The antibiotic prophylaxis included Cefazolin, Tazobactam, Cefazolin + Amikacin and Cefazolin + Tazobactam. The antibiotic therapy showed an improvement in the prophylaxis of surgical site infections compared to previous years.

Keywords: Sternal Wound Infections, Donor Site Infections, Antibiotic Prophylaxis

H-17

A Prospective Study on Monitoring the Effectiveness, Pharmacovigilance and Psychosocial Problems Associated with Contraceptive Methods in Women

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Abstract:

In the current research, a prospective longitudinal study was carried out with an aim to assess the effectiveness, pharmacovigilance and psychosocial problems associated with contraceptives like oral contraceptives, IUDs and tubectomy in women. The study was carried out in two primary health centers - Cheeratamanna and Thekinkode in Malappuram district for a period of 6 months. About 210 female subjects who started to use either Oral contraceptives, Copper T or have undergone tubectomy in the month of December were enrolled in the study. From the study, tubectomy (98.8%) was found to be the most effective method with least adverse effects followed by IUD (97.5%) and OC (88.9%). The major adverse effects of OC were found to be vomiting15.6%, headache11.1%, weight gain 4.4% and mood changes2.2%, Cu T causes bleeding5%, back pain2.5% and insertion site pain3.8%, while ectopic pregnancy1.25% and abdominal pain3.5% were found to be the adverse effects of female sterilization in enrolled subjects by using Naranjo scale. Results revealed that there is no positive impact on psychological problems with contraceptive usage by DASS scale since it was a short term study. It was concluded that more emphasis should be given on educating women regarding the right choice of contraceptive method and its various adverse effects and psychosocial problems.

Keywords: Contraceptives, Effectiveness, Adverse Effects

H-18

A Prospective Study on Monitoring the Profusion, Risk Factors and Complication of Polycystic Ovarian Disease

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Abstract:

In recent year's polycystic ovarian disease (PCOD) is a globally emerging endocrine or metabolic abnormality among women. Clinical manifestation of this disease includes Oligomenorrhea or amenorrhea, hirsutism, infertility and insulin resistance.The prevalence of PCOD among women at reproductive age was reported to be 5-10% according to Rotterdam criteria, which may vary depending upon the criteria used for diagnosis. The etiology of PCOD is still unknown. It has a strong genetic relation. The aim of this prospective cross sectional study is to appraise the profusion, risk factors and complication of polycystic ovarian disease in a tertiary care hospital at the Malabar region of Kerala. The patients attending the Gynecology outpatient department were considered for this study. Using inclusion and exclusion criteria the study participants were selected. The prevalence of PCOD in this study is about 8.70% and it is noted that most patients are from upper class family with low educational qualification. Major risk factors include 65.96%patients has improper food habit and 27.65% patient has a family history. In this study about 78.72% of infertility is the most seen complication. The conceived participants shown pregnancy complications like gestational diabetes mellitus, gestational hy-

pertension and pre-term labor. The study has provided significant information concerning the prevalence of PCOD and about different anthropometric etiological factor and commonly seen complication of PCOD.

Keywords: Polycystic Ovarian Disease, Oligomenorrhea

H-19

Impact of Patient Counselling and Education on Quality of Life in Patients with Metabolic Syndrome

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Abstract:

Metabolic syndrome is a major public health and clinical challenge worldwide The aim of the study was to provide patient counseling and education on various aspects of metabolic syndrome to improve QoL of the patients. The study was conducted for duration of 6 months in General medicine II Outpatient department. Patients with metabolic syndrome are identified according to NCEP ATP III and IDF guidelines. The data were collected using specific data collection forms and questionnaires from the medical records of the patient and also by direct interactions with the patients. The quality of life was assessed using WHO-BREF QOL questionnaire.The study population was randomly categorized into control and intervention group. The intervention group was provided with patient counseling and PILs along with usual care. The control group received the usual care provided by the doctors, nurses and technicians. The QoL of both groups was assessed using modified WHO-BREF QOL questionnaire during the subsequent follow-up. The prevalence of MetS was found to be 29.44%. It was found that there is a statistical significant difference in the physical, psychological and social domain values in the test group at baseline and after intervention phase with t value -10.574 ,-10.796 and -2.221 And in the control group, there was no statistical significant difference in all the four domains with t values -1.439, 0.518, -.903, 0.076 respectively .Clinical pharmacist's service can be very beneficial for the management and monitoring of MetS patients to improve their QoL.

Keywords: Quality of Life, Metabolicsyndrome, Patient Information Leaflet

H-20

Risk Stratification and Thrombo-Prophylaxis of Venous Thrombo-Embolism Among Non-Surgical Patients in a Tertiary-Care Hospital: A Clinical Pharmacist Directed Intervention

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Abstract:

The current study conducted in a tertiary care hospital was aimed at optimizing the prophylactic practices prevalent in Cardiology and Pulmonology departments through a clinical pharmacist directed multi-strategy approach. The study design was cross-sectional and a total of 100 subjects were enrolled of which 50 each were distributed under the control and interventional phases. In the control phase the existing prophylactic practices were assessed and compared against the standard recommendations as per ACCP 9th Antithrombotic Guidelines. The findings of this phase was disseminated to the physicians through a CME session. The intervention phase also involved estimation of the Padua score and recommending appropriate prophylaxis. A re-audit was conducted to assess the effectiveness of the interventions, and was found that the total compliance to the therapy increased from 29 in control phase to 43 in the interventional phase, and this increase was found to be significant with p=0.002. Subsequently, a hospital policy on VTE prophylaxis was also developed to assist in thromboprophylaxis. The study concluded that clinical pharmacist directed multi-strategy intervention was effective in enhancing the overall prevalence of prophylactic practices as well as improving the appropriateness of the prophylaxis as per the ACCP recommendation to an extremely significant level.

Keywords: Venous Thromboembolism, Pharmacist, Prophylaxis, Risk, Non-Surgical

H-21

A Study On Clinical Profile Of Metabolic Syndrome And Its Impact On Myocardial Infarction At A Tertiary Care Hospital

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Abstract:

Metabolic syndrome is a constellation of interconnected metabolic disorders of hyperglycemia, hypertension, dyslipidaemia and obesity and it represents as a major risk factor for the development of cardiovascular diseases such as myocardial infarction. The current study examined the clinical profile and prevalence of MetS among MI patients along with the estimation of associated risk factors and determined the components of the MetS which conferred the paramount cardiovascular risk. A prospective observational study was conducted for duration of 10 months on a total of 117 MI patients who were further categorized based on International Diabetes Federation (IDF) criteria for MetS at a tertiary care hospital in South India. Data on patient's demographics, co morbidities, risk factors, past histories, ECG findings, waist circumference, relevant lab investigation data, use of medications and invasive cardiac procedures were gathered from patients through case reports, medication charts, and in-depth interviews. Statistical analysis of collected data was done using SPSS 22 for windows version. Among all the parameters used for defining MetS, positive predictive value was highest for fasting blood sugar (p=0.001) followed by high blood pressure (p=0.005) and elevated triglycerides (p=0.850). MetS was significantly more prevalent in MI patients with a prevalence of 51.28% (p<0.001). The study depicted high prevalence of MetS among MI patients which implies greater risk of developing cardiovascular diseases. A systematic approach in identifying components of MetS and provision of appropriate management strategies remains a vital step in preventing further cardiovascular complications and improving quality of life of individuals.

Keywords: Metabolic syndrome, Myocardial infarction, International Diabetes Federation

H-22

An Cumulative Update From 2012 – 2017 on Dissemination of Sexually Transmitted Infections in Indian Tertiary Teaching Care Hospital

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Abstract:

Sexually transmitted infections (STIs) continue to be a major public health problem with significant burden on the society even after so many health care programs being organized by the governmental and non-governmental organizations. A retrospective chart review of the data collected from the clinical records of all STI positive patients, who had attended the skin OPD of Guru Gobind Singh Medical College, and Hospital, Faridkot, Punjab, for various complaints during the 5-yearperiod from 2012 to 2017 was carried out. All male and female patients diagnosed with STIs were included in the study and those patients without any evidence of STIs either clinically or serologically were excluded from the study. Out of the 2, 44,881 patient's cases who had attended the Skin OPD, 3751 (1.531%) patients had STIs. Balanoposthitis accounted for the maximum number among the STIs with 929 cases (24.8%), followed by Vaginal discharge 653(17.4%),GUD Herpetic 485 (12.9%),Scabies 433 (11.5%), syphilis 365 (9.7%), GUD non Herpetic 304 (8.1%), Warts 303(8.1%),Urethral Discharge270(7.2%) and HIV+9(0.2%). Viral STIs occur significantly more than the bacterial STIs because of their in curable and recurrent nature. Health programs should be still more focused on creating awareness about the minor STIs and to remove the stigma from the society so that the patients attend the proper health care facilities in the early stage itself for treatment there by and as a result complications and further transmission of the STIs can be avoided.

Keywords: Sexually Transmitted Infections, Genital Ulcer Disease, Out Patient Department, Balanoposthitis

H-23

Complexeties In Multi Drug Regimen – A Failure To Medication Adherence?

Is There A Need Of Clinical Pharmacist!

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Abstract:

Medication adherence (MA) is defined by the World Health Organization (WHO) as "the degree to which the person's behavior corresponds with the agreed recommendations from a health care provider. Non adherence to medication is multifactorial rather than a single factor which leads to woes and miseries,thereforeit poses a serious risk to the community and contributes to failure in eradicating the diseases globally along with the illness and economic burden to the patients. Each

factor like forgetfulness, confusion, can't take self-medication plays a predictor to decline in MA in due course, particularly in geriatrics poses a great problem, followed by unaware about indication, uncomfortable with medicines, side effects due to multiple drugs in general population. However assessment of MA remains a Herculean task. In developing countries like India where a doctor to patient ratio is low, a clinical pharmacist can be handy and play a bridge between doctor and patient. Thus the present study was aimed to improve the patient's knowledge towards their disease and assess the predictors for decline in MA and also to improve the medication adherence by means of patient education.

Key words: Medication Adherence, Patient Education.

H-24

A Study on Therapeutic Comparison Between Conventional Paclitaxel and Nanoparticle Albumin Bound Paclitaxel in Breast Cancer Patients

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Abstract:

Breast cancer is a heterogeneous disease in terms of gene expression, etiology, clinical course and response to treatment. The nanoparticle albumin bound paclitaxel (Nab.Paclitaxel), a novel drug which is free of solvents was compared with polyethylated castor oil based conventional paclitaxel (Con. Paclitaxel) in patients with metastatic breast cancer who were failed in their first line chemotherapy. It was a prospective observational study done at a cancer centre for 6 months with 40 patients (20 in each group) to assess the efficacy and safety of both drugs. Patients were assigned to 4 cycles of either Nab. Paclitaxel intravenously without premedication or Con.Paclitaxel intravenously with premedications. It was found that the overall response rate of Nab-Paclitaxel is higher (65%) when compared with Con.Paclitaxel (35%). Incidence of adverse drug reactions was higher in Con. Paclitaxel than the other group. Among them, grade 4 Neutropenia was high in Con.Paclitaxel group where as Peripheral Neuropathy was found more in Nab. Paclitaxel group. The hypersensitivity reactions were high in Con.Paclitaxel group. Nab.Paclitaxel is costlier than Con.Paclitaxel. Therefore, Nab-Paclitaxel was found to be more effective as a second-line treatment for patient with metastasis as the response rate to treatment was higher and the incidence of adverse drug reactions were less than the other. Though the cost of Nab-Paclitaxel is higher than Con.Paclitaxel, when compared to the benefits of both drugs, Nab-Paclitaxel is found to be the better choice of drug.

Keywords: Breast Cancer, Conventional Paclitaxel, Nanopartticle Albumin Bound Paclitaxel

H-25

Agenesis of Corpus Callosum: A Case Study

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Abstract:

Agenesis of the corpus callosum (ACC), a failure to develop the large bundle of fibres which connects the two cerebral hemispheres and has been reported in 1:4000 individuals and 2.3% of children with mental retardation. The defect may be complete or partial, depending on the stage at which callosal development is arrested. In most cases, the cause of ACC is unknown. However, it can be inherited as an autosomal recessive trait or an X-linked dominant trait. This disorder may also be due to an infection during pregnancy (intrauterine) leading to abnormal development of the fetal brain. ACC may initially become evident through the onset of epileptic seizures during the first weeks of life or within the first two years. However, not all individuals with ACC have seizures. Other symptoms are feeding problems and delays in attaining developmental milestones like holding the head erect, walking, talking and reading, impairment of mental and physical development. In some cases, symptoms may not appear for many years and in cases it may be overlooked due to lack of obvious symptoms during childhood. Treatment is symptomatic and supportive. Anti-seizure medications, special education, physical therapy, and related services may be of benefit depending upon the range and severity of symptoms. Here we are presenting a case of 6 month old child patient who was brought to hospital by his parents with the complaint of delayed in holding the head erect. The complete absent of corpus callosum was confirmed by the neurosonogrpahy and MRI scan.

Keywords: Agenesis, Genetic Disorder, Corpus Callosum, Cerebral Hemispheres, Seizures

H-26

Susceptibility of Commonly Used Disinfectants Against Multidrug Resistant Bacterial Pathogens Isolated From Tertiary Hospitals in India

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Abstract:

The aim of this study was to determine the activities of some common available biocides against bacterial isolates from tertiary hospitals in India. Twenty drug resistant strains including Vibrio cholerae , *Staphylococcus aureus* , *E.coli, Klebsiella pneumoniae* , *Pseudomonas* species were collected from clinical specimens such as urine, blood, wound swab etc submitted to diagnostic laboratory of the hospitals and tested for their sensitivity against the biocides commonly used including ethanol (70%), sodium hypochlorite (6%), chlorohexidine (4%), chloroxylenol (2.4%) and triclosan (4%).The plates were then incubated at 37°C overnight, and the zones of inhibition were calculated.. The number of strains were inhibited with different concentrations of various biocides (sodium hypochlorite, chloroxylenol, triclosan, chlorhexidine, and ethanol) using agar diffusion ut inhibition weweat a much higher concentration than commonly used. Sodium hypochlorite was more effective against all the strains compared to the other biocides while ethanol and triclosan were less effective even at the popular 70% for ethanol normally used for antisepsis. *S. aureus* showed 100% resistance to ethanol even at 100% concentration while some levels of activities were obtained at 80 – 90% for other tested bacterias like E.coli. However .*P. aeruginosa* was found to be 100% resistant to triclosan at all concentrations. It would be recalled that 70% ethanol has been widely used for ensuring antisepsis on the skin or in clinical settings for swabbing animate or inanimate objects as 100% alcohol cannot be used as a disinfectant because of its volatility and denaturation of external membrane proteins only. But we need to increase the concentration of ethanol as disinfectant/biocide to 80 – 85% as a matter of emergency with little or no economic cost due to the global high level bacteria resistance. The use of biocide in higher concentrations is inevitable due to the decrease in susceptibility as observed in this study. The more appropriate disinfectants for hospital disinfection are sodium hypochlorite and chloroxylenol.

H-27

A Study on Knowledge About Epilepsy in Primary School Teachers in Selected Schools of Chitradurga Taluk

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Abstract:

Epilepsy is the second most common chronic neurological condition seen by neurologists. It is estimated that there are 55,00,000 persons with epilepsy in India. To assess the baseline knowledge regarding EPILEPSY among the schoolteachers. A interventional study was carried out among the teachers in selected primary schools of both English and Kannada medium in Chitradurga taluk for a period of six months. A total of 100 teachers were enrolled into the study. SPSS Software was used to calculate the statistical estimation. *Results:* The knowledge about epilepsy in primary school teachers were low. Female teachers had better knowledge compared to their male counterparts. Hence, regular training is necessary and should be implemented in future for better management of epilepsy among children and others. The school teachers in chitradurga had, at the time of the investigations, a relatively low level of awareness, and understanding of certain aspects of epilepsy, and a minority of the study population demonstrated unfair discriminatory behavior toward children with epilepsy. Schools should offer information on epilepsy and assistance by the health services and physicians must ensure that teachers have sufficient knowledge of the condition. Also education campaigns of the general public on epilepsy should be encouraged.

H-28

Epidemiological Survey Regarding Awareness, Knowledge and Adherence in Hypertensive Patients

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Abstract:

The objective of the study was to assess the risk factors, co-morbidities associated with hypertension and prescription pattern of antihypertensive medication. The finding of the

study has demonstrated that most of the hypertensive patient has knowledge & awareness regarding hypertension and a medium level of adherence was seen among all the participants. Out of 120 participants, 55% were male while 45% were female involved in the study. Out of the 120 participants, 28.3% participants were of the age group of 50-59 years. Among 120 participants 27.5% having kidney disease only and 24.16% subjects having diabetes, as the most prevalent disease occur with hypertension. The study revealed that among 120 participants 40.8%, 37.5%, and 21.7% subjects having good average and poor knowledge & awareness regarding hypertension respectively and 23.3%, 40.8%, 35.9% subjects having high, medium and poor adherence scores respectively. This study depicts that most of the hypertensive subjects 40% were on 2 drug combination and 37% were on monotherapy. Out of all antihypertensive drugs used, diuretics were the most commonly used drugs 69.1% and angiotensin-converting enzyme inhibitors were least used drugs 4.2%. Thus it can be concluded that this study suggests focussing on the need of clinical pharmacist for patient care to decrease the disease condition, drug-related problem and encouragement of health education and promotion of adherence towards medications in the patient.

Keywords: Hypertension, Diuretics, Monotherapy, Angiotensin-Converting Enzyme Inhibitors

H-30

Impact of Medical Reconciliation in Transitions of Care for Patients with Cardiovascular Diseases

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Abstract:

According to the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), Medical reconciliation is the process of comparing a patient's medication orders to all of the medications that the patient has been taking. The objectives of this study were to bring out a rational prescribing pattern during transitions of care by avoiding medication errors, adverse drug events, drug interactions, minimizing treatment costs and drug related problems which lead to re – hospitalization. This was a Prospective Interventional Study conducted in Cardiology Department with Historical control which included patients with atleast three prescribed drugs, pregnancy and lactation. In Control group, Chart review was performed to identify DRPs. In Test group, Best Possible Medication History was taken within 48 hours of admission and Medical Reconciliation was done to identify Drug related problems (DRPs). These DRPs were classified according to PCNE V6.2. A total of 99 DRPs were found in 79 patients. The most commonly identified problems were untreated indication, non-allergic adverse drug event, unnecessary drug treatment and drug interactions which were caused by drug selection, inappropriate timing of administration and prescribing error. Factors associated with occurrence of DRPs include middle age, administering more than 10 drugs and in-hospital stay. Some of these DRPs were approved by prescribers and eventually solved. Thus, the involvement of pharmacist in conducting Medical Reconciliation has helped ameliorate drug related discrepancies in transitions of care.

Keywords: Medical Reconciliation, DRPs, Transitions of Care, Historical Control

H-31

Prescribing Pattern of Psychiatric Drugs in Commonly Occuring Psychiatry Disorders in a Tertiary Care Hospital, Bhimavaram

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Abstract:

The expanding field of psycho-pharmacology is constantly seeking new and improved drugs to treat psychiatric disorders. Although psychotropic drugs have had a remarkable impact in psychiatry, their utilization, effectiveness, and side effects in the clinical practice need continuous study. The present study was thus designed to analyze the pattern of psychotropic drugs prescription in a tertiary care hospital, Bhimavaram. A 6-month prospective observational clinical study was carried. The study enrolled a total of 64 cases to investigate the prescribing pattern of psychotropic medications using a predesigned format. In our study major psychiatry disease was found to be anxiety. In Anxiety patients present with Generalized anxiety disorder were 61% and Panic disorder were 38%. Our study reported that maximum number of anxiety and depression patients were commonly prescribed with combination of SSRI + Benzodiazepines,and maximum number of patients with mood disorder were commonly prescribed with Antipsychotics followed by Benzodiazepines and SSRI's,maximum number of Schizophrenia patients were commonly prescribed with Atypi-

cal Antipsychotics followed by combination of Typical antipsychotic agent + Antimuscarinic agent. So it was concluded that prescription pattern of drugs in this study is relevant with current trend of prescribing pattern of drugs in Psychiatry disorders.

Keywords: Psychiatry Disorders, Antipsychotics, SSRIs, BZD

H-32

Impact of Sleep Quality on Academic Performance

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Abstract:

Sleep has many important effects on the human body. One of its most important effects is on one's memory, where it plays a role in stabilizing perceived information and facilitating generalized knowledge. We attempted the quality of sleep and its effects on academic performance of health sciences students. A cross-sectional study was carried out in Hindu college of pharmacy, for 12 months starting September 2016 . Validated self-reports: Pittsburgh Sleep Quality Index (PSQI) Questionnaire ,demographic, and academic information were collected from 157 students of both genders through convenience sampling technique. PSQI measures quality and disturbance while assesses psychological and occupational wellbeing. We used frequency (%) for categorical variables and mean for continuous variables. Total score for PSQI scales were calculated and divided into categories based on quartiles. Person coefficient was used to examine correlation. Multiple linear regression model was applied to predict student grade-point average (GPA) from sleep quality score and to predict students GPA. We defined results to be statistically significant if $P < 0.05$. Results: PSQI scores did not appear to predict academic performance; there was no significant result GPA ($r2 = 0.091$, $P = 0.477$). On reversing model were found to significantly affect quality of sleep (odds ratio = 0.301, $P < 0.001$) while academic performance (GPA) was not found to significantly affect sleep quality ($P = 0.734$). We concluded that the effect of sleep quality and well-being on academic achievement is inconclusive.

Keywords: Sleep Quality, Academic Performance

H-33

A Study on Safety and Efficacy of SGLT-2 Inhibitors as an Adjuvant to Insulin Add on Therapy in Uncontrolled Type-2 Diabetic Patients

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Abstract:

Patients with uncontrolled diabetes have twice the risk for death related to cardiovascular disease than those without diabetes. The newer class of antidiabetic agents called SGLT-2 inhibitors has been introduced and has major advantages in terms of reducing HbA_1c, blood sugar levels and weight and may potentially reduce the cardiovascular risk. The objectives of the study are to compare relative cardiovascular risk reduction and adverse events in patients receiving adjuvant SGLT-2 inhibitor therapy in combination with insulin add-on therapy with those receiving insulin add-on therapy alone. The study was done in 100 patients with uncontrolled type 2 diabetes mellitus. 50 patients received SGLT-2 inhibitor along with gliclazide-metformin and insulin. Remaining 50 patients were received gliclazide-metformin and insulin. The changes in FBS, HbA1c, weight, BMI, blood pressure and cardiovascular risk of diabetic patients before the initiation of add on therapy and after 6 months follow up were measured. Diabetes related complications like foot ulcer, hypoglycaemic episodes and urinary tract infections were documented. Patients on SGLT-2 inhibitors as adjuvant to insulin add on therapy showed better glycemic control, reduction in weight, BMI, blood pressure and cardiovascular risk. SGLT-2 inhibitors are safe and effective treatment with glycemic and non-glycemic benefits contribiuting to their effect in reducing cardiovascular risk in uncontrolled type-2 diabetic patients.

Keywords: SGLT-2 Inhibitors, Add on Therapy, Cardiovascular Risk, BMI

H-34

Views of General Public and Creating Awareness on the Role of Pharmacist in Health Care

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Abstract:

Pharmacies are convenient for most people to get to and there is no need for an appointment to see the pharmacist which makes them natural first port of call healthcare providers in society. They bridge the gap between doctors and patients for optimal and rational use of the medicines. Public perception on pharmacists as a healthcare professional is ambiguous. There is a great need to generate awareness in the public as well as other health care professionals about the roles and responsibilities of pharmacists in the healthcare system. The objectives of this study are to assess of awareness and acceptance of general public on the role of pharmacist in health care and to create awareness by educating using pamphlets. A total of 450 individuals were approached for the study, where 400 participated and 50 showed no interest. A validated Pre-awareness assessment questionnaire containing 15 questions and a set of five post education awareness assessment questions were prepared to assess the improvement in awareness level after pamphlet education. The study indicated that most of the respondents had poor awareness about the role of pharmacist to healthcare. Education levels of respondents were significantly associated with awareness levels of participants. The approval level was found to be average. The awareness level improved after creating awareness by educating via pamphlet.

Keywords: Pharmacist's Roles And Responsibilities, Public Awareness, Acceptance

H-35

Clinical Management and Outcome Assessment of Generalised Anxiety Disorder and Panic Disorder in Refractory Gastro-Esophageal Reflux Disease: Evidence From a Prospective Interventional Study of Benzodiazepines and Sertraline

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Abstract:

The aim of the study was to investigate the relationship between GERD-related symptoms and psychological symptomatology, as well as clinically diagnosed generalized anxiety disorder (GAD) and panic disorder (PD) and effectiveness of Sertraline and benzodiazepines in controlling these conditions. A 6 months quasi experimental study was conducted in gastroenterology outpatient department of a tertiary care referral hospital. Refractory GERD was confirmed by assessing for PPI failure over 4-8 week trial of standard doses of PPIs. The therapy with Benzodiazepines and Sertraline was initiated in patients with refractory GERD having panic and anxiety symptoms associated with refractory GERD. Effectiveness of the therapy was measured using panic and agoraphobia scale and Hamilton anxiety scale. Reduction in the severity of GERD symptoms was assessed using GERD – HRQL scale. The occurrence of PD and GAD in patients with refractory GERD showing psychiatric symptomatology in our sample was found to be 68% and 32% respectively. There was a significant decrease in the score of GERD HRQOL after the administration of sertraline and benzodiazepines when compared to the score of GERD HRQOL before administration of interventional drugs (p=0.001). Our study investigated the role of anxiety and panic in GERD and their effect on quality of life. The results indicated that QOL of patients were highly improved as indicated by severity scores after administration with sertraline and benzodiazepines.

Keywords: Benzodiazepines, Generalized Anxiety Disorder, Panic Disorder, Refractory Gastroesophageal Reflux Disease, Sertraline

H-36

Complexeties in Multi Drug Regimen-A Failure to Medication Adherence? Is There a Need of Clinical Pharmacist!

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Abstract:

Medication adherence (MA) is defined by the World Health Organization (WHO) as "the degree to which the person's behavior corresponds with the agreed recommendations from a health care provider. Non adherence to medication is multifactorial rather than a single factor which leads to woes and miseries, therefore it poses a serious risk to the community and contributes to failure in eradicating the diseases globally along with the illness and economic burden to the patients. Each factor like forgetfulness, confusion, can't take self-medication plays a predictor to decline in MA in due course, particularly in geriatrics poses a great problem, followed by unaware about indication, uncomfortable with medicines, side effects due to multiple drugs in general population. However assessment of MA remains a Herculean task. In developing countries like India where a doctor to patient ratio is low, a clinical pharmacist can

be handy and play a bridge between doctor and patient. Thus the present study was aimed to improve the patient's knowledge towards their disease and assess the predictors for decline in MA and also to improve the medication adherence by means of patient education.

Keywords: Medication Adherence, Patient Education

H-37

Pharmacist Intervention and Preparation of Manual in the Administration of Drugs Through Enteral Feeding Tube

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Abstract:

Administration of oral drugs to patients through enteral tube feeding is a special challenge. Improper administration causes tube obstruction, increase in adverse drug reaction, decrease in drug effectiveness and drug nutrition incompatibility. This is an observational study conducted for 6 months in eight departments. The errors include crushed non crushable solid dosage forms, each drug not prepared separately, incorrect solution used for dilution, drugs mixed with feeding formula, each drug is not administered separately, not flushed before and after administration of each drug, and others (tablets are not crushed with proper device, motors and pestles are not cleaned). Using the data, a manual was prepared and submitted to the physicians of each department. The most prominent error was found to be that the drugs were not prepared and administered separately, tube not flushed before drug administration. Usage of non-crushable drugs was high in neurology. Correlation between the number of drugs prescribed per patient with incidence of error was found to be statistically significant. Pantoprazole enteric coated and prazosin modified release tablets were the most commonly used non crushable drug. The study observed the need for developing a standard protocol for drug administration through enteral feeding tube by the pharmacist along with physician, nursing team to improve the quality of enteral therapy.

Keywords: Enteral Feeding Tube, Drug Administration, Errors

H-38

A Descriptive Study on Assessment of Relationship Between the Dietary Behaviours and BMI in a Group of School Students in Bhimavaram Mandal, West Godavari District Andhra Pradesh

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Abstract:

Dieting ,the deliberate selection of food to control body weight or nutrient gain. Body mass index is a simple index of weight- for-height that is commonly used to classify over weight and obesity in adults .It is defined as a person's weight in kilograms divided by the square of his height in meters [kg/m2]. The study was aimed to assess the relationship between the dietary behaviours and BMI in a group of school students in Bhimavaram Mandal. It is a descriptive study that was conducted in primary and high school level students. In this a simple language questionnaire based on dietary behaviours was asked and the behaviour was calculated by using NHS choices. The study was conducted in 12,500 students in which males are 755 and females are 560 and the results are 28% students are underweight, 19% students are overweight and normal were around 53%. The knowledge were tested, in which 73.1%know the healthy eating through the classwork and 15.7% know the ways to lose weight, at the sametime 7% know the ways to gain weight. From this study, it is concluded that children who are leaving in rural areas are prone to malnutrition. Therefore attention should be given on intervention of malnutrition.

Keywords: BMI, Dietary, Malnutrition, Knowledge

H-39

Pharmacovigilance-Adverse Drug Reaction Monitoring and Reporting in Different Specialty Department of a Tertiary Care Teaching Hospital

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Abstract:

Adverse drug reactions (ADRs) are one of the leading causes of morbidity and mortality in world wide. Adverse drug

reaction is a harmful effect of drugs or irrational use of medicine. Objectives of the study were to determine the nature and characteristics of adverse drug reaction in hospitalized patients. A prospective study was conducted for a period of six months, patients attending the medicine OPD as well as IPD with complain of adverse drug reaction were enrolled in the study. Patient who developed an ADR was interviewed daily through their hospital stay from the day the ADR were reported. Naranjo ADR probability scale was used for the causality assessment. The results were observed and evaluated for the total 48 suspected ADRs were reported and evaluated from 150 patients. Total 1140 patients were admitted under the different wards of the hospital during the study period, out of these 793 were female and 347 were male. The drugs classes/ group most commonly associated with ADRs in patients were antimicrobials agents 25 (52.08%) no of incidences, NSAIDS and anti-hypertensive were 4 (8.33%) , Oral hypoglycemic 2 (4.6%) no of incidences and other like Anti T.B drugs 3(6.25),Anti-epileptic agent 2 (4.16%), Anti-histamine 1(2.08%). Hence, it was concluded that all the presented ADRs most of them were predictable and preventable, by the implementation of a successful multidisciplinary ADR surveillance system there can be a positive impact on the medication use system.

Keywords: Adverse Drug Reaction, Mortality, Patient, Naranjo Scale

H-40

Prevalence of Toxicity of 6-Mercaptopurine in Children on Maintenance Therapy for Acute Lymphoblastic Leukemia

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Abstract:

Leukemia accounts approximately for 1/3 of cancers occurring in early childhood, with Acute Lymphoblastic Leukemia (ALL) being the most common entity. 6-Mercaptopurine is found to be the crucial part of ALL therapy, both in terms of its efficiency (relapse risk) and safety (toxic side effects). The present study was designed to evaluate the prevalence of toxicity of 6-Mercaptopurine in children on maintenance therapy for Acute Lymphoblastic Leukemia. A prospective observational study was carried out in the Haemato-oncology ward, Department of Paediatrics, Government Medical College, Kozhikode for a period of 7 months. Patients who satisfy both the inclusion and exclusion criteria were included in the study. Patients were followed up for 4 months during the maintenance therapy. All relevant information for the study were collected from interview with the patient or caregiver, patient's case sheets and laboratory findings. The grading scale used for adverse event (AE) evaluation was assessed using the National Cancer Institute Common Terminology Criteria (NCI CTC) version 4. A total of 53 patients were enrolled into the study. 50 subjects were completed the study and 3 subjects were excluded because of relapse. 6-Mercaptopurine dose should be individualized depending on total WBC count, Absolute neutrophil count and SGPT levels of each patient while on maintenance phase, instead of giving a fixed protocol based dose. And that optimum dose should be continued for that patients. This may help to avoid frequent stoppage of 6-Mercaptopurine.

H-41

Assessment of Drug Related Problems in Obstetrics and Gynaecology in a Tertiary Care Hospital

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Abstract:

In current research, assessment of drug related problems (DRPs) in OBG was done. The objective behind the research was to identify the drug related problems like adverse drug reactions (ADRs), drug interactions (DI), over dose (OD),under dose (UD),treatment without indication (TWI),untreated indication (UTI). DRP admissions have been significantly increased over the past few decades. DRP is defined as an event or circumstance that involves a patient's drug treatment that acutually or potentially, interfers with the achievement of an optimal outcome. From current research, 200 cases are collected. Out of 200 patients, 130 patients are identified with atleast one drug related problems.258 DRPs are identified. In that 128 drug interactions, 7 treatment without indication, 25 untreated indication,5 lower dose, 9 under dose,33 ADRs,5 drug duplication. Therefore, drug related problems are prevalent in hospital inpatients. Pharmacists can play important role to identify and resolving DRPs. Thus, it can be concluded this study can be beneficial for the assessment of drug related problems in Obstetrics and Gynaecology.

Keywords: ADRs, DI, OD, UD, Rational Drug Therapy

H-42

Women Health Management Programme: Pharmacist's Care for Anemia

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Abstract:

Women health refers to the branch of medicine that focuses on the diagnosis and treatment of diseases and conditions that affects women's physical and mental and social well-being. Anemia is major challenging condition that impair women's health. Intake of oral anti anemic drugs is associated with gastro intestinal side effects which results in reduced adherence to the prescribed medications. Aim is to determine the impact of pharmacist's care in improving the health among anemic women by enhancing their adherence to oral anti-anemic drugs. The objectives include understanding the knowledge regarding anemia, its medications, symptoms, side effects, medication adherence level and causes of non-adherence. Participant's knowledge regarding anemia and its medications, symptoms, side effects, medication adherence level and causes of non-adherence were recorded and education was given to low adherence patients. The low adherence patients were grouped in to test (pharmacist's care provided) and control (no pharmacist's care provided). Follow up was done after 1 month to assess the improvement in knowledge, symptoms, side effects, medication adherence level. Descriptive statistics, Pearson correlation and ANOVA was done to analyse data. Knowledge regarding anemia and its medication were poor. Most complained symptom was fatigue. Most commonly reported side effects of oral anti anemic drugs are nausea and black stools. Medication adherence was low and main cause was forgetfulness. Pharmacist's care resulted in improvement in knowledge, symptoms, tolerance to side effects, medication adherence. Thus study concludes that pharmacists' care could improve health in anemic women by enhancing their adherence to oral anti-anemic drugs.

Keywords: Anemia, Women Health, Pharmacist's Care, Medication Adherence

H-43

A Pharmacoepidemological Study of Hypertension Among Women in Selected Areas of Chitradurga Taluk

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Abstract:

Hypertension ranks third, after underweight and unsafe sex, in the list of six major risk factors contributing to the global disease burden. Women with low status in this latter Socio Economic Status (SES) indicator had a significant 40% increased odds of hypertension compared to women of high status. Women working outside the home had a lower prevalence of both hypertension and pre-hypertension than women who stayed at home. In India, prevalence of hypertension was 69.9% residents from urban areas and 35.9% from rural areas. It is an important risk factor for future development of cardiovascular disease. Though the trends are improving, still many patients are not aware of their condition, are not receiving therapy when needed, when receiving therapy are not achieving recommended blood pressure goals. This represents a significant gap between recommended treatment goals and patients actually attaining those goals, is a clear opportunity for all health care providers to improve the outcomes of patient with hypertension.

Keywords: Hypertension, Women, Prevalence

H-44

Prevalence and Pattern of Hypertension in Diabetic Patients in Tertiary Care Hospital

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Abstract:

India presiding the world with largest number of diabetic patients and is often referred to as the diabetes metropolis of the world. Diabetes mellitus (DM) is a common secondary cause of hypertension, particularly, if glycaemic control is poor. The present study was planned to ascertain the prevalence, pattern of diabetic hypertension and also the use of antihypertensive agents. Prospective observational study was perpetrate at Basaveshwara Medical College & Research Center, Chitradurga on 134 diabetic patients and were disguised for hypertension (HTN). The congregated data were analysed by using SPSS software version 19. The work finished with the outcomes of that, the most of the diabetic patients were having comorbid condition of hypertension. Most universal pattern was stage

IHTN. Calcium channel blockerswere regularly used to treat the condition.

Keywords: Diabetes Mellitus, Prospective, Glycaemia, Prevalence

H-45

Role of Stress in development of Cardiovascular Diseases.

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Abstract:

According to Million death study CVD are the major cause of death in India (1.8-2.0 million per year). There are various risk factors associated with CVDs; they can be classified in to local and systemic factors. Systemic factors are further divided in to modifiable and non modifiable factors. Stress may be defined as Stress is often described as a feeling of being over loaded, wound up tight, tense and worried or it may be said as a state of mental and emotional strain or tension. Stress is divided in to three categories depending upon its duration and intensity which are acute stress, episodic acute stress and chronic stress. The main objective of this research survey was to establish role of stress in development of CVDs and to make people about stress and its relationship with CVDs and other diseases. There are many factors which are associated with development of cardiovascular disease and stress is one of them, stress is both harmful and useful for the body as small amount of stress is also necessary to maintain consciousness of an individual. If stress level is increased and if remains for a long duration it may cause affect to various body organs like brain, kidney, GIT system (stomach ulcers), thinking and memory problems, sleep disorders and which may even lead to death. In this research survey a questionnaire of 13 questions was used to collect data from population of 120 people out of which 103 people's data was screened out and analyzed, it consist of both male and female and people of different age group and occupation. In results it was found that most of the population knows the meaning of stress, but very less follow any kind of physical activity on the daily basis, preference for fast and processed food and method to release stress differs from person to person. Almost all the people found stress harmful and their tendency to over react depends upon situation.

H-48

A Study on Medication Therapy in Psychiatric Disorders in a Tertiary Care Hospital

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Abstract:

The expanding field of psycho-pharmacology is constantly seeking new and improved drugs to treat psychiatric disorders. Although psychotropic drugs have had a remarkable impact in the psychiatry, their utilization, effectiveness, side effect and adherence in the clinical practice needs continuous study. The study was thus designed to analyze the prescription pattern of psychotropic drugs and their adherence in patients in a tertiary care hospital.

Keywords: Psychiatric Disorder, Psychotropic Drugs, Medication Adherence, Prescribing Pattern

H-49

Knowledge of Health Policies in Indian Population: a Questionnaire-Based Survey

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Abstract:

The practice of public health has been dynamic in India, but has witnessed many hurdles in its attempt to affect the lives of the people of this country. Since independence, various health policies have been formulated and implemented for major public health problems like malaria, tuberculosis, leprosy, high maternal and child mortality and lately, human immunodeficiency virus (HIV). Several insurance schemes have also been formulated. Instead of these policies/schemes, the incidence rate of these diseases and mortality rate is increasing day by day. This may be happening due to failure of outstretch of these policies to common man. Thus, this study was undertaken to analyze the knowledge of health policies among Indian population. A questionnaire based survey was conducted among different population of Moga, Punjab, covering all kind of population. Questionnaires were filled with the help of inves-

tigators, physicians, social workers, freelancers, research professionals etc. There were 10 different parameters/data points for which the data was collected from 500 peoples among different population of Moga, Punjab. Descriptive statistics were used for analysis of data. The result of current investigation has shown poor knowledge of health policies among Indian population. It is concluded that there is lack of awareness towards health policies among Indian populations. Thus, there is need to organize various seminars, camps and drives to provide proper information among Indian population towards the betterment of their health by change in their lifestyles and utilizing the benefits of government's schemes in health sector.

Keywords: Public Health, Government's Schemes, Health Policies

H-50

A Study to Assess the Effect of Clinical Pharmacist Delivered Counselling on Medication Adherence in Patients with Diabetes Mellitus

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Abstract:

Diabetes Mellitus is a metabolic disorder characterized by hyperglycaemia due to defect in insulin secretion, insulin action or both. Medication adherence is considered as the major barrier in glycaemic control. The ultimate goal of patient counselling is to encouraging safe and appropriate use of medications thereby enhancing therapeutic outcomes. Objective of the study is to analyse and assess the impact of counselling by clinical pharmacist on medication adherence in diabetic patients, and to improve the patient's knowledge and awareness in response to the management of diabetes. A prospective observational study was conducted in a tertiary care hospital for a period of 6 months from November 2016 to April 2017 among Type 2 diabetes patients. 51 patients are enrolled and randomized in to test group and control group. Patient's demographic details, adherence level, and disease related information were collected in data collection form. Educational materials, patient counselling was given to control group in various follow up visits. Morisky scale was used to assess the medication adherence. These adherence scores and glycaemic levels (fasting plasma glucose and post prandial plasma glucose) were obtained compared between both groups at the end of the study. The result showed that statistically significant differences in glycaemic level ($p<0.05$) and medication adherence scores was observed in the final follow up in intervention group as compared to the usual care group. This study suggested that the clinical pharmacist delivered counselling has a considerable effect on medication adherence and glycaemic control in patients with diabetes mellitus.

Keywords: Diabetes Mellitus, Medication Adherence, Patient Counselling

H-51

Prescription Pattern in Respiratory Tract Infection Among Pediatric Inpatients: A Prospective and Observational Study

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Abstract:

Respiratory tract infection occurs both among children and adults. It is perceived as a main cause of morbidity and mortality in many developing countries and which eventuality cause 3.5 million children each year. A prospective and observation study was conducted in pediatric inpatients department, Shri Mahant Indresh Hospital, Patel Nagar, Dehradun, Uttrakhand. Total no of 100 patients were included in this study out of them patients showed that the significant uses of drugs were used for conditions like bronchopneumonia (41%), TB (5%), Bronchiolitis (17%), common cold (11%), tonsillopharnagitis (3%), asthma (10%), pneumonia (7%), other (6%). These conditions were most common reason for hospitalizations of the pediatric patients. Beta-lactam antibiotics were the main class of drugs prescribed (18.45%).

Keywords: Children, Pediatric Drugs Prescribing, Inpatients

H-52

Precision Medicine-An Advanced Study of Gene Sequencing

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Abstract:

Precision medicine is an emerging approach for disease treatment and prevention that takes into account individual variability in genes, environment, and lifestyle for each person. There is great potential for genome sequencing to diagnose various life threatening diseases like cancer, cystic fibrosis and to reduce adverse effects of drugs to a large extent. Various methods are developed to determine genome sequencing such as *linker analysis* and with proper alignment and arrangement to find the gene responsible. The main challenge in our pathway is to generate a secure pathway to store Pharmacogenomics of patients safely. Global sharing of this more accurate genotypic data will help scientist a lot in their research. Thus, a deeper understanding of disease will be realized that will allow its targeting with much greater therapeutic precision.

Keywords: Precision Medicine, Pharmacogenomics, Linker Analysis

H-53

A Case Study of Aarogya- The Health, Disease and Drug Information System (Future Prospects and Business Plans)

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Abstract:

The medical system in India is overburdened with the scenario being as poor as 1 doctor per 1700 people. As a result of this various health, medical and medicinal issues fail to get addressed properly. The current case studies deal with the inevitable requisite of addressing this important issues such as health and nutrition awareness, diseases and drug awareness, self- medication, irrational drug use as well as of providing secondary assistance in the form of personalized care to individuals with chronic diseases as well as patient counselling. The study is based upon the experience obtained from one to one interaction with thousands of people during the health, drug and disease information camp '*AAROGYA*' organized every year since 2009 by the Department of Pharmacy, S.G.S.I.T.S., Indore, (M.P.). In majority of cases people have appreciated the scope of such an assistance and information providing system. On the other hand govt. of India has also recognized the usefulness of pharmacist in consultation activities and an act regarding the same is also passed. The idea is to promote such camps on large scale in urban and rural areas and to commercialize the same and its gradual digitalization in the near future. The digitalization can be loosely based on the concept of a customer care centre in the form of a patient care centre. It also emphasises on involvement of pharmacist in providing personalized care to patient with chronic diseases.

Keywords: *AAROGYA*, **Health, Disease, Consultation**

H-54

Narrow Therapeutic Index Drugs - A Critical Study on Prescription Trends in South Indian Tertiary Care Hospital

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Abstract:

Narrow therapeutic index (NTI-drugs) are drugs with small differences between their therapeutic and toxic doses, implying that small changes in dosage or interactions with other drugs could cause adverse effects. The outcome of irrational use of medicines Thus there is a need for drug evaluating and making necessary modifications in the prescribing practices to achieve a rational drug use. The objective of study to evaluate prescription pattern of narrow therapeutic index drugs and to identify drug related problems associated with narrow therapeutic index drugs. A Prospective-observational study was carried out for a periods of six months and SPSS version 16 was used to calculate the descriptive statistical parameters. A total of 100 patients among which 34 were females and 66 were males. More number of patients were from middle age group. Amikacin (45.9%)was most commonly prescribed NTI antibiotic. antiepileptic drug Phenytoin was more frequently prescribed followed by valproic Acid.combination of etiofylline and theophylline was the most frequently prescribed drugs among all NTI drugs where as warfarin was more frequently used anticoagulant during the therapy. DRPs associated with the use of NTI Drugs were in the form of drug–drug interaction where significant interaction between (Theophylline-budesonides) were more prevalence (55.8%). Adverse drug reaction was more assesses in possible category(44%). This study was carried out in order to bring awareness in the health care professionals regarding the safe and effective use of NTI drugs.

Keywords: NTI, DRP, ADR, Drug- Drug Interaction, Rational Drug Use

H-55

Fiasp: A New Faster Acting Insulin Aspart Formulation for Diabetes

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Abstract:

Fiasp® (fast-acting insulin aspart), the only approved by FDA, new-generation, ultra-fast acting mealtime insulin, improved overall blood sugar (HbA_{1c}) and post-meal sugar (postprandial glucose or PPG) control over 52 weeks, compared to conventional insulin aspart (NovoRapid®), in new study findings. It was developed to more closely match the physiological insulin meal time response of an individual with diabetes. Vitamin B3 (niacinamide) and a naturally occurring amino acid (L-Arginine) were added to increase the speed of absorption and for stability, respectively. Fiasp is licensed for the treatment of diabetes in adults and is either injected subcutaneously as part of a basal-bolus regimen or used for continuous sub- cutaneous infusion via an insulin pump. In the clinical trial onset 1 trial, Fiasp was compared to conventional insulin aspart in type 1 diabetes over a 52-week study, split in two 26-week treatment periods. Over the 52-week period, Fiasp demonstrated a statistically significant greater overall blood sugar reduction of -0.10% adults with type 1 diabetes, in comparison to conventional insulin aspart. Fiasp also demonstrated a statistically significant reduction in 1-hour post-meal sugar increment of -0.91 mmol/L. However, no significant differences were noted in 2-hour post-meal sugar increment compared with conventional insulin aspart. People living with diabetes often struggle to control blood glucose around mealtimes, which can be extremely challenging and result in debilitating diabetes-related complications. With the approval of a faster-acting insulin, one that is closer to the natural physiological insulin response of a person without diabetes, we can further support people in managing their blood glucose levels around meals, which may help prevent hyperglycaemia, for instance, a condition that can cause serious complications for people living with diabetes.

Keywords: Insulin, Diabetes, Fiasp

H-56

Drug Related Problems in Patients with Type Two Diabetes Mellitus with Hypertension in Tertiary Care Teaching Hospital

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Abstract:

A Drug Related Problem (DRP) is an undesirable patient experience during drug therapy that actually or potentially interferes with the desired patient outcomes. The current study aims to identify the drug related problems in patients with type 2 diabetes mellitus and hypertension in a tertiary care teaching hospital. A prospective observational study was conducted for a period of eight months. 150 patients who were above 18 years of age of either sex with type 2 diabetes & hypertension and receives at least one anti-diabetic drug and anti-hypertensive drug in the general medicine department were reviewed and enrolled in the study. Results were expressed as frequency and percentage. A total of 98 drug related problems were identified in 87 patients. The most common DRP's identified in this study was potential drug-drug interactions 35 (23.3%) were 8 are found to be major followed by 20 moderate and 7 minor. Other DRP's identified are, untreated indications 32 (21.3%), failure to receive drugs 8 (5.3%), adverse drug reaction 7 (4.7%), and drug use without indications 2 (1.3%) The study results reveal the DRP's observed in patients with type 2 diabetes and hypertension. Early detection of types and pattern of DRP's can improve the treatment outcome and reduce the number of DRPs in these patients.

Keywords: Drug Related Problems, Type Two Diabetes Mellitus, Hypertension

H-57

Evaluation of Medication Error in Intensive Care Unit in Teritiary Care Hospitals

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Abstract:

The main objective of the study is to detect the medication errors in the ICU. A prospective case based observational study of medical and paramedical personnel prescribing and administration of drugs was carried out in ICUs of three tertiary care hospitals in Guntur. 87.5% (n=783) of prescribing errors, 12.41% (n=111) of prescription errors were detected for

the total 894 errors registered. Patients were hospitalized for 216.6±14.0 days and were on Mean±SD of 18.3±21.3 medications per day. The most common physician associated medication error was of incomplete orders (61.7%), monitoring drug errors (50.5%), over dose errors (44.3%). Improving the role of clinical pharmacist in ICU may help to prevent medication errors and improve patient safety.

Keywords: Medication Error, Intensive Care Unit, Clinical Pharmacist

H-58

A Case Control Study on Determinants of Childhood Asthma in School Children of Chitradurga City

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Abstract:

Asthma is a chronic airway inflammatory disease in which many cells and cellular elements play a role often arising from allergies, characterized by bronchospasm that subsequently cause shortness of breath, wheezing and coughing it affects children in different ways. To study the sociodemographic characteristics of asthmatic children and to compare the predisposing factors of asthma in children. A Community based Case control study in selected schools in chitradurga for a period of 6 months. A total of 90 children, among which 30 asthma children and 60 non asthma children were participated in the study from selected school of Chitradurga city. Results are analyzed using Epi info. Odds ratio will be calculated to know the strength of association. chi square test will be calculated to the significance. *Results:* A total of 90 children aged < 14 years data were collected in primary schools of chitradurga city. The study result shows that , Female children are more exposed to asthma than male. In childhood asthma age group between 10- 14years the age group of 10 year(26.7%) and 12 year (26.7%) were more exposed to the asthma. 56.7% of children in the case and 21% in the control of asthmatic and non asthmatic children were more exposed to pet animals . 60% asthmatic and 56.7% non asthmatic children were more exposed to allergy *Conclusion*: On the basis of the above discussion , it can be concluded that the asthma is a major health problem across the world in prevalence and severity. Chitradurga city, the study area, is of no exception with regard to case control. From the total of 90 children selected for the study majority were found risk factors affected. It was due to their family history, exposure to pet animals , allergy, age group, BMI and sex.

H-59

Nanomedicine: Its Current Status in the Treatment of Cancer

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Abstract:

Nanomedicine is now in a nascent stage of development. The scientists have successfully explored it in the effective treatment of various neuro-degenerative disorders like **Parkinson's disease** and Alzheimer's disease etc. According to the World Health Organization (WHO), there will be 15 million new cases of cancer which is emerging as the second leading cause of death after heart attack. Scientists are exploring the varied modern uses of nanomedicines to overcome the common shortcomings in the treatment of cancer. Antibodies are attached to carbon nanotubes in chips to detect cancer in blood stream and this is being currently tried as a novel diagnostic approach to detect cancer. Researchers in various laboratories are developing nanosponges with bismuth to concentrate radiation in radiation therapy thus restricting the action of cytotoxic agents to affected cells only. Nano-robots are being programmed to repair diseased cancers cells. Thus nanomedicines have immense future and invivo potential in effective targeted specific cytotoxic drug delivery to control various types of cancer.

H-60

Therapeutic Drug Monitoring (TDM): A New Updated Standard in the Treatment of (MDR-TB) and (XDR-TB)

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Abstract:

Tuberculosis (TB) is the world's second largest infectious disease leading to death of patients. Cases of multidrug-resistant (MDR-TB) and extremely drug-resistant (XDR-TB) have increased. For TB patients, TDM provides objective information for the clinician to make informed dosing decisions given by clinical pharmacist. Therapeutic drug monitoring (TDM) re-

mains a standard clinical technique for using plasma drug concentrations (using HPLC and LC-MS/GC-MS) to determine dose. Some patients are slow to respond to treatment, and TDM can shorten the time to response and to treatment completion. For practical reasons, only one or two samples are collected post-dose. A 2-hours post-dose sample approximates the peak serum drug concentration (Cmax) for most TB drugs. Adding a 6-h sample allows the clinician to distinguish between delayed absorption and mal absorption in case of HIV and Diabetes patients. Several review papers and research articles regarding TB drug pharmacokinetics, pharmacodynamics, and TDM have been published. A new standard guideline typically describe interactions between two drugs, whereas the clinical situation often is considerably more complex in pharmacy practice. TDM often is the best available tool for sorting out these MDR and XDR-TB interactions, and for providing the patient safe and adequate doses. TDM can be a decisive tool, allowing clinicians to successfully treat even the most complicated TB patients with multi drug resistant and extreme drug resistant Tuberculosis.

Keyword: Therapeutic Drug Monitoring (TDM), Tuberculosis (TB), MDR-TB, XDR-TB

H-61

Knowledge, Attitudes and Practice (Kap) Study Among Different Healthcare Professionals About Malarial Disease in Nims University

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Abstract:

Malaria is one of the most important infectious disease worldwide. In Africa, this bears the greatest burden of malarial disease. As per W.H.O estimate 2016 there were 212 million case of malaria in which 20.3% people died. Thus, local knowledge and practice related to malaria is important for the implementation of culturally appropriate, sustainable, and effective intervention. The study was conducted to understand these issues, which can be important step towards developing strategies, aimed at controlling malaria. An institutional based descriptive study was conducted in NIMS University. Questionnaire included 18 questions of qualitative and quantitative aspects which were self administered, the data was collected among 102 healthcare professionals. The study shows 35.61%doctors are more aware than 33.75%Pharmacists and 31.05%nurses than other healthcare professionals. Lack of knowledge and awareness about malarial disease was common among different healthcare professionals. The study highlights the need for conducting awareness program regarding management of disease. This awareness program should be conducted not only for malaria but also for other vector-borne disease.

H-63

Case Series Study of the Clinical Profile of H1N1 Swine Flu Influenza

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Abstract:

In the current study, clinical profile of positive H1N1 patients was collected. The objective behind the study was to examine the clinical profile of the H1N1 influenza cases attending Krishna Institute of Medical Sciences (KIMS), a tertiary care hospital in Hyderabad, India and give a description on the clinical features and outcomes of H1N1 positive patients. A total number of 68 H1N1 positive patients were admitted during the years 2016 and 2017 and studied retrospectively from June 2017 to October 2017. The collected clinical data was analysed with reference to age distribution, sex distribution, clinical manifestations, comorbidities, risk factors, complications and outcomes of patient after treatment and stay in the hospital. The analysed data suggests that the rate of reported cases and hospitalization rates was highest among individuals aged 35 to 75 years. H1N1 cases were equally distributed in both the sexes. In our study 70.58% percent of patients with H1N1 Influenza A presented with Fever, Cough and SOB, the most common triad of clinical manifestations. Pneumonia and Bronchial Asthma were found to be major risk factors for complications in H1N1 infection. The overall mortality rate was 16.17% and the most common cause of death in patients was due to Acute Respiratory Distress Syndrome. Ventilator requirement was associated with poor prognosis in H1N1 patients with 45% mortality rate in intubated individuals. Therefore, individuals with comorbid conditions were found to be severely affected due to higher risk of complications. Hence individuals with risk factors need to be protected by vaccination. Thus, it can be concluded that this study can be beneficial to assess the overall effect of the disease on the outcome of the susceptible individuals.

Keywords: Influenza A Virus, H1N1 Subtype, Retrospective Study, Comorbidity

H-64

Assessment of Prevalence of Drug Interactions in Anti Hypertensive Prescriptions

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Abstract:

A drug-drug interaction occurs when two or more drugs are administered concomitantly and the pharmacological effects of one drug are altered by another one, with the result of either increasing or decreasing the effect of the object drug or producing a new and unanticipated effect.DDIs are considered to be beneficial or harmful consequences of DDIs range from minor morbidities to fatal consequences. Hypertension is common disease in which blood flows through blood vessels at higher than normal pressures. There are two types of hypertension. First is primary hypertension that is a common type that develops over the years as the person ages. The second type of hypertension is the secondary one which is as a result of another medical condition or use of certain medicines. Example: Interaction between enalaprill and spironolactone are major interactions cause hyperkalemia which may be fatal, especially if the patients are dehydrated, diabetic have kidney disease or heart failure

Keywords: Ddis, Side Effects

H-65

A Study on Adherence to Standard Prescription Pattern and WHO Prescribing Indicators at a Tertiary Care Hospital of India

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Abstract:

The aim of present study was to analyze the prescriptions generated from department of medicine of a tertiary care hospital of North India. In the study parameters in accordance to standard prescription format, adherence to World Health Organization (WHO) core prescribing indicators, types of dosage forms and category of medicines prescribed were analyzed. A total of 1124 prescriptions from pharmacy were collected and analyzed after obtaining appropriate consent. Prescriber and patient identifiers were present in almost all prescriptions. Superscription was mentioned in 87.77% prescriptions. Dose and Dosage forms were mentioned in 79.76 and 81.10% respectively of total prescriptions. Average number of drugs prescribed per encounter was 4.60 which is more than three times of WHO standards. Only 10.91% drugs were prescribed with generic name which is drastically low while 47.68 drugs were prescribed from national essential medicine list of India. Instructions regarding drug use were present in 83.93% of total prescriptions. Percentage of Antibiotics was found to be 18.63 while that of injections was 11.35% which was less than WHO standard. Among prescribed drugs antacids and proton pump inhibitors were the most prescribed (62.82%) followed by vitamins and calcium supplements (61.93%) and cardiovascular drugs (28.39%). Tablets were highest prescribed dosage forms. Quality of prescriptions in terms of pattern was quite satisfactory. Adherence of WHO prescribing indicators was only with 2 out of 5 parameters. Poly pharmacy was observed with the prescriptions while rationality in terms of injections and antibiotics prescription was according to international standards.

Keywords: Prescription, WHO, Prescribing Indicators

H-66

A Pilot Study on Diabetic Risk Screening in Population of Two States of India Using Three Different Questionnaires

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Abstract:

Significance of early detection of risk for development of diabetes has been cited in many studies. Administering questionnaire in one of the popular risk assessment method for diabetes. This study was conducted with aim to compare the three questionnaire based diabetes risk assessment procedures namely Indian diabetes risk scoring (IDRS, Madras Diabetes Research Foundation-ICMR), Diabetes Risk Score (DRS, Diabetes UK) and Type 2 Diabetes Risk Assessment Form (DARF, Finnish Diabetes Foundation) in population of two states of India; Haryana and Punjab. Attempts were also made to correlate the risk scores obtained with random blood sugar (RBS) level. 250 participants aged 18 to 70 years of either sex with predetermined exclusion criteria were administered with three well defined

questionnaires IDRS, DRS and DARF. IDRS, indicated 38% of total participants fall in low risk category. 16.77% population from medium and high risk category was having RBS (taken at least 2-3 hrs after breakfast) greater than 160mg/dl. In DRS 24.8 % participants were in low risk group while RBS of 15.42% population was above 160mg/dl in increased to high risk category. Results from DARF questionnaire indicated that 69.6% participants were in low risk group and 18.42% were having high RBS level (≥160mg/dl) from slightly elevated to high risk group. From the studies it can be concluded that population specific questionnaires are to be prepared and should be supported with at least one laboratory parameter.

H-67

Comparison of Quality of Life in Type 2 Diabetic Patients With and Without Proliferative Retinopathy or Macular Edema

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Abstract:

Diabetic retinopathy is the most common diabetic eye disease and a leading cause of blindness in adults. In India diabetes is an epidemic, so the prevalence of diabetic retinopathy is also increasing. The main objective of the study is to compare both HRQOL and vision related QOL of type 2 diabetic patients with and without proliferative diabetic retinopathy or diabetic macular edema. A prospective, observational study was conducted at Govt. Medical College, Kozhikode, over a period of 7 months. Patients age between 33 – 76 years, suffering from type 2 diabetes mellitus either with or without proliferative diabetic retinopathy or diabetic macular edema were interviewed using EQ 5D 5L questionnaire and national eye institute visual function questionnaire to assess their quality of life. Out of 189 type 2 diabetic patients included in the study, 94 were with Proliferative diabetic retinopathy or diabetic macular edema and remaining 95 were without PDR or DME. Presence of PDR or DME does not affect health related quality of life ($p>0.05$). Severity of retinopathy significantly reduces health related QOL ($p=0.004$). Presence of PDR or DME reduces vision related QOL significantly ($p=0.000$). Vision related QOL is also affected by severity of retinopathy ($p=0.000$). There was statistically significant correlation between duration of diabetes and severity of retinopathy ($p=0.018$). Both HRQOL and vision related QOL were positively correlated ($p=0.001$).

Keywords: Proliferative Diabetic Retinopathy, Diabetic Macular Edema, Quality of Life, Vsisual Function

H-68

Risk Factors for Potential Drug-Drug Interactions in Intensive Care Unit Patients

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Abstract:

The purpose of this study is to determine risk factors for each severity-based category of potential drug-drug interactions (DDIs) encountered at intensive care unit (ICU) patients. This was a retrospective cohort analysis of patients treated at the ICU of the Clinical Center a public tertiary care hospital. Three interaction checkers were used to reveal drug-drug interactions: Medscape, Epocrates and Micromedex. The study included 201 patients, 66.19 ± 16.11 years of age. Average number of DDIs per patient ranged from 10.49 ± 8.80 (Micromedex) to 29.43 ± 21.51 (Medscape). Antiarrhythmic or Anticonvulsant prescription, Charlson Comorbidity Index, male sex, length of hospitalization, number of drugs or therapeutic groups prescribed and surgery increased the risk of DDIs in ICU patients, while presence of delirium or dementia and transfer from emergency department to ICU protected against. The rate of the DDIs in ICU patients at a tertiary care hospital is high, and adversely influenced by number of drugs or drug groups prescribed per patient, antiarrhythmic or anticonvulsant drug prescription, comorbidities, length of hospitalization and surgery. On the other hand, presence of cognitive deficit and transfer from emergency department to ICU protect ICU patients from the DDIs.

Keywords: Drug-Drug Interactions, Intensive Care Unit, Risk Factors

H-69

A Study on Prevention and Reduction of Radio Contrast Induced Nephropathy in patients undergoing Coronary Angiography and Percutaneous Transluminal Coronary Angioplasty

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Abstarct:

To evaluate the risk factors and suggest recommendations for prevention and reduction of radiocontrast induced nephropathy in patients undergoing CAG and PTCA.The objective of the study was to evaluate the risk factors, apply strategies to prevent CIN,ensure all risk reduction strategies are being followed, evaluation of N acetyl Cysteine efficacy along with iv hydration and statin pre-treatment in the experimental group and estimation of CIN incidence in all patients.The sample size was about 200 subjects categorizing into two groups[control(A) and test(B)]. The number of patients with serum creatinine value >1.8 mg/dl after PTCA in group A are 15 that is very high than group B patients which are only 5 in high risk patients. The number of patients with serum creatinine value >1.8 mg/dl after PTCA in group A are 6 that is very high than group B patients which are only 1 in very high risk patients. The incidence of Contrast Induced Nephropathy was found to be low in group B patients compared to group A. The application of NAC along with hydration and other risk reducing strategies in our study was found to be effective/showed positive results and favored in Preventing and reducing the risk and incidence of Contrast Induced Nephropathy.

Keywords: CAG, PTCA, CIN, NAC

H-70

Prospective Observational Study on the Outcome and Adverse Drug Reaction of Botulinum Toxin Injection in Writer's Cramp Patients in a Tertiary Care Hospital

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Abstract:

Writer's cramp is a form of task specific focal dystonia. It is common among Indian population but considered as a rare condition. The main treatment strategy for the particular condition is Botulinum toxin. Thus, results from this study will help to identify the outcome and the adverse drug reaction of the Botulinum toxin injection to the patient population affected with writer's cramp condition. Study was Prospective observational & carried out in a Tertiary care setting, Department of Neurology, Govt. Medical College Hospital, Thiruvananthapuram with a sample population 25. Most of the affected patients were taking the Botulinum toxin injection and after the review the outcome was measured and it was found to be Botulinum toxin injection is preferably effective to the patients suffering from writer's cramp. The Adverse Drug Reaction were assessed using Naranjo Adverse Drug Reaction Scale and found that majority of the patients reported with probable ADR (64%). The probability value determined as $p < 0.001$ which is functionally normal. Financial problems and lack of knowledge about the condition and its treatment were the next two important barriers of study. From this the effectiveness of Botulinum toxin injection towards the Writer's Cramp patients seems o be significantly improved.

Keywords: ADR, BTX, Injection, Pain, Writer's Cramp

H-71

The Prevalence and Prescribing Pattern of Dyslipidemia Among Diabetic Patients in General Medicine Department of a Tertiary Care Teaching Hospital

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Abstract:

Diabetes is one of the leading health problem faced by the world today, affecting millions of people. Prevalence rate of dyslipidemia mainly hypertriglyceridemia in diabetic population is high. One or another lipid level is found to be abnormal in most of the diabetic patients. The objective was to study the prevalence and prescribing pattern of hypertriglyceridemia among diabetic subjects. In this prospective observational study, patient details were collected from interview with the patient or caregiver, patients case sheets and laboratory findings. From the total population of 253 patients with diabetes mellitus 63.20 % were diagnosed as diabetic hypertriglyceridemia, 65.20 % were having elevated low density lipoprotein cholesterol, 61.30 % were having elevated total cholesterol, 51.80 % were having reduced high density lipoprotein cholesterol and 26.10% were having elevated very low density lipoprotein cholesterol. Statins were the most prescribed hypolipidemic agent. This study highlighted the very high prevalence of hypertriglyceridemia with mean triglyceride level 179.13 ± 99.29 mg/dl. Increase in new-onset diabetes and other cases have been observed in individuals treated intensively with statins. Therefore the whole lipid profile must be done and evaluated at regular intervals, strict control of diabetes in prevention and treatment of dyslipidemia associ-

ated with diabetes and consider alternative therapy with other hypolipidemic agents for treating individuals with severe hypertriglyceridemia.

Keywords: Dyslipidemia, Hypertriglyceridemia, Prescription Pattern, Prevalence, Lipid Profile

H-72

Pharmacoeconomic Evaluation of Antidiabetic Therapy in a Teritary Care Hospital

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Abstract:

Diabetes mellitus describes a metabolic disorder of multiple etiology characterized by chronic hyperglycemia with disturbances of carbohydrate, fat and protein metabolism resulting from defects in insulin secretion, insulin action, or both. The effects of diabetes mellitus include long-term damage, dysfunction and failure of various organs. To study the different prescription pattern in diabetic patients. A prospective observational study which were carried out for a period of six months at General Medicine Department of Basaveshwara Medical College Hospital and Research Centre (BMCH), Chitradurga. *Results:* A total of 90 patients aged ≥61 years data were collected in medicine department in which 46 were males and 44 were females. Hypertension is more prevalent in 46-60 age group people. We conclude this study as a successful treatment will come true when a pharmacist maintain a successful relationship with the physician which results in safe and effective therapy. Still some studies yet to be done to educate the population and bring awareness in the health care professionals for a treatment.

H-73

A Study on Antiplatelets Drug Utilization in Ischemic Heart Disease and Atrial Fibrillation Patients in a Tertiary Care Hospital

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Abstract:

A prospective observational study was carried out on Antiplatelets Drug Utilization in Ischemic Heart Disease and Atrial Fibrillation Patients in a Tertiary Care Hospital. The goal of the study was to assess the Antiplatelet drug usage in IHD and AF patients in a tertiary care hospital. The study includes assessment of demographic, prescribing pattern (based on brand & generic names for prescribing, single & dual antiplatelet usage and with hypolipidemic agents). The study result shows that out of 105 prescription 71 patients were male (67.61%) and 34 patients were females (32.38%), according to age category > 60year old people (57.14%) are more with IHD & AF than other age groups such as 20-45 years 14 (13.3%) and 46-60 years 31(29.5%). Prescribing pattern assessment revealed that 101 (96.19%) prescriptions were prescribed by brand names while 4 (3.8%) prescription by generic name, 76 (72.38%) patients received dual antiplatelet drugs followed by 29 (27.62%) patients single antiplatelet drug and 84 (80%) patients received hypolipidemics along with antiplatelets drugs as treatment regimen. Study concludes that more usage of aspirin and clopidogrel combination.

Keywords: Antiplatelets, Ischemic Heart Disease (IHD), Atrial Fibrillation (AF), Prescription

H-74

Dengue Fever and Respective Treatment Regimen in the Latur District Hospital

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Abstract:

Dengue is a vector-borne disease transmitted by the bite of an infected mosquito. There are 4 serotypes of the virus that causes dengue. These are known as DEN-1, DEN-2, DEN-3, and DEN-4. Symptoms are High Fever (40°C/ 104°F), Severe Headache, Pain behind the Eyes, Abdominal Pain, Muscle & Joint Pain, Vomiting, Bleeding, Breathing difficulty, Skin Rash. U.S. Food and Drug Administration (FDA) approved a blood test called the DENV Detect IgM Capture ELISA to diagnose people with dengue fever. The present study carried out to assess Dengue Fever and respective treatment regimen in the Latur District hospital. Dengue patient's data are collected from Kawalas Hospital, Alpha Super Speciality Hospital and Govt. District Hospital, Latur. Fever with chills, body ache and decrease platelet count are common symptoms in all cases. In all dengue infec-

tion is successfully managed with Cephalosporin's like Ceftriaxone, Cefotaxime and fluroquinolone like Ofloxacin, Levofloxacin.

Keywords: Dengue, Fever With Chills, Cephalosporin's, Fluroquinolone

H-75

Assessment of Discharge Prescriptions for Patients With Acute Coronary Syndromes in a Tertiary Care Hospital

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Abstract:

American College of Cardiology and American Heart Association (ACC/AHA) provides some standard recommendations for the treatment of Acute Coronary Syndrome (ACS) to obtain optimal therapeutic efficacy.A prospective observational study was conducted to assess the adherence to ACC/AHA guidelines among post discharge ACS patients for a period of six month. The study showed that the discharge cardiac medications are prescribed at suboptimal rates. Proper counseling and implementation of ACS discharge protocols are required to improve the quality of patient care and to achieve effective therapeutic outcome.

Keywords: Acute Coronary Syndrome (ACS), Discharge Prescriptions (DP)

H-76

Effect of Academic Detailing by Clinical Pharmacy to Improve Venous Thromboembolism Prophylaxis: A Prospective Interventional Study

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Abstract:

Considerable studies have raised the concern of rising incidence of venous thromboembolism (VTE), categorization of VTE risk factors using a standard tool and compliance assessment towards ACCP guideline. A pilot study at our institution revealed low utilization of VTE prophylaxis in critically ill patients and surgery ward. Aim of the study was to assess the effect of academic detailing on improvement of VTE prophylaxis and to check compliance towards the truncated ACCP guideline. Caprini VTE Risk Assessment Model was used by clinical pharmacist to identify risk factors and obtain risk score. 255 out of 592 patients were included in the study from which 177 (69.4%) patients were in the intensive care unit (ICU) and 78 (30.5%) in surgical ward. The majority of patients had 3.03 VTE risk factors indicating that all patients had 2 or more risk factors. Overall prescribing was still low in relation to pharmacological thromboprophylaxis used (144 of 255; 56.4%) but post academic detailing 21% significant improvement ($p<0.0001$) in utilization was observed. one fourth of them were not adhered for duration of therapy. Quantity of VTE prophylaxis improved significantly in ICU as compared to surgery ward patients (78% vs. 7.6%) though, the risk factor was significantly ($p<0.005$) higher in post surgical patients. Study confirms that overall prescribing of thromboprophylaxis was still low. Adherence towards duration of thromboprophylaxis was has to improve.

Keywords: Venous Thromboembolism, Venous Thromboembolism Prophylaxis, Critically Ill, Academic Detailing, Pharmacy Intervention

H-77

Implementation of Pharmacogenomic Screening in Individualizing Anticancer Therapy

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Abstract:

Interindividual variation is observed in anticancer therapy associated with response and toxicity at large scale. Interpatient variability in response to medications is related with spectrum of outcomes, ranging from failure to demonstrate an expected therapeutic effect to an adverse reaction which results in significant patient morbidity and mortality, as well as increasing healthcare costs. This issue is of paramount importance, as 5-FU remains the third most commonly used chemotherapy worldwide. The overall TPMT heterozygous carrier allele frequency was found to be 3.1%. Use of genetic information for guided drug dosing is significant for the chemotherapeutic agents, which affects tumor as well as non-tumor cells and thus have a narrow therapeutic index, with the potential

for life-threatening toxicity such as 5-flurouracil, irinotecan and 6-mercaptopurine have established evidence of involvement of DPD gene, UGT1A1 gene and TPMT (7TAA) gene, respectively. Recent studies have shown that 5-fluorouracil leads to approximately 6%-15% of early grade 3/4 toxicities, because there is growing number of patients who are likely to receive this fluoropyrimidine drug, this clinical incidence of DPD is a rising concern in oncology. Mutations in these genes leads to the deficiency of respective metabolic enzymes causing elevated plasma levels of drug rendering the patient susceptible to lethal toxicities. In such scenario, pharmacogenomics and gene sequencing can be used successfully to understand the individuals' response towards the drug, reduce the events of toxicity and help in providing a more personalized and specific therapy according to the patients individual needs. This review focuses on the efficient technical paths to state the role of pharmacogenomics concept.

Keywords: Pharmacogenomics, DPD Deficiency, UGT1A1, TPMT

H-78

A Study to Identify, Assess & Analyze the Incidence of Poisoning Cases in a Tertiary Care Teaching Hospital

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Abstract:

Poison is any substance that causes harmful effect when administered either accidently or intentionally. In India, as agriculture is the main occupation, pesticides are used to a greater extent and the poisoning with such products is far more common. The objective was to identify and assess the incidence of accidental or intentional poisoning and also to assess the relation between socio economic factors and poisoning. This prospective cohort study was conducted in the departments of medicine, pediatric, emergency and ICU of a tertiary care teaching hospital for a period of 6 months. A total number of 150 cases were collected and categorized into different classes based on type of poisoning agents. In that organophosphate accounts more 31.3% (n=47), followed by snake bite 20% (n= 30). Male predominance were seen 58.7% (n=88), while comparing to female 41.3% (n= 62). Based on economic study, low socio economic peoples were more prone to poisoning i.e., 54.7% (n= 82). Rural people were far front in poisoning i.e. 54.7% (n= 82) than urban and sub- urban. The literacy status showed that 78.7% (n=118) was literate. Poisoning incidence were more in married subjects i.e., 50.7% (n=76). While considering occupation, farmers were most 30.7% (n= 46). The study highlighted the lacunae of poisoning information services in hospitals. Clinical pharmacist's involvement can improve the identification of poison and toxicity rating.

H-79

A Case Report on Ludwig's Angina

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Abstract:

Ludwig's angina is a rare skin infection that occurs on the floor of the mouth, underneath the tongue. This bacterial infection often occurs after a tooth abscess, which is a collection of pus in the center of a tooth. It is a potentially life threatening severe form of diffuse cellulitis that present an acute onset and spread rapidly bilaterally affecting submandibular,sublingual,submental spaces resulting in state of emergency. It occurs in adults with concomitant odontogenic infections,mandibular fractures,pericoronitis,oral laceration/piercing and submandibular saladenitis. It includes clinicalmanifestations like bilateral lower facial edema,trismus,drooling,dysphagia,odynophagia,tongue displacement creating a compromised airways. It can be diagnosed by physical examination, fluid culture test from affected area and by ionising tests like MRI/CT scan. In early stage of disease patient may be managed with observations and IV antibiotics and advanced infections, however requires incision and drainage of abscess and maxillofacial surgery. Practicing good oral hygiene,having regular dental checkups, seeking prompt treatment for tooth and mouth infections and You should brush your teeth twice every day and use mouthwash with antiseptic liquid once per day are *preventive methods for causes* of this disease.

Keywords: Odontogenic, Odynophagia, Saladenitis

H-80

Systematic Study on HIV Infected Patients with Opportunistic Infections In Tertiary Care Hospital Khammam, Telangana

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Abstract:

HIV-related opportunistic infections (OIs) continued to cause morbidity and mortality in HIV-infected individuals. The objective for this study is to elucidate the OIs in HIV-infected patients in the District Govt Head Quarters Hospital, Khammam. The evaluation of the OIs was conducted by using the clinical data of 300 HIV-infected patients admitted in the District Govt Head Quarters Hospital, Khammam from January, 2017, to August 2017. We found that tuberculosis was most common opportunistic infection in both male and female 55.3%, followed by Herpes (19.3%), oral Candidiasis (17%), Gonorrhea infection (3.6%) and syphilis(4.6%). The study reveals that tuberculosis infection highly found out in stage 3 & 4 as an opportunistic infection which is observed mostly in males compared with females. The prevalence of OIs, and co-infections were discussed in this study. It would help increase the awareness for physicians to make a diagnosis and empirical treatment sooner and plan good management strategies, especially in resource limited regions.

Keywords: Opportunistic Infections, Candidiasis, Herpes, Tuberculosis

H-81

Study on Assessment of Self Care Practices in Diabetic Patients in Rural Area of Salem District Tamilnadu

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Abstract:

Diabetes care requires a multipronged approach, wherein the patient has an important role to play. This study was undertaken to explore self-care practices of diabetic patient residing in Salem district. A cross-sectional study, involving 100 diabetic patients was conducted in 2015-2016. The mean age of the patients was 58.23. The mean duration of their diagnosis was 84.13 months. 52% of the patients had a family history of Diabetes Mellitus and 24% of the patients were suffering from diseases other than Diabetes Mellitus. Out of the diabetes patients who participated in the study , low level of self-care recorded in domain of medication adherence (83.34%males,93.10% females),consulted the physician (50% males, 72.41% females),blood glucose level(38.09% males, 58.62% females),diabetic diet (73.80% males,68.96% females),physical activity (38.09% males,51.72% females), foot care (69.04% males,60.34% females),diabetic retinopathy(33.34% males,32.75% females). Females had a higher percentage (93.10%) of medical compliance than that of males (83.34%). It was also found that females had better diabetic self-care practicing behavior than males.

H-82

Prescribing Pattern and Potential Drug-Drug Interactions of Hypertension in a Tertiary Care Hospital- A Retrospective Study

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Abstract:

The objective of this study was to evaluate prescribing pattern and potential drug-drug interaction in hospitalized patients with hypertension. A retrorospective, observational study was carried out at inpatient department of a tertiary care hospital in Salem district, Tamilnadu, India from November 2015 to April 2016. The demographic details, disease and treatment data of 150 patients with hypertension were collected in a specially designed proforma. In hypertension amlodipine was the most frequently prescribed drug. Monotherapy was used for 50% patients and the remaining 50% patients were prescribed with combination therapy. 62 interactions were noted in 150 prescriptions. The potential drug-drug interactions are frequent in hypertension and hence deserve clinical attention. Implementation of an alert guidelines and a computer based screening would help to recognize and prevent potentially dangerous drug-drug interactions.

H-83

Evaluation of Drug-Drug Interactions in Patients of General Medicine, ICU & Emergency Departments at a Tertiary Care Hospital

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Abstract:

Drug-drug interaction (DDI) may be defined as the pharmacological or clinical response to the administration of a drug combination that is different from the anticipated known effects of the two agents when given alone and that can result in reduced effectiveness or increased toxicity. Mortality and morbidity are increased in patients experiencing drug-drug interactions. There is a paucity of literature describing clinically significant drug-drug interactions occurring in the General medicine, ICU & Emergency. Polypharmacy is one of the leading cause of DDI in patients. Thus DDI associated with these drugs may lead to non-compliance and at times discontinuation of therapy. Drug interaction occurs when a drug affects the action of another. Thus the present study was aimed to evaluate the drug-drug interactions and to identify the common drug groups involved in drug – drug interactions in In-patients treated in General medicine, ICU & Emergency departments.

Keywords: Drug-Drug Interactions, Polypharmacy

H-84

Clinical Status and Management of Ischemic Heart Disease in Tertiary Care Hospital in North India

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Abstract:

The aim of this study was to evaluate clinical status of Ischemic Heart Disease and to assess the prescribing patterns in patients with Ischemic Heart Disease. A prospective observational study was conducted in North India with 83 samples of subjects included into the study. The Clinical status of patients of Ischemic Heart Disease is evaluated as well as Prescribing Patterns in treating IHD patients were assessed. In the study it has been observed that among the 83 patients were 52 (63%) male and 31 (37%) were female. Mostly the age categories of Patient suffering from IHD among 83 were 22 from 41-60 years (27%) categories and 61 from 61-80 years categories (73%). Among 83 patients the cases of STEMI was found to be more (29%) followed by Stable Angina (27%), NSTEMI (27%), Unstable Angina (17%). This work has presented strong evidence that IHD is highly prevalent in the South Asian population. Among Clinical Profile 1st most prevalent symptom was retrosternal pain in chest without radiation, 2nd Perspiration and 3rd Dyspnoea. We found management of IHD was good in hospital and as per AHA guidelines but it was sad to know that no patient counseling was given to patient for both hospitalized and treated patient for their medications. Therefore there is huge need of Clinical Pharmacist to prevent these Medication Related Problems ,due to lack of clinical pharmacist these problems occurred.

Keywords: IHD (Ischaemic Heart Disease), STEMI (ST Elevated Myocardial Infarction) ,NSTEMI (Non ST Elevated Myocardial Infarction), AHA (American Heart Association), Angina

H-85

Interaction of Ebola Virus towards Major Histocompatibility complex (MHC): An In silico study

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Abstract:

Ebola virus (EBOV), a member of the Filoviridae family of negative-sense RNA viruses, causes severe hemorrhagic fever leading up to 90% lethality. The lethal cases of EBOV infections show signs of impaired adaptive immune responses. Major histocompatibility complex (MHC class I) molecules are found on nearly every nucleated cell of the body which displays peptide fragments of viral proteins to the cytotoxic T cells. In the literature, various reports have shown that EBOV alters the both innate and adaptive immune response signaling pathways but its mechanism is still unclear. Thus, in this present investigation, the interaction of Ebola viral proteins (VP24 and VP 35) with MHC-1 has been explored.The x-ray crystal structure of Ebola viral VP 35 and VP 24 respectively, were obtained from the protein data bank Research Collaboratory for Structural Bioinformatics (RCSB).The results obtained from Cluspro 2.0, the docked protein models with lowest energy with higher number of clustering were selected for studying the protein-protein interactions with help of Schrodinger LLC. In conclusion, these results demonstrated that Ebola virus proteins (VP35 and VP24) have a good binding affinity towards human MHC-1 which plays a key role in innate and adaptive immunity.

Keywords: Ebola Virus, Major Histocompatibility Complex, Immunity, Protein-Protein Interaction

H-87

Incidence of Microalbuminuria Among Type Ii Dm Patients and the Effect of Arb's in its Management

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Abstract:

Now-a-days diabetes is termed as a global problem and it is estimated that the global burden of type 2 diabetes mellitus for 2010 will be 285 million people (2010) which will be increase to 438 million by 2030. Similarly, in India prevalence is estimated to be 58%, from 51 million people in 2010 to 87 million by 2030. In Type II diabetes mellitus patients the development of Microalbuminuria will lead to increased risk for renal and cardiovascular disorders. The incidence of end-stage renal disease in type 2 diabetes mellitus patients has risen drastically in many regions of the world. There is evidence that normalization and reduction of proteinuria will be the key main goal for treatment and also for reducing the progression, incidence of renal disorders and possibly the cardio-vascular disorders. In our current research we estimate the incidence of the microalbuminuria in type II diabetes mellitus and the effect of the angiotensin receptor blockers (ARB's) in its management in 100 patients for 6 months period. From our study we conclude that the incidence of Microalbuminuria in type 2 Diabetes Mellitus patients was high in females when compared to males. Microalbuminuria prevalence is more at age group 51-60. When the duration of diabetes increases the risk of developing Microalbuminuria also increases. The patients with type II DM who are screened positive for Microalbuminuria has to be treated with ARB's (LOSARTAN), by this we observed better reduction in Microalbuminuria with a minimum of 6 months treatment.

Keywords: Type II DM, Microalbuminuria, Incidence, ARB,s

H-88

Assessment of Drug Prescribing Pattern at a Tertiary Care Hospital in Accordance to the World Health Organization's Drug Prescribing Guidelines

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Abstract:

Present study was conducted with objective to analyze the prescriptions generated from nine departments of a tertiary care hospital of North India. The study parameters considered were in accordance to drug prescribing guidelines given by World Health Organization (WHO). A total of 250 prescriptions from pharmacy were collected and analyzed after obtaining appropriate consent. Prescriber and patient identifiers were present in almost all prescriptions. Superscription was mentioned in 83.2% prescriptions. Dose and Dosage forms were mentioned in 72.8% and 99.2% respectively of total prescriptions. Average number of drugs prescribed per encounter was 3.58 which is more than two times of WHO standards. Only 29.6% drugs were prescribed with generic name which is drastically low while 56% drugs were prescribed from national essential medicine list of India. Instructions regarding drug use were present in 86.4% of total prescriptions. Percentage of Antibiotics was found to be 34% which more than WHO standard while injections prescribed were only in 12% of prescriptions that was in accordance to guidelines. Among prescribed drugs antihistaminics were the most prescribed (14.7%) drug category followed by vitamins and calcium supplements (10.8%) and antibiotics (9.5%). Tablets were highest prescribed dosage forms. Quality of prescriptions in terms of pattern was not quite satisfactory. Adherence of WHO prescribing indicators was 1 out of 5 parameters. Poly pharmacy was observed with the prescriptions while rationality in terms of antibiotics prescription was not according to international standards.

Keywords: Prescription, WHO, Prescribing Indicators

H-89

Drug Utilization Evaluation of Anti-Diabetic Medication through Prescription Monitoring

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Abstract:

Diabetes mellitus (DM) is a group of metabolic disorders of fat, carbohydrate, and protein metabolism that results from defects in insulin secretion, insulin action (sensitivity), or both. Diagnosis of diabetes is made by four criteria: fasting plasma glucose ≥126 mg/dL (≥7 m mol/L), a 2-hour value from a 75-g oral glucose tolerance test ≥200 mg/dL (≥11.1 m mol/L), a casual plasma glucose level of ≥200 mg/dL (≥11.1 m mol/L) with symptoms of diabetes, or a hemoglobin A_{1c} [HbA_{1c}] ≥6.5% (≥0.065; ≥48 m mol/mol Hb). This study was carried out on outpatient medicine department of various hospitals of Dehradun, in this study 100 patients diagnosed with diabetes were enrolled and it is seen that male patients were 36 accounting for 36 % of study population, whereas female patient were 64 accounting for 64 % of total study population. Out of 100 patients 84 patients were diagnosed with type 2 diabetes mellitus and 16 were diagnosed with type 1 diabetes mellitus. In type 2 DM mostly Glimepiride were prescribed in 42 (42%) patients , followed by Metformin about 22 (22%) patients, then Gliclazide about 20 (20%), and in type 1 DM Human Insulin were prescribed in 16 (16%) patients. While studying about the combination of drugs used in Diabetes Mallitus, Glimepiride & Metformin combination were prescribed mostly in 30 (30%) of the total patients, followed by Gliclazide & Metformin combination about 20 (20%) of the total patients, and least prescribed combination was Glipizide & Metformin within 2 (2%) of the total patients.

H-90

Pregnancy Outcome in Oligohydramnios

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Abstract:

Oligohydramnios is a condition in pregnancy characterized by a deficiency of amniotic fluid. The objective behind the research was: (i) To assess whether oligohydramnios is associated with adverse pregnancy outcome and (ii) To compare the pregnancy outcome in this study group with a control group and determine the difference in outcome between the two groups. This prospective study was conducted over a period of 1 year. The study was conducted on 80 pregnant women with gestational age > 34 weeks and they were divided into a study group of 40 patients having oligohydramnios and a control group of 40 patients without oligohydramnios. Amniotic fluid assessment was done by ultrasound and an AFI of 5cm or less was taken as the criteria for diagnosis of oligohydramnios. The outcome of pregnancy in study group was compared with that of control group. The indications of ultrasound examination were similar for cases and controls. They included suspected IUGR (Intra uterine growth retardation), maternal hypertension and decreased fetal movements. There was a significantly higher rate of induced labor, cesarean section, IUGR babies, still births, low Apgar score and meconium-stained amniotic fluid in the study (oligohydramnios) group as compared to control group. The results of present study indicate that the risk of adverse pregnancy outcome is increased in patients with oligohydramnios. So, its management warrants increased antepartum surveillance for early detection of pregnancy complications and fetal scanning to diagnose malformations or growth restriction.

Keywords: Oligohydramnios, Amniotic Fluid Index, Induced Labor, Intrauterine Growth Retardation, Still Birth

H-91

A Study on Drug Utilization Pattern of Cephalosporins in General Medicine and Surgical Inpatient Department

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Abstract:

Drug utilization studies aim to evaluate factors related to the prescribing, dispensing, administering and taking of medication, and its associated events. It can be used to estimate the numbers of patients exposed to specified drugs within a given time period. Antibiotics are among the most common medications prescribed both in the hospital setting and the community setting. Cephalosporins are a commonly used group of antibiotics in hospitals and health care facilities around the world. These are used widely to treat various bacterial infections including bronchitis, pneumonia, bone infections, abdominal infection, skin infections and urinary tract infections**.** *OBJECTIVES:* To assess percentage of drugs prescribed by generic & brand name of cephalosporins. *Materials and Methods:* It is a prospective observational study conducted in Basaveshwara Medical College, Hospital and Research Centre for a period of six months. Patients admitted in General medicine and Surgical

department above the age of 18 yrs are included. The data was collected from medical records of the patients and documented in suitable designed form. *Results:* A total of 110 patients were enrolled during the study period, majority are males(54.5%). Majorly 3rd generation Cephalosporins (86.4%) are prescribed among the patients and others classes of drugs are also administered. Majority of patients were 32 belonged to age group of above 60 years (29.1%). used generic (15) 13.6% and brand drugs was (95) 86.4%. *Conclusion* : This study revealed the wider usage of Cephalosporins especially third-generation Cephalosporins. A careful selection for patients requiring antibiotics on admission to the ICU will dramatically reduce drug expenses and improve antibiotic performance.

H-92

Stress, Anxiety and Depression Among Pharmacy Students: A Cross-Sectional Study in ISF College of Pharmacy

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Abstract:

In literature, various studies have reported anxiety and depression among medical students across the world but in Pharmacy students very few studies are available. Thus, this study was designed to assess the traits of depression, anxiety, and stress among pharmacy students of ISF college of Pharmacy, Moga in relation to potential underlying reasons. A questionnaire based survey was conducted in ISF college of Pharmacy, Moga, Punjab, covering all kind of students. The questionnaire was given to 500 pharmacy students who had spent more than 6 months in college and had no self reported physical illness. Prevalence of stress, anxiety and depression was assessed using a structured validated Depression, Anxiety, and Stress Scale-21 (DASS-21) questionnaire. Descriptive statistics were used for analysis of data. Out of 500 students, 480completed the questionnaire with a response rate of 96%. The mean age of students was 20.66 +/- 1.8 years. Prevalence of anxiety and depression among students of final year was> fourth year > third year > second year >first year respectively. Female students were found to be more depressed than male students. The students had high "baseline" traits of depression, anxiety, and stress, and these were higher if an examination was near. Smoking and female sex predicted higher levels of "baseline" depression, anxiety, or stress. Students suggested that study burden and a busy schedule were the major reasons for their high DASS-21 scores.

Keywords: DASS, Examination, Pharmacy Education, Depression, Anxiety, Stress

H-93

A Study of Seizures in Pediatric Patients With Special Reference to Antiepileptic Drug Utilization

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Abstract:

The main objectives of this study were to assess the prevalence of different types of seizure in pediatric patients, determine the prescribing pattern of antiepileptics in pediatrics patient, compare brand versus generic prescriptions, and also to evaluate drug interaction of AEDs(Antiepileptic Drugs) with other drugs. A total of 112 patients age less than 18 years were enrolled for the study and Patients with generalized tonic clonic seizures. The study shows that most of the patients 40.2% were from the age group of 1-12 years; followed by 30.1% of patients in the age group of 0-1 month and 26.8% from 1 month -1 years and 1.8% from 12-18 years respectively. 84.82% prescriptions were prescribed by brand names while 15.18% prescription by generic name. Most commonly prescribed class of AEDs were barbiturates which accounts for 39.6%, followed by hydantoins 34.02%. Out of 112 prescriptions, major interaction were 16.07%, followed by moderate 30.35% and minor 2.67%. Pharmacist's intervention is necessary for the management of pediatrics seizures and to educate the parents about the importance of initial management and lifestyle changes.

Keywords: Antiepileptics, Drug Interaction, Pediatric

H-94

Incidence of Atrial Fibrillation After Cardiac Surgery

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Abstract:

The study aims to determine the incidence of POAF and to identify the risk factors associated with post-operative atrial fibrillation. A prospective observational study was carried out

for a period of six months between October 2016 and March 2017 among patients who underwent cardiac surgeries that includes CABG, mitral valve replacement (MVR) and aortic valve replacement (AVR).Inpatients of either gender, aged 18 years and above scheduled for CABG, valve surgery or mixed were included whereas, patients with severe congestive heart failure and those not willing to participate in the study were excluded. Patients who underwent cardiac surgery were assessed for the incidence and risk factors of POAF. Out of 83 patients, 15 patients developed POAF and the incidence was 18.07%. The incidence was greater in patients who underwent MVR (80%) than after CABG (20%). Amongst the patients who experienced POAF, females (66.66%) were found to have an increased incidence than males (33.33%). Female (66.66%) gender is significantly associated with the development of POAF than males (33.33%) with p value 0.0001. The patients who developed POAF had RHD (53.33%), HTN (40%), diabetes (20%) and COPD (6.66%) as comorbidities. Rheumatic heart disease is significantly associated with the development of POAF with p value 0.000(table 1). Out of 83 patients, 9.63% of patients had social habits. Out of 15 POAF patients, 6.66% were smoker, 6.66% were alcoholic and 6.66% patients had substance abuse. Alcohol is significantly associated with the development of POAF with p value 0.032(table1). Patients who developed AF post operatively had a longer length of hospital stay than those who did not develop AF (median 9days vs. 7days) and illustrated in figure 1. In this study, the incidence of atrial fibrillation in patients who underwent cardiac surgery was 18.07%.The predisposing factors for the development of POAF include rheumatic heart disease and alcohol. POAF patients had a longer length of hospital stay when compared to patients without POAF. Collaboration of physician with pharmacist will definitely help to improve the quality of life and reduce any further complications or adverse events in POAF patients.

H-95

Assessment of Adverse Drug Reactions in Dermatology Department of a Teaching Hospital

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Abstract:

Drug induced skin reactions are common and account for 30% of all reported Adverse Drug Reactions (ADRs). Some skin related ADRs include Toxic Epidermal Necrosis (TEN) and Steven-Johnson Syndrome (SJS) are life threatening and requires hospitalization there by increases the economic burden to the patients. The objectives behind the study is to assess the incidence, causality, severity and preventability of drug induced skin reactions. A prospective observational study was carried out for 8 months in the Dermatology Department. The suspected ADRs were evaluated for causality, severity and preventability by WHO, Hart wig and Schumock-Thornton scale respectively. A total number of 200 patients were enrolled. Out of 200 patients, the incidence of dermatological ADRs was 9%. Most commonly encountered ADR was SJS with a 22.2% incidence. Maximum number of ADRs were observed with antibiotics (33.5%), followed by antiepileptic drugs (16.7%) and NSAIDs (16.7%). According to WHO scales 61.1% reactions were probable where as 66.6% of ADRs were moderately severe and 55.6% were not preventable. Clinical spectrum of cutaneous ADRs ranging from mild urticaria to serious TEN were observed. SJS and rashes were the most commonly observed clinical pattern of ADRs. Dermatological ADRs was varied in their causality, severity and preventability.

Keywords: Adverse Drug Reactions, Steven-Johnson Syndrome, Toxic Epidermal Necrosis

H-96

Prescribing Patterns in Coronary Artery Diesease in a Teritary Care Hospital

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Abstract:

Coronary artery disease (CAD) is the leading cause of death in the world. Study of drug prescription pattern can give an information about the uses of various drugs used in coronary artery disease in treating alone and when comorbidities are present.. A cross sectional observational study was carried out in cardiology wards, cardiology out patients and cardiac intensive care unit for a period of eight months from October 2016 to March 2017. Drug therapy details by medication chart review and clinical review in patients with CAD was carried out and was analysed to study the prescription patterns based on monotherapy and combination therapies given to the patients. The prescriptions analysed were 99 and the total number of

drugs prescribed were 665 and the average drugs prescribed per prescription were found to be 6.67%. Both monotherapy and combination therapy were given. The major classes of drugs given to the patients were, antiplatelets (77.7%), anti hyperlipidimicis (79.7%), antianginal (74.7%), anti-hypertensive (64.6%), anti-diabetics (28.2%) and anticoagulants (10.1%). Prescribing pattern provides a classic frame of trends in prescribing according to various general practioners and it will help to improve patient management by rationalizing drug use.

Keywords: Coronary Artery Disease, Antiplatelet, Prescription Pattern, Hypertension

H-97

Assessment of Antibiotic Prescribing Pattern in Caesarean and Normal Delivery Cases at Tertiary Care Hospital

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Abstract:

Antibiotics are crucial to treat infections during delivery and postpartum period to reduce maternal mortality. Institutional deliveries have the potential to save lives of many women but extensive use of antibiotics lead to the development and spread of antibiotic resistance. The aim of this study was to investigate antibiotic prescribing pattern and their efficacy. A prospective cross-sectional study was conducted including women who underwent vaginal delivery or a caesarean section in the hospital. Of the total 200 women under study, 80 (40%) had a vaginal delivery and 120 (60%) had a caesarean section. Sixty-two percent of the women that had a vaginal delivery and 75.8% of the women having a caesarean section were prescribed prophylactic antibiotics. The mean number of hospitalization days (without any prophylaxis) for the women with a vaginal delivery was 5.61 days and for the women with caesarean section were 16.11 days. On the other hand, after prophylactic treatment, average number of hospitalization days were comparatively lower i.e. 4 for vaginal deliveries and 10.09 for caesarean section. 71.5% of all women under study were prescribed antibiotics post-operatively. Comparing with WHO guidelines, prophylactic antibiotics were prescribed for less number of women having caesarean section whereas was too high for women undergoing vaginal deliveries and reason could not be understood in this study setting. Henceforth, on the basis of the present study it may be concluded that specific policies and guidelines on regarding antibiotic prescription during delivery at health care facilities are needed to be strictly followed.

Keywords: Caesarean Section, Antibiotics, Postpartum Period

H-98

Diabetes Risk Screening Procedure in Context to India

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Abstract:

Diabetes mellitus (DM), commonly referred to as diabetes, is a group of metabolic disorders in which there are high blood sugar levels over a prolonged period. There is increasing risk of diabetes in due to inappropriate life style. Madras Diabetes Research Foundation (MDRF) has developed Indian Diabetes Risk Score (IDRS) to detect undiagnosed Type 2 diabetes. IDRS has been shown to be a useful screening tool for undiagnosed cases of Type 2 diabetes and to find the prevalence of undiagnosed Type 2 diabetes in Indian population. In India where resourceful clinical settings are lacking in many parts and available one are overburdened. Henceforth, a cost effective risk screening tool is very much needed. Though many studies have been performed using IDRS scoring, the validity of tool is yet to be established in larger population of India. There are many risk scoring tools employed and studies worldwide and are being used, few of them are American Diabetic Association's diabetic risk scoring, Finnish Diabetes risk scoring. This study aims to review the results of the various questionnaire tools available with special emphasis on IDRS.

Keywords: Diabetes, Screening Tools, IDRS

H-99

Susceptibility of Commonly Used Disinfectants Against Multidrug Resistant Bacterial Pathogens Isolated From Tertiary Hospitals in India

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Abstract:

The aim of this study was to determine the activities of some common available biocides against bacterial isolates from tertiary hospitals in India. Twenty drug resistant strains including *Vibrio cholera*, *Staphylococcus aureus, E.coli, Klebsiella pneumoniae*, *Pseudomonas* species were collected from clinical specimens such as urine, blood, wound swab, etc submitted to diagnostic laboratory of the hospitals and tested for their sensitivity against the biocides commonly used including ethanol (70%), sodium hypochlorite (6%), chlorohexidine (4%), chloroxylenol (2.4%) and triclosan (4%).The plates were then incubated at 37°C overnight, and the zones of inhibition were calculated. The number of strains were inhibited with different concentrations of various biocides (sodium hypochlorite, chloroxylenol, triclosan, chlorhexidine, and ethanol) using agar diffusion but at a much higher concentration than commonly used. Sodium hypochlorite was more effective against all the strains compared to the other biocides while ethanol and triclosan were less effective even at the popular 70% for ethanol normally used for antisepsis. *S. aureus* showed 100% resistance to ethanol even at 100% concentration while some levels of activities were obtained at 80-90% for other bacteria like E.coli. However .*P. aeruginosa* was found to be 100% resistant to triclosan at all concentrations. It would be recalled that 70% ethanol has been widely used for ensuring antisepsis on the skin or in clinical settings for swabbing animate or inanimate objects as 100% alcohol cannot be used as a disinfectant because of its volatility and denaturation of external membrane proteins only. But we need to increase the concentration of ethanol as disinfectant/biocide to 80 – 85% as a matter of emergency with little or no economic cost due to the global high level bacteria resistance.

H-100

Drug Induced Cushing's Syndrome - Chronic Use of Steroids

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Abstract:

Corticosteroids are the drugs that are used commonly as pain relievers but these corticosteroids can affect the immune system. So corticosteroids are the reason for occurrence of the infections. Chronic use of corticosteroids mainly induces crushing's syndrome, osteoporosis, diabetes mellitus, tuberculosis, jaundice etc. In this case studies, we have discussed regarding steroid induced Cushing syndrome who were admitted in the general medicine department at Santhiram medical college & general hospital in Nandyal region. Prescribing of steroids by RMP's is increasing day by day, hence as role of clinical pharmacist. In these cases, the patients were on corticosteroid treatment prescribed by the RMPs. It is advisable to create an awareness on usage of steroids to the local pharmacies and RMP's by better training.

Keywords: Corticosteroids, Cushing's Syndrome, Management

H-101

To Study a Case Report on Patient With Juvenile Arthritis in a Tertiary Care Hospital

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Abstract:

Juvenile arthritis is any form of chronic arthritis or arthritis related conditions which affects individuals under the age of 16. Juvenile arthritis is caused by the body attacking its own healthy cells and tissues, i.e. autoimmunity, causing the joint to become inflamed and stiff. The incidence and prevalence of chronic childhood arthritis are 0.07-4.1 per 1000 children, with an incidence of 0.008 to 0.226 cases of JA per 1000 children. A 9 year old male patient was admitted in pediatric ward of the tertiary care hospital with major complaints of fever from 1 week, rashes at night and pain as well as swelling in both knees from 2 days. There was no history of present medical condition. There was family history of arthritis as the patients mother was also a patient of arthritis. On investigation, based on present complaints and family history, patient was assessed a case of juvenile arthritis. Laboratory data confirmed high content of ESR, RDW and Neutrophils and low content of lymphocytes. PCR test was positive. During hospital stay the patient was treated with prednisolone 10mg TDS, Ibuprofen 400mg OD, levocitirizine 5mg+montelukast 10mg OD, Ranitidine 2.5mg, Amoxicillin 500mg+potassium clavulanate 125mg TDS, Paracetamol 650mg TDS. The patient was observed for 5 days and patient showed good compliance towards the prescribed medications.

During the case study it was found that prednisolone is very useful for the treatment of arthritis. After 5 days of hospital stay patient showed clinical improvement and normal vital signs and was discharged.

Keywords: Juvenile Arthritis, Autoimmunity, Prednisolone

H-102

Rationality Assessment of Vitamin Formulations available in India

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Abstract:

The present study was designed to evaluate the marketed vitamin formulations for assessment of prevalence of multivitamin formulations with respect to contents with their dose, type of dosage form and unit price of formulation. In addition, the knowledge, perception and opinions of Pharmacists, Physicians and Public on rational use of vitamin formulation were also evaluated. A total of 70 single vitamin formulations and 525 multivitamin formulations were studied with respect to contents with their dose, type of dosage form and unit price of formulation. A total of 43 Pharmacists, 36 Physicians and, 135 Persons from general public were interviewed with pre designed questionnaire having open / closed questions. Out of surveyed vitamin formulations, surprisingly 76.7% of single vitamin formulations and 38.1% of multivitamin formulations were found irrational due to having higher contents of them in comparison to standard recommended dietary allowance (RDA).More than one forth of surveyed formulations had combination of vitamin B_1, B_6 and B_{12}, the same is a banned combination since 2001. From the survey conducted on physicians it was revealed that vitamin formulations were more commonly prescribed by them without evaluating the content of vitamins present in different tonics. In case of interview conducted on Pharmacists, we found that only 5.5% of them were aware about the hypervitaminosis. More than 80% of surveyed public has presumption that vitamins are energy booster and harmless at all. Pharma industries seem to be interested making profit by manufacturing multivitamins formulations. Vitamin deficiency is not properly diagnosed and irrational prescriptions are written by physicians and so filled blindly by Pharmacists. Public has also assumed Vitamins as harmless and just as dietary supplement, which may be detrimental to them. So, there is need for launching an educational program for the masses on the need and rational use of vitamins.

H-103

A Cross Sectional Study on Effect of Alcohol on Blood Pressure

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Abstract:

Alcohol abuse is a frequent contributor to elevated blood pressure and may be the most common cause of secondary hypertension. In most cases, the blood pressure elevations are reversible and return to normal upon discontinuation of alcohol use. In this questionnaire based cross-sectional study we aimed to identify the association between alcohol consumption and blood pressure changes. The study was conducted in rural villages of Karnataka. Our study comprises 300 populations, out of which 250 were alcoholic and 50 were non- alcoholic. Among 250 alcoholic populations, 223 were males and 27 were females. The blood pressure of 250 alcoholic population were measured by sphygmomanometer and a special epidemiological questionnaire was completed by each participant. The prevalence of hypertension was high in people drinking every day. For every day drinkers the blood pressure was independent of the amount they consume. Blood pressure was high in chronic drinkers. Our study concluded that there is a positive association between alcohol consumption and hypertension. The highest range of blood pressure among alcoholic population was found to be >180/>110mmHg.

Keywords: Alcohol, Hypertension, Blood Pressure, Alcoholic Population, Chronic Drinkers

H-104

A Case Report on Adverse Drug Reaction of Phenytoin in the Treatment of Epilepsy

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Abstract:

A 14 years old male patient admitted in the hospital with

presenting complaints of three episodes of seizures. The description of seizures is that, it started with headache with sudden rhythmic movements of upper and lower limbs, froth from mouth with up rolling of eyes with loss of consciousness. His past medical history showed that boy was had attack of febrile seizures when he was 9 months old and he is a k/c/o Attention deficit hyperactivity disorder (ADHD) .The EEG, CT scan and MRI reveals no change or anomality in the brain tissue. His serum urea levels are raised. Based on clinical presentations, the patient is diagnosed with generalized tonic clonic seizures (GTCS). The patient was treated with phenytoin (Anticonvulsant) stabilized and discharged with phenytoin .After some days, the patient readmitted with complaints of rashes all over body. It was diagnosed as phenytoin induced rashes. The patient was advised to stop phenytoin and treated with newer class of antiepileptics-Levetriacetam. Now with this study, we have to compare the two groups of Antiepileptic safety profile.

Keywords: Age, Epilepsy, ADHD, Phenytoin, Rashes, Febrile Seizures

H-105

Assesment of Antibiotic Usage in Post Operative Patients in Surgery Department of a Tertiary Care Teaching Hospital

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Abstract:

Surgery has not always been considered as a global health priority, but certain surgical conditions will reduce the burden of disease and promotes the cost-effective intervention. Chances of infection shows higher after surgical procedure. Choice of antibiotics is mandatory for the prophylaxis as well as for the treatment of post-operative infections. Inappropriate prescription of antibiotics can extend the hospital stay as well as increases the mortality rate and also affect the wound healing phenomenon. This study examines the prescribing patterns of antibiotics and also encounter the suspected organisms responsible for the surgical site infections (SSI's) after post-operative procedures. A prospective observational study was carried out for a period of 6 months. Drug details were collected from patient's medication charts and the incidence of SSI's was identified through patient's case notes and laboratory investigations. Majority of the patients were given combination therapy (93%). Most frequently prescribed antibiotic was cefoperazone plus salbactam (21.6%) and the single drug was metronidazole (15.9%). The common causative organism isolated was E.coli (66.66%). Analyzing the prescribing pattern can help to improve prescribing habits, to avoid antibiotic resistance and to decrease the SSI rates.

Keywords: Prescribing Pattern, SSI, Antibiotics, Surgery, Infections

H-106

A Study on Knowledge and Practices of Over The Counter (OTC) Medications Among Pharmacy Students

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Abstract:

Use of over the counter drug as well as self – medication is a very common problem in India. Medical students are of no exception at this mal-practice. This study was to assess the extent of knowledge and practices of over the counter (OTC) drugs among pharmacy students of Indo-Soviet Friendship College of Pharmacy. A questionnaire based study was conducted among 200 numbers of pharmacy students. Among the participants, 84% know what OTC drugs is and 71% know which drugs fall under OTC category. They took self-medication approximately four to five times on average in last one year. Most common conditions/symptoms for self-medication were fever (89%), cough and cold (75%), headache (67%), diarrhoea (33%), any type of pain (53%) followed by minor cut, vomiting. Antipyretics (82%), cough and cold preparation (51%) and pain-killers (49%) were the most common medicines taken. 15% of them experienced adverse reactions on OTC self-medicated drugs. 58% followed the instructions as per Package Insert and 40% recommended the medicine to others with similar problem. OTC medication is widely used among medical students who are studying pharmacology. It is important to create awareness about harmful effects of OTC drugs among medical students as they are future health care providers and prevent untoward consequences.

Keywords: Over the Counter Drug, Self-Medication, Questionnaire

H-107

A Prospective Observation Study of Tissue Necrosis in Hemorrhagic Stroke Patients with

Treatment Regimen and Outcomes

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Abstract:

A prospective observational study was carried out in a tertiary care hospital to evaluate tissue necrosis in hemorrhagic stroke patients with treatment regimen and therapeutic outcomes by the medication. Our study was hospital based prospective observational study conducted for a period of 12 months in a tertiary care hospital using a questionnaire which was prepared based on information collected from the patients with patient consent and ethical committee by the hospital. The data was analysed by different softwares and was typed in Microsoft word 2010. Out of 90 patients, 72 patients cooperated with us and provided the information that was the treatment regimen of stroke, reasons for admission and the results were discussed. Out of 72 patients in our study who were suffering with hemiplegia are with an age group of 35-70 years. The reasons for the admission of patients were trauma, hypertension, diabetes mellitus and the co morbidity for the hospitalization was hypertension and diabetes mellitus. The maximum time taken to reach the hospital was 24-36 hours. Normal parameters were recorded, CT and MRI were performed for the final diagnosis and to treat stroke. The treatment regimen for the stroke and general symptoms are mainly antibiotics, anti platelets, multivitamins and the treatment therapies and outcomes were analyzed. Our study concluded that the patients who are suffering with stroke are of age group 35-70 years are maximum due to traumatic conditions and complications occurred in the life. It is mostly a cost effective and cost economic disease which will increase the burden on patient family and shows the different ailments to become normal condition. It mainly depends upon the regularity of medicine; any serious events can take place at any time. The government should provide health insurance for the treatment and surgery in an easy way.

H-108

Prescribing Pattern of Antihypertensives in Type II Diabetic Patients

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Abstract:

Rational drug prescribing is defined as the use of least number of drugs to obtain the best possible effect in shortest period and at a reasonable cost. The prescribing pattern of drugs used for treating hypertension changes over time in response to changes in recommended guidelines and innovations in drug formulations. The objective behind the research is to study the current trend of prescribing pattern of antihypertensive class of drugs in type 2 diabetic patients and also to evaluate most preferred category of antihypertensive that are used for the treatment in them. Proper pattern in prescribing drugs plays an important role in rational drug therapy and in enhancing patient's quality of life. Hypertension and diabetes when present together are associated with a multitude of complications, all of which result in increased morbidity and mortality. Prescribing patterns of antihypertensives were studied in 459 patients in a tertiary care centre. The number of drugs per prescription ranged from 1 to 9 while that of antihypertensives varied from 1 to 4. The most frequently prescribed antihypertensives were ARBs(67.75%), β-blockers(11.25%), calcium channel blockers(12.5%), Diuretics(5.0%), and angiotensin converting enzyme inhibitors(3.0%). Antihypertensives prescribed as monotherapy included Olmesartan. Among the combination therapy drugs were angiotensin receptor blockers plus diuretic. This study reveals a need for continuing education and standard treatment guidelines for rational prescribing of antihypertensive drugs in diabetic patients.

Keywords: Hypertension, Prescribing Patterns, Diabetes Mellitus

H-109

Case Presentation on Myelodysplastic Syndrome

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Abstract:

Myelodysplastic Syndrome (MDSs) are a clonal disorders of the haematopoietic stem cell characterized by ineffective haematopoiesis leading to peripheral blood cytopenias, also characterized by abnormal development of immature blood cells in bone marrow. MDSs develops when a cell within a mutation replicates and the resulting copies begin to predominate in the bone marrow and suppress healthy stem cells which occur generally through genetic predisposition or from injury to the DNA caused by chemotherapy or any radiation reflecting defects in erythroid, myeloid and megakaryotic maturation.

The other predisposing factors include heritable, acquired, genotoxic and autologous transplantations which occurs rarely in thousands of population. A 46 year old male patient was hospitalized with the complaints of weakness and shortness of breath since one year, having fever and chills along with non productive cough since three days. After reviewing the past medical and medication history it was found that he was suffering from 5q-deletional disorder in myeloma and discontinued therapy of Lenalidomide. However repeated blood tests and other lab investigations were done and was found to have severe refractory macrocytic anaemia after bone marrow examination it was diagnosed as Myelodysplastic Syndrom hence immediate blood transfusion therapy was given. Deletion syndrome in myelodysplastic syndrome being mostly genetically acquired cannot be completely cured being a rare disorder it can be treated with several combinational therapies such as lenalidomide along with folic acid and surgical procedures like bone marrow stem cell transplant.

Keywords: Myelodysplastic Syndrome, 5q-Deletion Syndrome, Refractory Macrocytic Anaemia, Lenalidomide

H-110

Biological Rhythm Disturbances in Patients with Bipolar Disorder Under Remission

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Abstract:

Biological rhythms are very important aspects governing the human life. The patients suffering from bipolar disorder have lot of issues which play an important role in the course of their illness. Hence it should be focused which may help in improved compliance with better quality of living. Thus, reducing the need for hospitalizations. 30 subjects with bipolar disorder according to ICD10 and fulfilling the criteria for remission were compared with 30 age matched normal subjects using the Biological Rhythms Interview of Assessment in Neuropsychiatry (BRIAN) to assess biological rhythm disturbance. It is an 18-item interviewer-administered instrument which allows us to investigate the main areas related to circadian rhythm disturbance (sleep/social, activities, and eating pattern) in bipolar disorder. The BRIAN (total) scores were 23.37 +/- 2.76 for the patients vs. 18.43 +/- 0.77 for controls were significant. Significant correlation was observed between total duration of illness (in years) and total number of episodes in the sample patient population. The correlation was of statistical significance with relation to age of onset (in years) with BRIAN's Activity pattern (r=0.517, p=0.003 and Social pattern (r=0.409, p=0.025) and the BRIAN (Total) scores (r=0.486, p=0.007). The results suggest a potential association between biological rhythms and Bipolar disorder pathophysiology. There is need to for working other specific psychosocial interventions as a supplement to the psychopharmacological treatment of bipolar illness episodes.

Keywords: Bipolar Disorder, Biological Rhythms, Remission

H-111

To Study the Clinical Profile, Management and Outcome of Diabetic Pregnancies in a Rural Tertiary Care Hospital

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Abstract:

Gestational diabetes mellitus develops due to an inability to compensate for physiological increase in insulin resistance that develops progressively throughout pregnancy as a consequence of multiple factors including placental hormones, increased caloric intake and reduced physical activity. Many studies report increased incidence of adverse fetal and maternal outcome in diabetic pregnancy. The objective behind the research was to study the clinical profile, management and outcome of diabetic pregnancies. The present study is a retrospective cum prospective analysis done for one year period. Patients with diabetic pregnancies who had delivery in our institution were included. Patients having some endocrinopathy as thyroid disorder were excluded from the study. Total number of diabetic pregnancies during the study period were 76 among them 15 were PGDM and 61 were GDM. Gestational age at diagnosis in PGDM group is 13.42±1.2 weeks versus 29.62±4.53 weeks. Maximum patients (70.5%) in GDM group were managed by diet and exercise, while in PGDM group maximum patients (93.3%) needed insulin for glycemic control. Most common complication was hypertensive disorders of pregnancy. 11.8% neonates had a birth weight of >4 kg (macrosomia). 77% of neonates in GDM group had an uneventful outcome. Prenatal counseling for established diabetics, screening and diagnosis for all pregnant population , good control from conception till delivery , antepartum fetal surveillance and appropriate neonatal sup-

port are the key to successful outcome in diabetic pregnancy.

Keywords: Gestational Diabetes Mellitus, Outcome, Treatment

H-112

Assesment of Drug-Drug Interactions in Cardiac Patients

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Abstract:

Drug-drug interactions (DDIs) occurs when the effectiveness of one drug is changed due to the continuous administration of another drug. Cardiovascular disease patients usually suffer from multiple diseases and hence they receive complex drug regimen which increases the risk of drug-drug interactions. The study was aimed to identify the drug-drug interactions in hospitalized patients of cardiology department. It was also planned to analyze the severity of the identified interactions. A prospective observational study was conducted for a period of 6 months . A sample of 100 cardiac patients who were taking at least two drugs were involved in the study. Data were collected and compiled in excel and potential drug-drug interactions were analyzed by using Micromedex- a complete drug information software. In this study 95 patients were identified to have drug-drug interactions (DDIs). Among these patients, a total of 551 potential DDIs with 55 interacting pairs were identified. On analyzing the severity of interactions it was found that 300 (54%) were major interactions, 251 (45%) were moderate interactions and 6 (1%) were minor interactions whereas, The most common pair of drug found to cause DDIs was Aspirin - Clopidogrel 87(15.79%) which was a major interaction. The chance of Bleeding (89%) was found to be the highest clinical outcomes in our study.

Keywords: Cardiovascular Disorders, Drug-Drug Interactions, Poly-Pharmacy, Severity

H-113

Comparitive Study of Effects in Alcoholic and Non-Alcoholic Smokers on Cardiac and Respiratory Systems

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Abstract:

Alcohol & nicotine of cigarettes both are major independent risk factors for various cardiovascular disorders (CVD) and respiratory disorders(RD). The people who were consuming alcohol has significant impact on the prevalence of CVD,where as Alcoholics assosciated with smoking had more significant impact on RD and CVD. In Non-alcoholic smokers the incidence of respiratory diseases is significantly less proportional than with alcoholic smokers. In this study the comparision of the prevalence of CVD and RD in patients with hypertensive diabetics and non- hypertensive diabetics in response with alcoholism and smoking is done. Patients admitted in MGM hospital, with known cases of hypertension were enrolled. Patients were clinically evaluated based on social history and past medical history. 11 hypertensive patients were examined out of which 3 were alcoholic smokers , 6 were non alcoholic smokers, 2 were alcohol withdrawl with smoking. In non-alcoholics out of 6, (3 are non-diabetic smokers and 3 are diabetic non-smokers). Alcoholic smokers had increased risk of CVD and no effect on RD. Non-alcoholic smokers had risk of both RD and CVD. Alcohol withdrawals with smokers have impact on respiratory system and no effect on cardiovascular system. We conclude that smoking alone have an increased risk of both CVD and RD.

Keywords: Respiratory Disorders, Cardiovascular Disorders, Alcoholic and Non alcoholic smokers

H-114

Dynamic Methods for Involving Community Pharmacists in the Dots Provision and Tuberculosis Care Role in Bangalore City (a Part of COPE DOTS Study-an open label, Randomized Controlled Trial)

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Abstract:

India is the country with highest burden of Tuberculosis (Tb). One of the important aims of National Strategic Plan (NSP) for Tuberculosis is to involve Community Pharmacists (CPs) in DOTS (Directly Observed Treatment-Shortcourse) provision

role. Indian Pharmaceutical Association-Community Pharmacy Division (IPA-CPD) took initiative in year 2006 and developed model in 2010 for CPs in TB care and control in Maharashtra and 5 other states. Aim of the study was to create awareness, training and enrolling Community Pharmacists (CPs) as a DOTS provider. Prospective-Educational Interventional method was followed to assess the awareness level of pharmacist DOTS provision role. The Knowledge, Attitude and Practicing (KAP) interests of CPs were assessed using standard Questionnaire. This study was carried out in 2 methods. Method I: A CPE (Continuous Pharmacy Education) model was followed in coordination with Drugs Control department. A notification/appeal to register and participate in CPE programme was circulated to chemists in Bangalore city (Circle 6) from Drugs Control Department, Govt of Karnataka and training was prganised. Method II: Investigator listed the chemist with the help of RNTCP-Tb treatment and trained them at their place. 189 chemists were trained where 125 CPs participated in the CPE & 64 participated by Method II. The awareness on the existence of the DOTS role by the CPs and their benefits was nil (0%) amongst the participants. Of the 189 CPs attended, 168 (88%) showed their interest in taking up DOTS provider role.

Keywords: DOTS, Community, TB

H-115

Sleep Disorders in Children with Chronic Kidney Disease

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Abstract:

This case-control study assessed the prevalence of sleep disorders among children with chronic kidney disease (CKD), either maintained or not maintained on haemodialysis (HD), and compared them with healthy age and sex matched children. Patients and methods: The total study population included 95 children, 54 of whom were CKD patients, 22 maintained on HD and 32 not maintained on HD; 41 healthy children of matched age and sex composed the control group. Subjective impairment of sleep quality was assessed using the Arabic version of the Children's Sleep Habits Questionnaire (CSHQ). Daytime sleepiness and restless leg syndrome (RLS) were assessed using a paediatric modification of the Epworth sleepiness scale (ESS) and RLS Questionnaire, respectively. Results: Sleep disturbances were detected in 75.9% of the studied children with CKD: 81.8% in children with CKD undergoing dialysis, and 71.8% in children with CKD not on dialysis. Excessive daytime sleepiness (EDS) and RLS symptoms were reported in 22% and 20.4% of the studied children with CKD, respectively. Conclusions: Sleep disturbances are very common among children with CKD. Sleep disturbances in patients with CKD include restless legs syndrome (RLS), excessive daytime sleepiness (EDS), sleep-disordered breathing (SDB), behavioral insomnias, and parasomnias.

Keywords: CKD, Haemodialysis, Children, Sleep Disorders, Restless-Leg Syndrome

H-116

A Case Report on Ludwigs Angina

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Abstract:

Ludwig's angina is a potentially life threatening severe form of diffuse cellulitis that present an acute onset and spread rapidly bilaterally affecting submandibular, sublingual, segmental spaces resulting in state of emergency. It occurs in adults with concomitant odontogenic infections mandibular fractures, pericoronitis, oral laceration/piercing and submandibular saladenitis. It includes clinical manifestations like bilateral lower facial edema, trismus, drooling, dysphagia, odynophagia, tongue displacement creating a compromised airways. It can be diagnosed by physical examination, fluid culture test from affected area and by ionising tests like MRI/CT scan. In early stage of disease patient may be managed with observations and IV antibiotics and advanced infections, however requires incision and drainage of abscess and maxillofacial surgery.

Keywords: Ludwig' S Angina, Odontogenic Infection, Tracheostomy

H-117

A Clinical Study on Prevalence of Tuberculosis in Khammam District, Telangana - An Observational Study

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Abstract:

Tuberculosis (TB) is a bacterial disease which is caused by *Mycobacterium tuberculosis* in humans. The major areas that are affected are lungs but any part of the body can be affected, including bones, abdominal glands, spine and nervous system. The World Health Organization reports that TB infects one new person every second and is the world's leading infectious cause of death next to HIV. The aim of the study is to evaluate the prevalence of tuberculosis in Khammam district. The objective is to create awareness among healthcare personnel and patients regarding tuberculosis. A total of 440 pulmonary TB cases and 60 extra pulmonary TB cases were studied. According to age groups 370 subjects are in the younger and middle age groups which comprise a total of about 74% where as in early age there are 6.8%. Many variables are considered in this study out of which alcohol was rated as highest because 59.2% subjects in the study were alcoholics. A total of 31.8% smokers were found out. A total of 22% of subjects were suffering from TB with HIV. Diabetes was also a variable with 16.2% subjects suffering. The study reveals that tuberculosis is a disease that mainly affects the people of age groups 20-50 and is more prevalent in males than that of females. Variables like alcohol consumption rated as highest risk factor followed by smoking, HIV and diabetes respectively.

Keywords: Prevalance, Smoking, Human Immuno Deficiency Virus, Diabetes

H-118

Role of Pharmacists in Counseling of Asthmatic for Better Drug Compliance

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Abstract:

Multi-drug treatment is necessary for control of the asthma, but it can be well managed by diet, physical exercise and stress management, rational utilization of drugs and devices. Patient ignorance and poor compliance are the main hurdles in the management of asthma. There is a need to overcome these problems and increase the patient compliance by counseling about, diet, importance of yoga and exercise, stress management, impact of addiction, safe use of drugs and devices. The role of pharmacist in counseling of asthmatics for better drug compliance can also be achieved by patient counseling and educating the patients for proper and safe use of inhalers. The pharmacist should also monitor the safe use of drug. Certain drugs like Beta blockers (including eye drops), aspirin and NSAID, hypotonic nebulizer solution or solution with preservative, ACE inhibitors should be avoided as they can induce asthma. We found patient ignorance and poor compliance are the main problems in the management of asthma. Due to rapid civilization and modernization lifestyle of each individual is changing and furthermore environmental factors have a great deal of impact on asthma. Thus the pharmacist is the person who can be actively involved in the counseling of asthmatics by guiding about diet, importance of yoga and exercise, stress management, impact of addiction, safe use of drugs and devices. In this way pharmacist can be a good counselor for asthmatic and can help to increase patient compliance.

H-119

Study on Clinical Pharmacist Intervention to Improve Health Related Quality of Life in Diabetic Patients in Rural Population

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Abstract:

The main objective of the study is to assess the impact of clinical pharmacist provided patient education on Quality of life outcomes in diabetic patients in rural population. A prospective observational parallel design study was conducted to outpatients of a Primary health Centre located in Tirupati rural area. The enrolled patients were segregated into control group and intervention group. Patient counselling provided to intervention group in the aspects of disease awareness, usage of medication and life style modifications where the control group patients were not. The mean blood glucose levels are significantly decreased from 263±12mg/dl at baseline to 195.8±6.5 mg /dl at follow up in Intervention group, where control group shows no significant improvement in the management of diabetes. The percentage of correctly answered patients towards diabetes KAP questionnaire is significantly increase in the intervention group from 56±9.6% at baseline to 85±3.7% at follow up, where control group shows no significant improvement in the diabetes awareness. The mean health related quality of life score is improved in the intervention group from 57.82±1.5 at baseline

to 69.4±0.96 at follow up, where the control group shows a very little improvement in the health related quality of life.

Keywords: Clinical Pharmacist, Patient Counselling, HRQOL

H-120

Role of Pharmacist in providing Quality Pharmacy Services through Telepharmacy in Rural Communities in India

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Abstract:

Telepharmacy is the delivery of pharmaceutical care via telecommunication to the patients in locations where they may not have the direct contact with a pharmacist in remote and rural communities. It is an instance of the wider phenomenon of telemedicine, as implemented in the field of pharmacy. Telepharmacy is a rapidly growing field of pharmacy in rural areas. Telepharmacy is a more recent concept that refers to pharmaceutical service provision, enables healthcare services, such as medication review, patients counseling and prescription verification by a qualified pharmacist for the patients located at a distance form a remotely located hospital, pharmacy or healthcare centre. The objective behind the current paper is to highlight the role of pharmacist in providing quality pharmacy services through Telepharmacy in remote locations, pros and cons of Telepharmacy, steps involved in Telepharmacy, its types and also technological/ legal issues in Telepharmacy services in India. Telepharmacy has many recognizable benefits such as the easy access to healthcare services, economic benefits, patient satisfaction as a result of medication access in rural areas, provide effective patient counseling and minimal scarcity of pharmacists. Execution and implementation of comprehensive and uniform Telepharmacy law is still a problem. A well developed system however can change the practice of Telepharmacy. Despite of some technological and regulatory issues, Telepharmacy can be widened to ensure the coverage of pharmacy services, underserved the areas and manage to bridge the gaps in the pharmaceutical care in rural communities with minimal dispensing errors and adverse effects of the medicines.

Keywords: Remote Locations, Scarcity, Pharmacist, Telepharmacy, India, Technological Issues

H-121

Differentiation of Bronchial Asthma and Viral Bronchitis with Reference to Spirometer

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Abstract:

It is to observe changes in disease pattern of bronchial asthma and viral bronchitis with reference to the spirometer and The St George's Respiratory Questionnaire (SGRQ) and to evaluate polypharmacy and cost associated with each disease. It is an observational case study of two patients within the same family. Prescriptions and pulmonary function test (PFT) reports of each patient are analyzed. The impairment and risk of asthma assessed by spirometer and SGRQ. The DUE and its cost associated with each case are measured and compared. There are slight changes in PFT. The percentage predicted FVC, FEV_1, FEV_1/FVC%, and PEF are 56.41, 39.81, 73.47, and 35.6 in allergic bronchitis while it is 75.36, 84.43,113 and 113.1 in viral bronchitis respectively. Similarly HRQOL of earlier disease in terms of symptom, activity, impact and total scores are 53.5, 79.52, 63.58, and 66.82 while it is 21.2, 46.17, 56.71 and 47.63 in later disease respectively. The cost of bronchitis is Rs 1454.16 while it is Rs 1273/- for viral bronchitis per month. The study concluded that a good response to the steroidal anti-inflammatory drugs of asthma. And the impairment and risk is concerned it is slight severe in bronchial asthma in relative with viral bronchitis. The cost associated with each disease is more or less same, but bronchial asthma is a chronic disease.

Keywords: Bronchial Asthma, Spirometer, Anti Inflammatory Drugs

H-122

A Case Study on Adverse Drug Reaction Monitoring in Leprosy with Type-ii Reactions and its Management

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Abstract:

Leprosy is a chronic mycobacterial infection caused by mycobacterium leprae which is a slow growing intracellular bacillus that infiltrates in the skin the peripheral nerves, the nasal

and other mucosa and the eyes. Leprosy can affect all ages of both sexes. The prevalence of the leprosy was yearly reducing with a one case per 10000 populations worldwide. The treatment of leprosy requires multi drug therapy with long term management, because of these complexity in treatment of leprosy there may be a chance of producing unwanted effects in the patient. We report a case of leprosy with Erythema Nodosum Leprosum (ENL) reactions. A 35 years old female patient was admitted with complaints of fever, multiple skin coloured painful raised lesions all over the body since 10 days. The past history of the patient was, she had taken a treatment of Mycobacterium- Multi-Drug Therapy (MB-MDT) since 4 months. During the course of the treatment she complained about multiple Hypopigmented macules and patches of skin, bilateral pedal oedema, congestion of eyes, dryness of skin and on laboratory investigation, patient was anaemic without morphological change of red cells. These observations in the patient may suspect the adverse effects of the drug clofazimine. Naranjio ADR probability scale was applied to this adverse drug reaction and according to this the reaction was probable. After identifying the probability of the adverse drug reaction dechallenge action was taken by the health care professionals and discontinue the suspected medication the patient was recovered from ADR. In this present case we manage the ADR by withdrawal of drug, providing specific and symptomatic treatment and with ADR alert card notification.

Keywords: Leprosy, ENL, Hypopigmented Macules, Congestion

H-123

A Study on Non-Compliance to Pharmacotherapy in Psychiatric Patients

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Abstract:

Non-compliance or non-adherence to treatment is the degree to which a patient does not carry out the clinical recommendation of a treating physician or in other words it is failure of the patient to follow the prescribed treatment regimen. Non-compliance is a significant problem in all age group patients, from children to elderly. It applies to nearly all chronic diseases and tend to worsen as longer a patient continues on drug therapy. The goal of the study was to evaluate the patients with non-compliance to therapy. To study the reasons for non-compliance. To assess attitude towards medication intake. A prospective observational study was carried out for a period of six months at Psychiatry department of Basaveshwara Medical College & Hospital, Chitradurga. Total 82 patients are included. 50 were males and 32 were females. The most skin disease are seen in the age group of 18-30 years, 31-40years, 41-50years, 51-60years, 61-70years, Above 70years. The major psychiatry disease are seen in the study are BPAD(31.7%), schizophrenia (20.7%), anxiety (13.41), ADS (9.7%), psychosis (8.5%), OCD (6.09%), panic disorder (3.6%), migraine (2.4%), epilepsy (2.4%), parkinsonism (1.2%). Benzodiazepine (35.79%), antidepressant (22.1%), antipsychotics (21.59%), selective serotonin reuptake inhibitor (7.95%), opioid antagonist (1.13%), dopamine agonist (2.83%), muscarinic antagonist (0.5%), anticonvulsant (7.95%) are majorly prescribed drugs. The study showed that there was a extremely significant improvement in compliance of patients in comparison with first follow visit result and second follow up visit. Whose P value is (<0.001) extremely significant. Therefore the present study is conducted by the pharmacist patient education found to have significant influence on improve the patient knowledge towards their disease and medication which shows the positive impact on drug compliance among the patients of psychiatry diseases.

H-124

A Retrospective Study of Antimicrobial Resistance Pattern of Pseudomonas Aeruginosa Isolates From Culture Sensitivity Reports in a Tertiary Care Hospital

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Abstract:

Problem of antibiotic resistance is compounding day by day because of overuse and misuse of antibiotics. There is no systematic national surveillance of antibiotic resistance and insufficient data is available to quantify the problem in our country. This study aims at studying the changing pattern of antimicrobial resistance of Pseudomonas aeruginosa isolates from patients of various infections in a tertiary care hospital. A retrospective, record based study carried out based on the records of C/S (Culture sensitivity) reports of indoor patients, during the year 2016-2017. The types of organisms causing urinary tract infections were noted and the drugs still effective for the Pseu-

domonas aeruginosa were noted. Pseudomonas aeruginosa is inherently resistant to many antimicrobial agents. Analysis of the results indicated that the lowest percentage of resistance manifested against imipenem. Resistance for Fluoroquinolones decreased over few months. Over the successive months, the resistance to ceftriaxone tends to increase from 80% (January 2016) to 92.59% (August 2017). C/S reports showed on an average 69% were resistant to amino glycosides. Multi drug resistant pseudomonas percentage resistant to Fluoroquinolones, third generation cephalosporines and amino glycosides were 78% (January 2016) to 80.33% (August 2017) over the consecutive months. The antimicrobial resistance patterns are constantly evolving and vary from region to region it has become a necessity to do constant antimicrobial sensitivity surveillance. This will help clinicians to provide safe and effective empirical therapies.

Keywords: Antibiotic Resistance, Prescriptions, Changing Pattern

H-125

A Prospective Observational Study of Urinary Incontinence in Hemiplegia and Prostate Cancer Patients with Treatment Regimen

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Abstract:

Urinary incontinence is a condition in which urgency of urine takes place without any intimation in a condition with effects of stroke, epilepsy, prostate cancer and often makes a sense which results in cause of depression and psychiatric illness. Renal incontinence occurred unknowingly to the person and leads to severe infections; it's also a type of disease known as bed wetting. Our study was hospital based prospective observational study conducted in tertiary care hospital. The study was done by collecting information by using patient case sheets, based on the data a questionnaire is prepared according to the guidelines of WHO and HRQOL. Nearly data of 72 patients were included in the study with all the details of past medical history and the treatment regimen and laboratory parameters with frequency are collected. The duration of the study was 11 months from September 2016 to August 2017. Inclusion criteria- Patients suffered with stroke, Patients suffering age above 36, Patients of both sexes. Exclusion criteria-off-sane minded, Pediatrics, comatic patients. Out of 81patients 72 patients are willing to give the information regarding the condition out of which 18 females, 54 males are included in the study with a mean age of 22-60 years and suffered with Hemiplegia, seizures and prostate cancer (prostatomegaly) and the treatment regimen was tabulated as below. Out of 72 patients who are suffering with renal incontinence are of age group 22-60 and both sexes with secondary education level and nutritional level of mostly average. The reasons for admission in the hospital are due to Hemiplegia and diabetes mellitus. The duration of renal incontinence is higher in below 3 years. The classes of drugs prescribed for renal incontinence are mostly anticholinergics and alpha blockers. The complications are mostly due to hemiplegic drugs and urinary tract infections, the treatment for renal incontinence is Darifencin and all the laboratory parameters and therapies, counseling aids was analyzed and discussed. Our study concluded that the people suffer with renal incontinence is due to Hemiplegia, prostate cancer and seizures. The condition is mainly due to drugs used for Hemiplegia.

H-126

Drug Utilization Study at Tertiary Care Hospitals in Punjab

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Abstract:

Drug utilization (DU) or Drug use evaluation (DUE) studies is an ongoing, authorized and systematic quality improvement process. These studies designed to review drug use and prescribing patterns of drug with current recommendations or guidelines for the treatment of a certain disease. DUE provide feedback of drug utilization data to prescribers related to number of cases of adverse effects adverse drug reactions, specific drug –drug, drug -food interactions and medication errors. This study shows the evaluation of current prescribing pattern to identify different adverse drug reactions, specific drug –drug, drug -food interactions and medication errors at tertiary care hospitals in Punjab.

Keywords: Drug Utilization (DU), Drug Use Evaluation (DUE), Adverse Drug Reactions (ARD), Drug Interactions (DI), Medication Error (ME)

H-127

Analysis of Prescription Pattern and Evaluating Prescription from Three Wards at Tertiary Care

Hospital of India

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Abstract:

The intend of present study was to analyze the prescriptions generated from department of medicine, tuberculosis and psychotic of a tertiary care hospital in India. In the study parameters in accordance to standard prescription format, adherence to World Health Organization (WHO) core prescribing indicators, types of dosage forms and category of medicines prescribed were analyzed. A total of 1520 prescriptions from pharmacy were collected and analyzed after obtaining appropriate consent. Prescriber and patient identifiers were present in almost all prescriptions. Superscription was mentioned in 85.65% prescriptions. Dose and Dosage forms were mentioned in 76.90% respectively of total prescriptions. Average number of drugs prescribed per encounter was 5 which is more than four times of WHO standards. Only 45.59% drugs were prescribed with generic name which is drastically low while 47.68 drugs were prescribed from national essential medicine list of India. Instructions regarding drug use were present in 83.93% of total prescriptions. Percentage of Antibiotics was found to be 23.20% while that of injections was 10.52% which was less than WHO standard. Among prescribed drugs antacids and proton pump inhibitors were the most prescribed (59.60%) followed by vitamins and calcium supplements (58.81%) and cardiovascular drugs (27%). Tablets were highest prescribed dosage forms. Quality of prescriptions in terms of pattern was not quite satisfactory. Adherence of WHO prescribing indicators was only 2 out of 5 parameters. Polypharmacy was observed with the prescriptions while rationality in terms of injections and antibiotics prescription was according to international standards.

Keywords: Prescription, WHO, Prescribing Indicators

H-128

Comparing the Effect of Teneligliptin and Sitagliptin among Type 2 Diabetic Patients

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Abstract:

Diabetes mellitus is a leading cause of mortality and an increasing health burden with a prevalence of 8.3% globally and 9.1% in India. Type 2 diabetes mellitus (T2DM) affects over 300 million people worldwide. Prevention of complications and improving quality of life are the principle goals in its management. DPP-4 inhibitors have a potential vasoprotective effect. Teneligliptin a novel, highly selective agent compared to Sitagliptin. It provides sustained glycaemic control, decreases cardiovascular complications, has additional pleiotropic metabolic effects and also safe in renal impairment. The aim of study is evaluate the glycaemic and non-glycaemic effects of Teneligliptin vs Sitagliptin as add on therapy to metformin. After obtaining Institutional Ethics Committee approval and written informed consent, 60 subjects with T2DM taking metformin (500mg TID) for 3 months were randomized to receive Teneligliptin 20mg OD and Sitagliptin 100mg OD as add on therapy. Patients were followed up to 12 weeks for glycaemic and non-glycaemic effects. Adverse drug reactions (ADRs),were recorded and graded according to severity. There was a statistically significant decrease in FBS ($p<0.001$) and PPBS ($p<0.001$) in patients treated with Teneligliptin on week 8 & week 12 from baseline compared to those treated with Sitagliptin. The reduction in HbA1c ($p<0.0001$), LDL-CH ($p<0.0001$) & TC ($p<0.001$) on week 12 from baseline was also significantly more in the Teneligliptin group. Teneligliptin may be an effective and safe treatment option in reducing both glycaemic and non-glycaemic parameters as an add-on therapy in Type 2 DM.

Keywords: Teneligliptin, Sitagliptin, Diabetes Mellitus, ADRs, Metformin

H-129

Analysis of Dose Calculation of Medicines Prescribed in Pediatric Age Group

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Abstract:

Weight-based dosing is needed for majority of drugs in paediatrics that requires more accurate calculations than for adults. This study was aimed to analyze the appropriateness of the dose of medicines prescribed children and comparison of the prescribed dose with that of standard dosing guidelines for paediatrics. Total 150prescriptions were included in the study [100 from out-patient department of paediatrics of santhiram

hospital SRGH and 100from private [out-patients only] paediatric clinic. Prescriptions which contain at least one of antibiotics, non steroidal anti inflammatory drugs, cough treating agents or anti-histaminic drugs were included. Dose was calculating by using dosing guidelines mentioned in the standard paediatric textbook or the rules frequently found in paediatric reference textbooks and literature. The prescribed dose for compare to the standard doses [mg/kg/day]. In our study azithromycin and amoxicillin were commonly prescribed antibiotics and the prescribed doses were found to be same of doses recommended for guidelines. For NSAIDS classes, dose of paracetamol was found to be varying significantly in both SRGH and private clinic. In anti-histaminic classes, the chorpheniramine maleate was prescribed maximally and prescribed dose was found to be differing in SRGH, both in private as compare to standard dose. Very less cough treating preparation were prescribed in SRGFH in compared to private paediatric clinic, irrational prescribing was found with cough treating agents and prescribed dose was found to be differing from accurate dose for many of prescribed drugs.

Keywords: Antibiotics, Anti-Histaminic, Cough Treating Agents, Dose Calculation, NSAIDS, Paediatrics

H-130

The Role of Orexins in the Pathogenesis of Obesity

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Abstract:

Obesity is a pandemic disease which leads to the development of diabetes and various cardiovascular diseases. There are so many pathophysiological mechanistic aspects behind the development of obesity and the research till now have proved that homeostatic regulation of food intake and energy expenditure relies on central and peripheral signals that are processed within brain centers and peripheral organs (Heinonen et al., 2008). Obesity get started via deregulation in the circuitry of these central and peripheral anorexigenic (Melanocortins, leptin, insulin, glucagon like peptide, cholecystokinin, pancreatic polypeptide etc.) and orexigenic (orexin, Melanin-concentrating hormone, Agouti-gene related protein, Galanin-like peptide, ghrelin etc.) neurons present in the different brain regions. Various preclinical as well as clinical studies have reported the role of orexins in the development of obesity and other disorders of metabolic origin. Some have reported that orexin via upregulation of OX_1R induces hyperphagia while others have stated the down regulation of orexin neurons in the obese animals. Moreover, the central administration of orexin-A has shown an important role in food intake and regulation of energy metabolism whereas, deletion of orexin or the cognate receptor results in late-stage obesity, despite hypophagia. So, this review will highlight the summary of various recent studies of orexin involvement in metabolism with the conclusion that orexin acts as an integrative homeostatic signal influencing numerous brain regions, and via central and peripheral integration, it may have some pivotal role in the pathogenesis of obesity and might prove as as pharmacological tool in the management of obesity and associated disorders.

Keywords: Obesity, Orexin, Hypothalamus, Metabolism

H-132

Micronutrient Abnormality in Patients with Heart Failure

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Abstract:

In the current era, despite the deficit of empirical treatment with supplements, research on micronutrients in heart failure (HF) is still mounting up. The objective behind this study was to examine the micronutrients importance in the HF development and progression; which may possibly promote/worsen the condition through re-hospitalization. The micronutrients (sodium, potassium, magnesium, calcium, iron, total-iron binding capacity (TIBC), unbound-iron capacity (UBIC), zinc, copper) were measured in 48 fasting samples of HF patients (men=29; women=19), compared with 48 healthy controls (men 28; women=20) to identify the significant difference $p<0.05$. Mean age of study population was 56.21yrs (HF) and 41.99 yrs (controls) with a significant difference of ***p=0.0002. Among HF, 25% are underweighted, 50% were malnourished, 41.67% were at risk of malnutrition and women are dominant than men in malnutrition. Anaemia was found in 100% HF group where non-iron deficiency anaemia (66.67%) was high than iron deficient anaemia (33.33%). Sodium, TIBC, UBIC are significantly different at $p<0.0001$; potassium, magnesium, iron, zinc, copper show significant difference at $p<0.005$ and no difference found with

calcium when compared with control group. There was no significant difference in micronutrients within the HF (Diabetic *Vs* Non-Diabetic HF; Cardiomyopathy *Vs* Coronary artery disease) which indicates that imbalance is similar in all the cardiovascular diseases. Abnormality was found with zinc-79.17%, magnesium-75%, calcium-75%, sodium-56.25%, iron-41.67%, copper-41.67% and potassium-25% which may be the provoking factors for re-hospitalization. Thus, the study can be beneficial for promoting the micronutrient targeted treatment as supplements in abnormality which is an important and frequently neglected health issue.

Keywords: Heart Failure, Micronutrient Abnormality, Nutrition

H-133

Acute Eczema with Cellulitis and Eruption on Both Legs-Case Study

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Abstract:

Acute eczema is a chronic, relapsing, inflammatory skin condition characterised by an itchy red rash that favours the skin creases such as the folds of the elbows or behind the knees. Cellulitis can happen when bacteria enter a break in skin and spread. This results in infection, which may cause swelling, redness, pain or warmth. A 60 years old male patient was admitted in hospital with chief complaints of icthing, pain over both legs, pus formation, redness and swelling of both legs, oozing from skin lesions, multiple tiny itchy skin lesions all over the body, skin lesions over both foot for past 20 days. His culture reports and physical examination reveals that he was with Acute eczema with cellulitis. The patient was with confined therapy of antibiotics and topical agents along with 12 hourly observations. The patient was on rational antibiotic regimen along with regular counselling sessions, which included points regarding the disease, treatment, and the life style modifications. Pharmacists have an essential role in analysing a case study of patients, and result excellence outcomes of the patient and better quality of life.

Keywords: Acute Eczema, Cellulitis, Skin Eruptions

H-134

Effect of Lifestyle Modification in the Management of Diabetes Mellitus Type-II

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Abstract:

The global prevalence of diabetes has risen from 4.7% (1980) to 8.5% (2015) among adults over 18 years of age. . Diabetes and its complications cannot solely be managed with use of anti-diabetic agents therefore non-pharmacological treatment plays a significant role in the management of diabetes. The objective behind the research was to study the effect of exercise and diet management along with the therapeutic management in controlling the blood glucose levels.A prospective comparative case study was conducted at the department of medicine of a tertiary care hospital. Diabetic patients were recruited and randomized into test and control groups. The test group patients receiving anti-diabetic medications and were given education about disease, diet and lifestyle modifications along with patient education leaflets whereas the control group were only taking anti-diabetic medications. Follow up was taken after one month for two consecutive months. Patient's plasma random blood glucose, , food habits and physical workload were assessed. In our study 150 patients were enrolled and it was observed that patients who followed dietary recommendations and physical activity have significant decrease in Random Blood Sugar(RBS) after 1st, 2nd and 3rd follow up (9.39%, 10.33% and 18.45% respectively) as compared to the patients who didn't follow dietary recommendations and physical activity (5.43%. 7.01% and 11.63%) respectively. The RBS of the patients who slept for 7-8 hours was decreased up to 7.52% after the first follow up, decrease in RBS after second follow up was 9.09% and decrease in RBS after two months collectively was found to be 15.61%.Providing information on lifestyle modifications resulted in better treatment outcomes in diabetic patients.

Keywords: Diabetes Mellitus, Lifestyle Modifications, Exercise, Diet Management

H-135

A Case Report on False Pregnancy

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Abstract:

False pregnancy, clinically termed pseudocyesis, is the belief that you are expecting a baby when you are not really carrying a child. People with pseudocyesis have many, if not all, symptoms of pregnancy with the exception of an actual fetus. Some men experience a related phenomenon known as couvade, or sympathetic pregnancy. They will develop many of the same symptoms seen. In a case of false pregnancy, no baby will be seen on the ultrasound, and there won't be any heartbeat. Sometimes, however, the doctor will find some of the physical changes that occur during pregnancy, such as an enlarged uterus and softened cervix. Urine pregnancy tests will always be negative in these cases, with the exception of rare cancers that produce similar hormones to pregnancy. Here I report a case of 33 years female patient admitted in hospital with chief complaints of amenorrhea, morning sickness, weight gain, abdominal enlargement, quickening movements since 5 month due to no pregnancy since 5years and possibly caused due to increase in estrogen, prolactin, and cortisol levels. ultrasound scan was diagnosed as pseudocyesis or false pregnancy.computed tomography of brain did not reveal any abnormalities. She was treated with anti-psychotics (resperidone-3mg/day) and should be under the care of psychotherapist for treatment. It is generally believed that it is caused due to changes in endocrine system of the body leading to secretion of hormones that cause physical changes similar to those during pregnancy.

Keywords: Pseudocyesis, Courage, Amenorrhea, Delusion

H-136

Study of Effective Documentation of Pharmacist Interventions in the Patient's Medical Record

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Abstract:

Documentation is a record of events which outlines the health record of the patient according to what evaluation has occurred, based upon a physical findings, prior test results, assessment, diagnosis, through standardized review of body systems and to document their results using a universally accepted, standardized, systematic process, and what the plan for the patient's treatment is, along with identified health risk factor, patient's progress of the disease, responses, and most importantly changes in the treatment if required. Prescribing errors could result in adverse events and harm to patients. Pharmacist has an identified role in minimizing and preventing such errors. The objective behind the study was to investigate and highlight the importance of performing pharmacist intervention that can change the curing system of the patient, improve the fidelity of the prescription method and improve the patient health condition, patient safety, and increase prescribing efficiency. The study reports on drug errors detected and addressed by clinical pharmacists in numerous health systems. Medications prescribing errors were intervened during the study period by the pharmacist.Most drug errors reported did not result in patient harm, however, severe harm and death due to drug errors were reported. Moreover, over half of the reported errors were corrected and prevented by the clinical pharmacist before the drugs were taken by the patient.

H-137

A Case Report on Situs Inversus with Dextrocardia with Pneumonia

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Abstract:

Dextrocardia is a rare congenital condition in which the apex of the heart is located on the right side of the chest instead of left side of your body. It is a rare condition which affects one in 10,000 people. Less than 1% of the general population is born with dextrocardia. Clinical manifestations include breathing difficulty, bluish skin and lips, fatigue, failure to grow and gain weight and repeated sinus or lung infections like pneumonia. When dextrocardia occurs the organs of the abdomen and lungs will often also be arranged in a mirror image. Diagnosis is based on the presence of signs and symptoms however it is discovered by X-ray or ultrasound, CT scan is typically the preferred method to confirm the diagnosis of dextrocardia with situs inversus. Treatment include pace makers and surgery to repair septal defects can help the heart work normally. Here, I report a case of 11years old boy presented to a walk-in MGM hospital with the chief complaints of high grade fever with chills, productive cough with purulent sputum. He had been ill with influenza and was recovering when the cough developed and his fever returned. He had history of chest pain since 10days. He is a known case of TB in contacts. His chest X - ray showed left lower lobe consolidation and gram stain was positive. He was directed with Tab. Amoxiclav, Syp. Ambroxyl , Tab.

PCM, Inj. Ampoxin and he was treated for pneumonia and advised to follow-up for further echocardiographic evaluation of his cardiac structure. Dextrocardia alongwith pneumonia if untreated, it may lead to severe damage of immune system which affects the quality of life.

Keywords: Dextrocardia, Situs Inversus, Pacemakers

H-138

Drug Use Evaluation and Assessment of Antibiotics Prescribed in Medical Wards of a Secondary Care Hospital

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Abstract:

Drug use evaluation sometimes referred to as drug utilization review, is a system of continuous, systematic, criteria based drug evaluation that ensures the appropriate use of drugs. Antibiotics are powerful medicines that fight bacterial infections. Used properly antibiotics can saves lives. Over usage of antibiotics leads to antibiotic resistance. Our study mainly based on the usage of antibiotics in medical wards of a secondary care hospital.

H-139

A Growing Age with BPH and its Challenges

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Abstract:

BPH usually refers to the palpable enlargement of the prostate gland which means the benign proliferation of the stroma and epithelium. This case study is of a patient who was alcoholic since 10yrs which lead to the scarring of liver cells resulting in portal hypertension. As a complication of PHTN, ascites got developed. In addition BPH caused urinary blockage which resulted in ARF.The case was analysed and studied on the basis of complaints on admission, lab reports and final diagnosis along with patient profile form. Mutual interlink between the different final diagnosis were studied and hypothetical pathogenesis was created. As the patient is aged there had been endocrine changes which lead to the development of BPH. BPH resulted in the urinary retention. Here the urinary obstruction might have lead to ARF which progressed to poorly controlled HTN and activation of RAAS leading to elevation in BP. On the other hand due to increased sympathetic activity (in case of renal failure and hypertensive patients) both HTN and BPH also got aggravated. From the above mentioned pathophysiology we can conclude that BPH is related with ARF and HTN. Further studies should be carried out so that a better pathogenesis can be developed.

Keywords: Alcoholism, PHTN, BPH, ARF

H-140

Risk Factors for Coronary Artery Diesease in a Teritary Care Hospital

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Abstract:

Coronary artery disease (CAD) is the leading cause of death in the world.A cross sectional observational study was carried out in cardiology wards, cardiology out patients and cardiac intensive care unit for a period of eight months from October 2016 to March 2017. Risk factors were identified by direct interview and clinical review in patients with CAD.The study on risk factors for CAD involves increasing age, co morbid diseases like diabetes mellitus and hypertension, social habits like smoking and alcohol. The study concluded that management of these risk factors can decrease the mortality in patients.

Keywords: Coronary Artery Disease, Risk Factors, Age, Diabetes Mellitus

H-141

A Study on Prescription Pattern in the Management of Osteoarthritis and Rheumatoid Arthritis in a Tertiary Care Hospital

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Abstract:

To study the prescription patterns in the management of Osteoarthritis and Rheumatoid arthritis. The prospective observational study performed on outpatients in the Department of Rheumatology of a Tertiary care Hospital. The study shows that out of 100 arthritis cases, 25(25%) are males and 75(75%) are females. OA and RA were commonly seen in female patients [27 (77.1%), 48 (73.8%)] than in male patients [08 (22.9%), 17 (26.2%)] respectively. Age distribution in OA is found to be more prevalent in the age group between 51-60 years (45.7%) and RA is found to be more prevalent in the age group between 41-50 years (35.4%). The study shows that a total of 239 drugs were prescribed, out of which Aceclofenac 10 (26.31 %) and Naproxen 10 (26.31%) were the first choice of drugs prescribed for OA patients and Methotrexate 51 (25.4%) for RA patients. The study concludes Disease modifying anti-rheumatic drugs (DMARDs) as the first line drugs followed by Steroids and Non-steroidal anti-inflammatory drugs (NSAIDs). The first line DMARD was found to be Methotrexate. Combinational therapy was preferred over monotherapy.

Keywords: Prescription Patterns, Rheumatoid Arthritis, Osteoarthritis, Dmards

H-142

A Prospective Observational Study and Drug Use Evaluation in Post- Operative Patients with Analgesics and Antibiotics used in Surgical Wards of a Tertiary Care Hospital

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Abstract:

Drug Use Evaluation is a method that focuses on improving and evaluating medication use processes with goal of improving outcome of patient. Most of the Drug Related Problems such as Adverse Drug reactions, Drug non-compliance can be prevented by Drug Use Evaluation Program. Our study was hospital based prospective observational study conducted in a tertiary care hospital. The duration of the study was 9 months from Nov 2016 to July 2017. The study was done in the department of surgical wards. The study was done by collecting information by using patient case sheets, based on the data a questionnaire prepared Nearly data of 3600 patients were collect which include case history, demographic details and reason for admission, PMH, laboratory parameter and drug dose regimen with frequency were collected. A total of 360 patients who had undergone surgery were admitted in the surgical wards. Out of which 207 males and 153 females, the most frequent affected age group was 21 to 52. In this 54 % were married and remaining are students. Out of this all patients received antibiotics and analgesics as well. The prescriptions are irrational due to the treatment is giving in multiple times for pain. So many interactions are identified during study with analgesics and antibiotics prescribed. Out of 360 patients were of age group between 21 to 52, the most of the people admitted were males 207(57.50%) the analgesics prescribed were diclofenac 153(42.50%), tramadol 153 (42.50%) aceclofenac 108(36%) and least analgesics prescribed were paracetmol 20% and antibiotics were cefatrixone 207 (57.5%), cefpodoxime 162(45%) and the least antibiotic was Gentamycin and the reason for admission was mainly due to orthopedic surgery and trauma, The patients have not have effective in treatment and maximum patients felt as average. The side effects of the drugs are observed and it's mainly of constipation no serious side effects are observed and the drugs evaluation by the physician and advices are very much less and physicians are also not available all the time.

Keywords: Analgesics, Antibiotics, Post-Operative, Surgical Wards

H-143

Effect of Co Morbidities on Target Blood Pressure and Treatment Intensification in Hypertensive Patients

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Abstract:

Hypertensive patients with comorbidity are at risk of poor outcomes; however, there is little information known about the association of comorbidity with outcomes i.e., blood pressure control, treatment intensification and medication adherence. Our aim is to investigate their association with hypertensive patients. A retro-prospective observational study was

conducted on 231 hypertensive patients for six months in Karimnagar. They were assigned as groups i.e., Only HTN (63), HTN with DM (56), HTN with CVA (58) and HTN with CHD (54). Recommended BP control levels were ≤140/90mmHg in general and ≤150/90mmHg in >60yr HTN without any comorbid. The overall BP control rate was 53.67%. HTN with CVA had higher odds of uncontrolled BP (OR 7.38, 95% CI: 3.26 to 16.72, P<0.001) and higher odds of medication non-adherence (OR 2.48, 95% CI: 1.17 to 5.23, P=0.017). HTN with CVA or CHD increased the chance of treatment intensification by 5 fold (P=0.0001/0.0003 respectively). Approximately 1 out of 2 hypertensive patients met BP targets, suggesting that the patients either not treated aggressively enough or not adhered to medication. BP control rates differ substantially within comorbidities. Hypertensive patients with DM or CHD have association with only treatment intensification whereas, medication adherence does not appear to contribute to low rates of BP control. On the contrary, Hypertensive patients with CVA shown poor BP control rates and appear to have association with treatment intensification and medication adherence. Therefore, study directed at improving blood pressure control among hypertensive patients with comorbidities should devote attention to understanding and improving appropriate treatment intensification

Keywords: Hypertensive, Comorbidities, Blood Pressure Control, Treatment Intensification, Medication Adherence

H-144

Assessing the Risk Factors and Pharmacological Treatment Approaches in Heart Failure Patients

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Abstract:

Heart Failure is one of the most common cardiovascular problems leading to morbidity and mortality, particularly in elderly population. Identification and management of risk factors is an important aspect for the treatment of heart failure. This study aims to evaluate the risk factors and prescribing pattern of drugs inthe heart failure patients. A prospective observational study was carried out over a period of sixmonths. A total of 150 patients were enrolled. Patient demographic details, clinical diagnosis including risk factors, comorbidities and drug therapy details were collected from medication chart and analysed. The study results suggest that Coronary Artery Disease (CAD) was the most common (66.7%) risk factor for heart failure followed by hypertension (47.3%) and Diabetes Mellitus (40%). The drugs prescribed for heart failure management include Nitrates (13.38%) followed by Diuretics (12.03%), Beta Blockers (7.66%), ACEIs (6.16%), Calcium Channel Blockers (2.7%), Digitalis (2.25%), Beta Agonist (2.25%) and other class of drugs. Antiplatelet agents and Statins were the most frequently administered drugs as a supportive care in heart failure patients with 25.56 and 14.73 percentage respectively .The identification and management of risk factors can reduce the complications of heart failure which there by reduces the economic burden and improves quality of life.

Keywords: Heart Failure, Risk Factors, Coronary Artery Disease, Treatment

H-145

Prospective Study of Effectiveness of H.Pylori Eradication Therapy and Utilization of Acid Suppressant Medications in Patients with Peptic Ulcer Disease

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Abstract:

The study is to assess the Effectiveness of Helicobacter Pylori Eradication Therapy and Utilization of Acid Suppressant Drugs in patients with Peptic ulcer disease at Gastroenterology department of MMCH hospital at erode on MAY 2017 to OCT 2017. Totally 280 patients profile is taken for the study from this 82 patients age comes below 65 years and 198 patients were above 65 years, Proton pump inhibitors has prescribed to 208 patients by Omeprazole has given to 122 patients followed by Pantoprazole to 87 patients and others PPIs for 71 patients, histamine receptor antagonist has given to 44 patients and other ASMs used to 34 patients.66% patients prescriptions has changed from PPIs to H2RAs and similarly 46% prescription has changed from H2RAs to PPIs. 74% patients prescribed ASDs for 1- 3 month duration and remaining 26% patients receiving over prescribing, ASMs has prescribed to 41% patients is for correct indications (justified) the remaining was considered as unjustified cases. 60 patients undergone H.Pylori eradication therapy, 51 out of 60 patients receives complete H.Pylori eradication by

using Tetracycline,Bismuth chelatewithMetronidazole combination therapy. The current study found that quadruple therapy is highly effective, well tolerated anti-Helicobacter regimen in primary health care setting. General practitioners to review their ASMs prescribing pattern to treat the in appropriate indications and prophylaxis uses.

Keywords: Patient Profile, Effectiveness of Eradication, Prescriptions, Drug Therapy

H-146

Assessing the Rational use of Antibiotics in Hospital

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Abstract:

Hospital is a place where physicians and nurses provide continuous monitoring and care. Despite improving patients' outcomes, there is still a relatively high mortality rate in hospitals in particular, the ICU. The most leading cause of death in ICU is infection and related sepsis.Mortality rate is 5 to 10 times more in ICU patients.Antimicrobials were developed to inhibit the growth of microorganisms.Mostlybroad spectrum antimicrobialswere given as prophylactics in hospitals.The present study deals with the determining therational usage of antibiotics among the patients of ICU and generalward of Vendanta Hospitals, Mangaldas Nagar, Guntur. For the study the list of commonly prescribed anti microbial drugs are analysed and the swab samples from the premises of ICU and general wardswere cultured on agar media, the observed colonies were shifted as inoculum on to the medium for microbiological assay. The most commonly used antibiotic, Ceftriaxone(1g) was used for the assay. There were no traces of growth on the medium after 24 hours of incubation. From the study, it was identified that the premises of ICU and General ward of this hospital are not sterile. Care should be taken to fumigate the ward properly and use of antibiotics was rational.

Keywords: Hospital, ICU, Infection, Anti Microbial Agents, Ceftriaxone

H-147

Assessment of Drug Related Problems in Community Healthcare Setting

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Abstract:

Pharmacotherapy is an important tool to achieve better therapeutic outcomes but it can also result in drug related problems (DRPs). As the DRPs are very in community settings early detection and prevention of DRPs is necessary. The aim of the study was to assess the incidence and pattern of DRPs in community healthcare setting and also to determine the predictors of DRPs. A prospective observational study was conducted in selected community pharmacy. All the relevant data was collected from patient's record and reviewed to detect drug related problems by using Micromedex. All the data were analyzed for various parameters such as incidence, type of DRP, disease conditions, predictors of DRPs and individual drugs implicated in DRPs. A total of 338 DRPs were identified from 605 patients. The incidence of the DRPs was found to be 42% .Most commonly implicated drug class and individual drug was antihypertensive (18.93%) and aspirin (15.08%) respectively. Drug-drug interactions and failure to receive drug accounted for 55.9% and 7.98% respectively while adverse drug reactions accounted for 7.7%. Majority of the ADRs (61.4%) and DDIs (56.61%) were 'moderate' in their severity. Majority (73.51%) of the interactions were found to be pharmacodynamics in nature. The advanced age, comorbid conditions, use of multiple medications and increased number of doses per day were found to be statistically significant (p=<0.05) predictors of drug related problems. The overall incidence of DRPs was high in the community setting. Community pharmacists have greater role to play in early detection, prevention and resolution of drug related problems occurring in the community practice.

Keywords: Drug Related Problems, Pharmacist, Community, Drug-Drug Interaction

H-148

A Case Report on Chronic Insomnia

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Abstract:

Insomnia is difficulty falling asleep or staying asleep, even when a person has the chance to do so. People with in-

somnia can feel dissatisfied with their sleep and usually experience one or more of the following symptoms: fatigue, low energy, difficulty concentrating, mood disturbances, and decreased performance in work or at school. Insomnia may be characterized based on its duration. Acute insomnia is brief and often happens because of life circumstances. Many people may have experienced this type of passing sleep disruption, and it tends to resolve without any treatment. Chronic insomnia is disrupted sleep that occurs at least three nights per week and lasts at least three months. Changes in the environment, unhealthy sleep habits, shift work, other clinical disorders, and certain medications could lead to a long-term pattern of insufficient sleep. People with chronic insomnia may benefit from some form of treatment to help them get back to healthy sleep patterns. Here I report a case of 65 years male patient was admitted in hospital with chief complaints of sleeplessness since one month due to stress.The patient was treated with clonazepam 0.5 gms,Nitrazepam 10mg, Mirtazapine 7.5mg for about 4 years. Drug Clonazepam is actually contraindicated for the people suffering from glaucoma. But In this case the patient was found to get glaucoma after two years even though the drug was not abandoned either it might be because of physician's wrong perspective or absence of other alternative drug for insomnia.

Keywords: Insomnia, Glaucoma

H-149

A Case Study on Actinomycosis Foot

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Abstract:

Actinomycosis is a rare infectious disease caused by the actinomyces species (actinomyces israelii & actinomyces gereseriae). The prevalence of Actinomycosis infections are 70% due to actinomyces israelii and gereseriae. These bacteria are present in the mouth, intestine and in female reproductive system as commensal. Trauma, foreign bodies or poor oral hygiene may favor tissue invasion. These bacteria cause infections when mucosal layer is damaged. The clinical manifestations are painful abscess in the mouth, lungs, breast and gastrointestinal tract. In severe cases the infection spreads to the bone. In this case the patient is having Actinomycosis foot which is a rare bacterial infection. We observed a case of actinomycosis foot in Santhiram medical college and general hospital with chief complaints of pain and swelling over right foot since 3 months. Skin culture test revealed presence of actinomyces species (A.israelii).The treatment plan followed was surgery (cyst excision). Actinomycosis is a rare bacterial infection at foot region. Surgery is the better way to treat Actinomycosis. We counseled the patient regarding the disease, medications, and hygienic environment, healthy diet (iron rich food) which helps the patient recover fast and prevents the reoccurrence.

Keywords: Actinomycosis, Foot, Cyst Excision.

H-150

A special focus on prevalence of depression in diabetic patients in a tertiary care hospital

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Abstract:

Diabetes mellitus (DM) is one of the most common chronic medical diseases worldwide with an estimated prevalence of detected DM being 3 to 4% in the general population. Depression is a major public health problem associated with substantial suffering, reduced functioning decreased quality of life along with higher health care utilization and costs and disability in general, depression is associated with chronic illness and in diabetes in particular. In the present study, the goal was to detect the prevalence of depression in diabetic patients in a tertiary care hospital the study design was Prospective observational study was conducted for a period of 6 months in Santhiram general hospital, Nandyal. In the study we included 230 subjects who are diagnosed with type 2 diabetes.

Keywords: Diabetes, Depression, Prevalence, PHQ, 9 Scale

H-151

Assessment of Hospital Pharmacist Role on Medication Adherence andnd Practice of Hypertensive Patients in a Private Multi-Specialty Hospital

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Abstract:

Hypertension is becoming one of common issue in developing countries. It is immensely co-related to different factors like aging of the populations, socioeconomic Changes favoring sedentary habits, obesity, alcohol Consumption, salt intake and urbanization. For obtaining optimum result in hypertension management, both pharmacological treatment and non-pharmacological life style modifications are to be taken care, Lifestyle measures for lowering BP include more exercise, reduced sodium chloride intake, focus on overweight etc. This was a prospective, open label study which is aimed to determine the impact of hospital pharmacist education on patient's adherence, and practice on hypertension in a private multispecialty hospital. The study was approved by ethical committee. A patient information leaflet was prepared which contains questionnaire for demographic data, basic medication usage, and practice of hypertension. The details were collected from an interview and prescriptions. Patients were informed to meet doctor monthly once for three months. Each time at the end of interview patients received counseling regarding their disease and medication usage. At each meeting blood pressure and adherence were assessed. Medication adherence and practice of hypertension were assessed at first and forth visit. The study concluded that, at baseline most of patients exhibited poor adherence to their therapy. This was reflected in their inadequate blood pressure control. At the end of the three month study period, the patients who had received extensive counseling from a pharmacist regarding their disease and its management showed a greater improvement in treatment outcomes, adherence, and practice.

Keywords: Adherence, Lifestyle Measures, Counseling, Treatment Outcomes

H-152

Medication Therapy Management in Pharmacy Practice and Pharmacoeconomic Outcomes

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Abstract:

Medication therapy management (MTM) is medical care provided by pharmacists whose aim is to optimize drug therapy and improve therapeutic outcomes for patients.Data from retrospective analysis and stand-alone basic plan beneficiaries participating in MTM programs.The trial is designed as a randomized controlled study of an MTM program structured to prioritize patient safety that is being conducted at three sites. The main components of the patient safety-oriented MTM model used in this study are medication reconciliation (MR), assessment of DRPs, and resolution of identified DRPs. Data from retrospective analysis of MA-PD and stand-alone basic PDP plan beneficiaries participating in MTM programs showed that participants with congestive heart failure (CHF), chronic obstructive pulmonary disease (COPD), and diabetes had significantly higher rates of adherence than similarly situated beneficiaries not enrolled in MTM programs (approximately 11- 40 percent higher for those with CHF, 11-26 percent higher for those with COPD, and 15-35 percent higher for those with diabetes, compared to the respective control populations).PDP beneficiaries with diabetes or CHF who also received CMR also had decreased utilization and costs for Medicare Parts A and B (Rs 24000/- and Rs 32000/- reduction in inpatient costs, respectively, after risk-adjustment), although similar results were not statistically significant for those with COPD or for MTM participants who did not receive a CMR. The interventions resulting from the MTM service contributed to improve or to maintain the PD patients' quality of life, especially their emotional wellbeing. MTM had a positive effect in the decrease of medicine-related problems, especially regarding improvements in the treatment adherence. These results represent clinical and humanistic outcomes of the MTM service.

Keywords: Medication Therapy, Cost Reduction, Patient Safety

H-153

Aadhaar Card Linked Prescription System for the Prevention of Irrational use of Antibiotics in India

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Abstract:

Antibiotics resistance is the matter of concern of WHO &India is amongst the countries where highest rates of antibiotic resistance are seen. Recent report showed that the antibiotics resistance is increasing due to irrational and inappropriate use for the treatment of various infectious & non-infectious diseases. The use of antibiotics are essential in many life-threatening diseases whereas overuse & misuse of antibiotics can be dis-

astrous in the long run. Therefore, rational use of antibiotics is required. Healthcare professional must think about the acceptable strategies for rational use of antibiotics. However, Major challenge to prevent irrational use of antibiotics is the absence of a good surveillance or monitoring system for prescriptions & sale of antibiotics. Implementation of e-health care system using Aadhaar card can be thought about.A12 digit unique identification number "Aadhaar" is provided by Indian Government agency i.e. Unique Identification Authority of India(UIDAI). World's largest biometric ID system Aadhaar is having 1.171 billion people enrollment. Till date over 95% of Indians had been enrolled in Aadhaar & its use is limited for public distribution system like kerosene, LPG, fertilizer distribution system and for opening bank accounts. This UIDAI system could be effectively used for management of healthcare system including drug prescription records. The objective of this paper is to propose a model for providing Aadhaar card linked prescription system for the effective management of antibiotic and other drugs.

Keywords: Aadhaar Card, Antibiotic Resistance, Prescriptions

H-154

Hypertension-Prescription Pattern and Control in Patients attending on Outpatient Department in a Tertiary Care Hospital

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Abstract:

The study is aimed at determining the prescribing pattern and control of antihypertensive drugs in hypertensive patients at a tertiary care hospital, depending on the level of their blood pressure. As there is a growing evidence of irrational prescribing of antihypertensive, which leads to an increased cost burden on health care system, so it is necessary to analyze the prescribing patterns and the extent of adherence to prescribing guidelines, by the prescribers. This study will help to find out the prescribing pattern of antihypertensive. This study is Prospective Observational study conducted in outpatient Department of Medicine, MES Medical College, Perinthalmanna. Study population who satisfy the inclusion criteria and exclusion criteria. Study period is 6 months and sample size 200 patients. Inclusion criteria are patients treated with antihypertensive agents, of either gender ≥18 years of age. Exclusion criteria are patients from all department, except medicine department, pregnancy and breast feeding and patients with improperly and incompletely prescription. From these study calcium channel blockers are found to be more commonly prescribed compared to the other antihypertensive drugs. From the all antihypertensive drugs calcium channel blockers accounts for 50.34%, followed by ARBs 24.13%, ACEIs 18.62%, Beta blockers 6.89% and least common agent was diuretics.

Key words: JNC, Dietary Approaches to Stop Hypertension, Diabetes Mellitus, BMI

H-155

An Epidemiological Study of Adverse Drug Reactions of Short and Long Term Administration of Methotrexate in Rheumatoid Arthritis

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Abstract:

The aim of the study is to conduct the surveillance of Adverse Drug Reactions on short and long term administration of Methotrexate. The objectives of this study are to assess the causality, severity, probability and preventability of the Adverse Drug Reaction reported by using assessment scales. A total of 300 cases were covered in this cross sectional study on rheumatoid arthritis, out of which 15.66%were males and 84.33% were females. Out of300 cases collected, adverse effects were observed in 23.66% of subjects in which 90.14% were females and 9.85% were males. The most common adverse reactions identified in our study are gastrointestinal problems and alopecia. Some serious complications related to liver like altered SGOT and SGPT levels are also seen. These adverse reactions were found in the percentage of 0.33% to 2.66%. Majority of the adverse reactions are seen in females of the age group 41-60. Least number of adverse reactions was observed in the age group of < 20.The most common adverse reactions identified in our study are gastrointestinal problems and alopecia. Some serious complications related to liver like altered SGOT and SGPT levels are also seen. from our observational study, we conclude that Methotrexate taken in correct dose and dosage form causes minor adverse reactions in very less percentage of the patients who are treated for Rheumatoid Arthritis as long as the folic acid supplement is taken regularly.

Keywords: ADR, Methotrexate, Rheumatoid Arthritis

H-156

Knowledge Attitude and Practice of Community Pharmacists Towards Adverse Drug Reaction Reporting

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Abstract:

Adverse drug reaction is defined as one which is noxious and unintended and which occurs in doses normally used in humans for prophylaxis, diagnosis or therapy of disease or for the modification of physiological functions.The study was a Prospective Questionnaire based study conducted in Community Pharmacies located in Rajahmundry urban area for a period of 3 months. A well designed questionnaire was prepared with the help of HCP's and it is validated. The contents of the questionnaire was explained to the Community Pharmacists working in the Community Pharmacies and asked to answer the Questionnaire. Prior permission was taken from the Drug Inspectors of the Particular area. After Collecting the answered questionnaire it was analysed to assess the knowledge regarding the study. A total of 165 Pharmacists were asked to participate in the study out of which 138 are participated in the study. In this study Male Pharmacists (113) and Female Pharmacists (25) are participated. The results shows that only 84 were know about what is ADR.116 patients don't know about national PV Programme. Only 21 knows about national PV Programme.Out of which 11 persons know about regional reporting centers .Only 6 persons knows about nearest AMC's. Only37 Community Pharmacists are thinking that all the drugs available in the market are safe. The overall conclusion of the study is concluded that there is a need of Awareness in increasing the knowledge attitude and practice of Community pharmacists. It will increase the attitude of community pharmacists towards ADR Reporting and their by they will involve in safe guarding the people.

H-157

A Study on daily exercise activity among general population

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Abstract:

Exercise is any physical activity that maintains the fitness of the body and keeps our mind calm. Exercise is one of the most important aspects of life which is often neglected. The many benefits of exercise are not fully understood by the society. The Centers for Disease Control and Prevention recommends 30 min of exercise for at least 5 days a week for all healthy individuals. There are many types of exercises like walking, jogging, yoga, aerobic exercise with each one having its own effect on our body. The objective of the study is to analyze the people who exercise and to check their knowledge about the benefits of exercise. An online survey was conducted among the general public with the help of a questionnaire. 268 responses were received among which 176 were female and 92 were male. It was found that about 151 people exercised among which only 56 people exercised every day, 75 people exercised sometimes, 20 people exercised 4-5 times in a week . It was found that 117 people did not exercise at all. Among the population of people who exercise majority of the people exercise sometimes. Even though a good number of people exercise but very few people exercise every day. Majority of the people exercise for weight reduction, they do not aim for complete body fitness. As the sample size is small the data maybe insufficient more study can be done.

Keywords: Exercise, Body health, Fitness.

H-158

An overview on Drug Information Service and Drug Information Bulletin

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Abstract:

Polypharmacy and complex drug treatment regimens are turning out to be progressively basic, which may lead to drug interactions, adverse drug reactions and increasing costs and thus challenge the rational use of drugs. At the same time, the openness of drug information increases, and health care experts may have limited opportunities and capabilities to search and critically evaluate drug information. Clinicians have reported troubles in searching the best data and translating study conclusion into clinically significant information applicable to specific patients. Thus Drug information service has been established. The service should include collecting, reviewing,

evaluating, indexing and distributing information on drugs to health workers. Drug and poisons information centers are best established within major teaching hospitals.Information present in the current presentation will not only enlighten the role of Drug information service but also focused on Drug information bulletin.

Keywords: Drug Information Service, Drug Information Bulletin, Inappropriate Prescribing

H-159

Prescription Pattern of NSAIDS and the Prevalence of Adverse Effects

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Abstract:

NSAIDS are widely used and misused group of drugs. They have analgesic, antipyretic and anti inflammatory action in different measures. They are commonly used as many are OTC drugs. People are not concerned about the after effect because of its rapid healing action. The survey is to analyze the prescription errors of NSAIDS, number of NSAIDS per prescription, presence of ace inhibitors or diuretics along with NSAIDS. These drugs acts by inhibiting cyclooxygenase 1 and 2 which is the enzyme for the conversion of arachidonic acid to prostaglandin. Major ADR by the NSAIDS are gastrointestinal like gastric bleeding, gastric irritation, erosion,peptic ulceration.Renal failureis seen when the patient takes ACE inhibitors and diuretics along with NSAIDS, so called triple "whamming effect".These provide symptomatic relief from dental, menstrual pain,post operative pain, headache and migraine. It isalso given in neonates whose ductusarteriosus has not close within 24 hours of birth.They are often taken without prescription for minor aches and pains. Case series from 213prescriptions were done.From theseparacetamol was used most commonly98 whileAspirin is-for 86.Since the NSAID have a property to reduce the action of antihypertensive this also analysed, 28 patient who have HTN using ACE inhibitors and Diuretics along with NSAIDS.

Keywords: Aspirin, Paracetamol, Gastric bleeding

H-160

A Study on Overuse of Dietary Substitute as Dietary Supplement

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Abstract:

The purpose of this study was to explore assess to consumers knowledge ,practices and attitudes regarding the use of dietary supplement and to determine the prevalence of supplement use in general. Dietary supplement are considered neither as food nor as drug. Presently, around 80% of the world's population uses dietary supplement which has steadily increased over time. We conducted a survey in general population above 18. From 214 participant 53% men and 51% was women in which 44 % women and 18% men have used dietary supplements in past years. Dietary supplements are most frequently used and for which there is little evidence of beneficial effects in certain specific situations. They may be purchased without prescription and federal regulation of these products differs significantly from that of food or drugs. 18% of our participants takes supplements without the recommendation ,thus higher intake and Repeated use of specific supplements might have allowed attainment of steady state Pharmacokinetics ,which might cause harmful effects , so to foster better nutritional and health status consumer should read labels carefully and consult their health care provider to ensure appropriate dietary supplement use. Thus from our study, we concluded dietary supplements should be used as what they are not as substitutes. Over 50% of participants believed DS to be essential to health, only 42% felt confident in choosing appropriate DS for themselves. So efforts to monitor dietary supplement behaviour and methods that may improve the accuracy of assessment and monitoring should be encouraged.

Keywords: Dietary Supplements, Vitamins, Minerals, Harmful Effects

H-161

Pulmonary Tuberculosis Associated Anemia in Telangana-Case Series

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Abstract:

In developing countries pulmonary tuberculosis(PT) is still a common disease. Different types of hematological chang-

es have been seen in patient's with PT such as iron deficiency anemia, hemolytic anemia and folate deficiency anemia. Here, we reported 3 cases of PT associated with anemia of both gender and varying age group. From the laboratory investigations of the 3 cases presence of anemia can be found in PT patients. Case 1 , 62 years old female patient and case 2, 59 years old male patient were diagnosed with iron deficiency anemia(IDA) and case 3 , 57years old male patient was diagnosed with hemolytic anemia. Anemia is the most common hematological disorder in pulmonary TB patients. It can be resolved with proper anti- tubercular therapy with iron and mineral supplements. Proper observation and counselling to patient is needed to be aware about the compliance and importance in anti- tubercular therapy.

H-162

Effect of Registered Medical Practitioner Treatment (Rmp) on Rural Area Population-A Pharmacovigilant Approach

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Abstract:

In developing countries like India, majority of healthcare is borne to private sector, resulting that most of the people levy on local /available unrecognized medical practitioners. The RMP's are very popular in the rural areas and urban slums because they are the primary contact in the medical emergencies that leads to some drug related errors, adverse effects and interactions. The quality of life in developing countries can be improved by enhancing the standards of medical treatment at all levels of the health care delivery system. This can be achieved through interventions, continuous medical education programs, effective implementation of therapeutic strategies. Our investigation is to study about the impact of RMP's treatment and to ensure the drug safety by clinical pharmacy services in rural India.

H-163

A Study of Clinical Findings of Dengue Fever in Urban Hospital and its Prevention and Control

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Abstract:

Dengue fever and dengue hemorrhagic fever (DHF) are acute febrile diseases, found in the tropics, with a geographical spread similar to malaria. Dengue virus (DEN) is a small single-stranded RNA virus comprising four distinct serotypes (DEN-1 to -4).These closely related serotypes of the dengue virus belong to the genus Flavivirus, family Flaviviridae. Dengue fever has been reported from India over a long time, but dengue haemorrhagic fever was first reported in 1963 from Calcutta city. According to WHO, During the past five decades, the incidence of dengue has increased 30-fold.Up to 50-100 million infections are now estimated to occur annually in over 100 (only 9 counties in 1955) endemic countries. Almost half of the world's population at risk. Disease occurs more frequently in the rainy season and immediately afterwards (July to October) in India. .The rapidly expanding female aedes bite Dengue is a public health challenge with an economic burden that can be turn aside by licensed vaccines, ayurvedic treatments (papaya,kalmegh,Amrita,) or vector restraint strategies. This review highlights present contemporaneous about dengue, including clinical manifestations, pathogenesis, diagnostic tests and especilally how can ayurvedic medicine (i.e natural & ancient Indian medicine) cure dengue, its management & prevention.

Keywords: Dengue, Dengue Hemorrhagic Fever, Dengue Shock Syndrome

H-164

Role of Clinical Pharmacist in Interpretation of Liver Function Test and Dose Adjustments in Patients with Hepatic Impairement

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Abstract:

Hepatic impairment may lead to failure to form active and inactive metabolite, drug accumulation, and increased bioavailability after oral administration, possible alteration in drug protein binding, and kidney function. The objective of the study was to assess the role of clinical pharmacist in monitoring hepatic function and suggestion of an appropriate dosage regimen and find out the formulas for dose adjustment in hepatic failure patients.Clinical pharmacist will identify patients receiv-

ing these drugs on daily basis review their demographic data and assess laboratory findings and give interventions if needed. Pharmacokinetic and physiologic factors are relevant in considering dosage of a drug in patients with hepatic impairment. The LFT assess the liver has been damaged; with the presence of clinical pharmacist we can identify the effect of the drugs in liver function test. Starting therapy with low doses and monitoring response or plasma levels provide the best opportunity for safe, efficacious treatment. The study concluded that in hepatic impairment, the dose adjustment of drugs and determines the exact clinical significance of laboratory investigations are required to prevent drug accumulation and thus avoiding of toxicity or decreasing drug-related adverse effect and decreasing hospitalization stay and costs so the Presence of clinical pharmacist is important in hospital.

Keywords: LFT, Hepatic Impairment

H-165

Strategies for Clinical findings and Pharmacotherapy Management of a *Necrotizing fasciitis* for the Betterment of Patient's Quality of Life and Financial Status

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Abstract:

Necrotizing fasciitis (NF) is a rare and life-threatening infection that involves deep soft tissue; it is characterized by widespread fascial necrosis, with a mortality rate of 25-73%. The current research explores the early diagnosis of necrotising fasciitis and its beneficial outcomes. A prospective and observational study was conducted for a period of 6 months in the Department of Surgery at Shri B.M. Patil Medical College Hospital and Research Centre. A total of 80 patients were enrolled to extract the necessary data. Major factors contributing to the development of Necrotizing fasciitis were analyzed and the micro-organisms involved were provided. The NF was affected in geriatricians, in the age group of 60-70 years. The clinical symptoms of NF were fever, swelling, pain and pus discharge. Early diagnosis of disease is useful for determining the causative organisms involved and establish the specific antibiotic therapy, which further curtail the severity of infection and length of the hospital stay. Supportive therapy is essential component of treatment regimen in order to improve the quality of life of a patent and symptomatic management. Early diagnosis and specific antibiotic therapy with supportive symptomatic management improve the quality of life of a patient and reduce the financial burden.

Keywords: Necrotizing fasciitis; Microorganism; Pharmacotherapy; Quality of life; financial status.

H-166

Estimation of Prevalance on Self Medication Among Pharmacy Students

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Abstract:

This study aims to provide the basic information on self medication practices among health sciences students in Hindu college of pharmacy which is affiliated to Acharya Nagarjuna University, A.P, India . It also estimates the prevalence of self medication in the study population. There is evidence that more and more people are taking greater responsibility for their own health , as witnessed by the self help movement of seventies and boom in herbal shows the little sign of abating. A self-administrated questionarie based on google form was created and was send for more than 200 students for their email address, based on calculated sample size using raosoft sample size caluculator. Pharmacy students of different catagories were analysed that B.pharmacy students - 116 students there is 59.8% and Pharma D students for 60 students 31% and M.pharmacy students for 18 students -9.2%. Self medication is prominent among the pharmacy students with 76% of respondents using some form of medications ,mostly pain killers and anti histamines. :

Keywords: Raosoft Sample Size Caluculator, Prevalence

H-167

Collaborative Practice for better Health Outcomes

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ana, India-135001
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Abstract:

Strong working relationships between pharmacists and physicians are needed to optimize patient care. Understanding attitudes and barriers to collaboration between pharmacists and physicians and the solution to these barriers as well as attitudes may help in better delivery of primary health care services. Our objective is to capture the opinions of physiciansand pharmacists regarding collaborative practice and thus it will help in determination of improvement in medication management. This practice will benefit the patients, pharmacists, and physicians. The benefits are: Benefits for patients: More informed care from physician and pharmacist, Better adherence to medication regimens, fewer hospital readmits, Lower insurance costs.Benefits for pharmacists: The ability to see the patient through a wider lens, the ability to integrate services like vaccinations into the pharmacy's offering, the ability to build deeper, lasting relationships with patients by positioning the pharmacy as an integral part of community healthcare. Benefits for physicians: Fewer office visits alleviates pressure on the healthcare system and the patient, the ability to work with a partner who is specifically trained in medications, drug interactions, Reduction of medication errors, with more eyes on all phases of a patient's treatment plan. Thus removal of barriers like lack of Compensation, Need to Collaborate with Multiple Pharmacists, Lack of Decision Makingand Personal Comfort Zone will be helpful for better diagnosis.Thus, Collaborative pharmacy practice is truly an idea in which pharmacists are well-positioned to serve an active role in treating and managing many chronic diseases.

H-168

A Survey Based Study on Diabetic Foot Ulcer Management in a Tertiary Care Hospital

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Abstract:

Diabetic foot ulcer is a common complication of diabetic world over. We conducted this study to determine commonly prescribed therapy in diabetic foot ulcer at a tertiary care hospital and their management, 50 postsurgical patients were selected in based on inclusion and exclusion criteria. Patients were treated with anti –microbial agents the comparison of mono, dual and triple therapy is studied.

Keywords: Diabetic Foot Ulcer, Debridement, Anti-Microbial

H-169

Nux Vomica - A Research Prospective

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Abstract:

The medicine in present era is much advanced and evidence based. Ayurveda offers a unique opportunity to evolve a science of healthy, harmonious and long life. Therapeutic efficacy of any drug or formulation mainly depends on quality control of pharmaceutical processes. A great argument is emerging time to time that the Rasa drugs like Strychnos Nux-vomica are toxic which may harm to body. The medicinal herb Strychnos nux-vomica known for its medicinal values in alternative systems of (Ayurveda, Unani, Siddha, Homeopathy and Chinese) holistic health and herbal medicine. It is clearly mentioned in Ayurveda that this drug should be purified and detoxified first. Strychnos nux-vomica is an evergreen tree native to the Andhra Pradesh, India and it is used for diseases of the digestive tract, disorders of the heart, circulatory system and in skin diseases. It is also used for nerve conditions, depression, migraine headache, symptoms of menopause, and a blood vessel disorder called Raynaud's disease. Brucine is the active component in traditional Chinese medicine with capabilities of analgesic, anti-inflammatory, anti-tumor and so on. The purpose of this review is to provide comprehensive and relevant information on the utilization of Strychnos nux-vomica Linn. (Loganiaceae), used for the treatment of various diseases. Currently researcher's thrust area to use nux vomica for the life frightening diseases like cancer, and diabetes.

Keywords: Strychnos Nux-Vomica, Brucin, Anti-Cancer, Anti-Diabetic

H-170

Role of Pharmacists in Counseling of Asthmatic for Better Drug Compliance

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Abstract:

Multi-drug treatment is necessary for control of the asthma, but it can be well managed by diet, physical exercise and stress management, rational utilization of drugs and devices. Patient ignorance and poor compliance are the main hurdles in the management of asthma. There is a need to overcome these problems and increase the patient compliance by counseling about, diet, importance of yoga and exercise, stress management, impact of addiction, safe use of drugs and devices. The role of pharmacist in counseling of asthmatics for better drug compliance can also be achieved by patient counseling and educating the patients for proper and safe use of inhalers. The pharmacist should also monitor the safe use of drug. Certain drugs like Beta blockers (including eye drops), aspirin and NSAID, hypotonic nebulizer solution or solution with preservative, ACE inhibitors should be avoided as they can induce asthma. We found patient ignorance and poor compliance are the main problems in the management of asthma. Due to rapid civilization and modernization lifestyle of each individual is changing and furthermore environmental factors have a great deal of impact on asthma. Thus the pharmacist is the person who can be actively involved in the counseling of asthmatics by guiding about diet, importance of yoga and exercise, stress management, impact of addiction, safe use of drugs and devices. In this way pharmacist can be a good counselor for asthmatic and can help to increase patient compliance.

H-171

Scope of Clinical Pharmacist in Management of Drug-Food Interactions

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Abstract:

Drug-food interactions in hospitalised patients may result in decreased drug efficacy or increased drug toxicity. Healthcare providers should develop methods for identifying and preventing clinically significant drug-food interactions. This is a retrospective, observational study conducted over a period of 1 year on a population of 20 patients. Inclusion criteria consists of hospitalized patients. The data was evaluated using Micromedex, drugs.com, Medscape. Reviewed data suggest that drug treatment should be increasingly custom tailored to suit the individual patient and that appropriately co-prescribed diet and herbal remedies, could increase drug efficacy and lessen drug toxicity. Drug–food interactions have garnered attention. Interdisciplinary communication among medical doctors, and dietetic experts needs to be improved and encouraged. Internet resources for obtaining current information regarding drug–drug, drug–herb, and drug–nutrient interactions are provided. Results showed that most of the drug-food interventions haveoccurred during the administration of antibiotics and inappropriate follow up of diet. Antibiotics are part of every patient's treatment chart and lack of proper awareness in patients about diet to be followed, have resulted in interactions.This study helps to assess the importance of clinical pharmacist in managing drug-food interactions in hospitalized patients.

Keywords: Clinical Pharmacist, Drug-Food, Healthcare Providers, Retrospective, Micromedex

H-172

Neurocystucrcosis in Paediatrics - A Case Report

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Abstract:

Stevens-Johnson syndrome is a rare, serious disorder of your skin and mucous membranes. It's usually a reaction to a medication or an infection. It affects 1-2 million people each year. Stevens-Johnson syndrome is a medical emergency that usually requires hospitalization. Treatment focuses on eliminating the underlying cause, controlling symptoms and minimizing complications as your skin re grows. Recovery after Stevens-Johnson syndrome can take weeks to months, depending on the severity of your condition. If it was caused by a medication, you'll need to permanently avoid that drug and others closely related to it. Here, we are presenting a case of a 61 year old male patient who was a known case of tuberculoma with neurocysticercosis. During the therapy in the hospital he develop rashes on his body due to the anti- tubercular drugs (AKT4).

Keywords: Steven-Johnson Syndrome, Tuberculoma, Anti-Tubercular Drugs

H-173

Evaluation of Prescription Pattern of Antibiotics for Surgical Prophylaxis in Secondary Care Hospital

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Abstract:

Antibiotic prophylaxis is defined as the prevention of infections using antibiotics. Antibiotics for surgical prophylaxis are the prevention of surgical site infection. This study evaluates the rational use of antibiotics prophylaxis prior to surgery amongst hospitalized patients. Objectives of the study were to investigate the utilization and evaluation pattern of antibiotics for surgical prophylaxis in surgery department. A prospective observational study was conducted for a period of 8 weekson 100 patients receiving antibiotics in the Surgery Department of a secondary care hospital. The results were observed and evaluated for the appropriate use of prophylaxis of antibiotics. Majority of patients were of age group 18-30 years, followed by 41-50 years, 51-60 years, and majority were reported in female patients than male. 86 (86%) patients were prescribed with Cephalosporin, 64 (64%) followed by Amino glycosides, 53 (53%) followed by Ampicillin, 19 (19%) patients were prescribed with Antiameobiasis and 15 (15%) with Fluoroquinolones. The overall scenario of antibiotic usage in a Hospital was as per standard recommendations and all the antibiotics used were according to their standard adult and titrated doses and frequencies. In this study we found that Cephalosporin, Penicillin, Amino glycosides and Nitroimidazole were mostly used classes of drug. Adverse Drug Reactions were minor and well managed.

Keywords: Antibiotic, Adverse Drug Reaction, Prophylaxis, Surgical Site Infection

H-174

Knowledge, Attitude, and Practices on Vector-borne disease in Guntur (A.P)

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Abstract:

Outbreaks of vector-borne diseases (VBDs) such as dengue and malaria can overcome while health systems in resource-poor countries. Environmental management plane that reduce or eliminate vector breeding sites combined with improved personal prevention strategies can help to significantly reduce transmission of these infections.. The aim of this study was to prove the knowledge, attitudes, and practices (KAPs) of residents in Guntur (A.P) regarding control of mosquito vectors and protection from mosquito bites. A cross-sectional study was conducted between May and August 2017 among patients or family members of patients waiting to be seen at hospitals in Guntur (A.P). Participants completed an interviewer-administered questions on socio demographic factors and KAPs regarding VBDs. KAP scores were calculated and categorized as high or low based on the number of correct or positive responses. In all, 150 (85 men and 65 women) people participated in the study. Most participants (87%) scored low on knowledge and practice items (78%). Conversely, 78% scored high on attitude items. By multivariate logistic regression, housewives were 82% less likely than laborers to have high attitude scores. The study revealed poor knowledge of VBDs and poor prevention practices among participants. It identified specific groups that can be targeted with vector control and personal protection to decrease transmission of the infections.

Keywords: Dengue, Malaria, Vector Born Disease

H-175

Drug Utilization Evaluation of Anti-Diabetic Drugs among Patients with Type II Diabetes Mellitus in a Tertiary Care Hospital

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Abstract:

The aim was to evaluate the drug utilization pattern of anti-diabetic drugs in patients with Type II diabetes mellitus in a tertiary care hospital. A prospective observational study was carried out in diabetic patients of different age group visiting the outpatient Departments of General Medicine and Endocrinology of a tertiary care hospital for duration of four months. In this study Demographic data, drug utilization patterns of anti-diabetic drugs were summarized. During the study period, a total of 86 prescriptions were assessed out of which, 37(43.02%) were females and 49(56.98%) were males. Out of 86 patients 27(31.40%) patients were on Monotherapy, 43(50.0%) were on

Combination therapy and 16(18.60) were indication without drug. 37(49.33%) of the total drugs were fixed-dose combinations. Two, three and four drugs were prescribed in 25(29.07%), 14(16.28%) and 4 (4.65%) patients, respectively. 3drugs per prescription and 0.87 antidiabetic drugs were prescribed. Among these patients, the greatest numbers were in the age group of 51–60 years i.e. 28 (32.56%). A total of (258) drugs were prescribed. Of which 75 (29.06%) antidiabetics, were prescribed. Amongst antidiabetics, the most frequently prescribed drugs were insulin 39 (52.00%), metformin 9 (12.00%), glimepiride 8 (10.67%) followed by teneligliptin 4 (5.33%) and pioglitazone 4 (5.33%).Hypertension was the most common co-morbid seen. From this study we can conclude that insulin was the most commonly used drug. The prescribing trend also appears to be moving towards combination therapy particularly two drug therapy.

Keywords: Drug Utilization, Diabetes Mellitus, Anti-Diabetic Drug

H-176

A Case Study on Epidermiolysis Bullosa

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Abstract:

Epidermolysis bullosa is a group of rare genetic connective tissue disease that cause blisters on the skin and mucosal membranes with an incidence of 20 per million newborn. It is a result of a defect in anchoring between the epidermis and dermis resulting in friction and skin fragility. A 1 year old male child with Epidermiolysis bullosa (BUTTERFLYCHILDREN) associated with immune suppression was admitted to hospital with complaints of fever, muscular weakness. On physical examination, prominent rash on the face and dorsal side were noticed which caused difficulty to sleep and wear clothes. There was a noted variation in the weight of the patient (i.e.3 kg less than the normal). This leads to complications like chronic constipation, malnutrition, dysphagia, chronic anemia, rarely dilated cardiomyopathy and osteoporosis. Epidermolysis bullosa is a rare genetic disease which has no cure but can be monitored by maintaining proper skin care and good diet to prevent blisters and infection.

Keywords: Epidermolysisbulllosa, Butterfly Children, Immune Suppression, Dysphagia, Anemia

H-177

Non Pegylated Doxorubicin Formulation in Cancer Therapy

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Abstract:

The burden of cancer is continuously increasing, and is rapidly becoming a global pandemic. The first liposomal encapsulated anticancer drug which received clinical approval against malignancies including solid tumours, transplantable leukemias and lymphomas was Doxorubicin HCl. This review is aimed at providing an overview of doxorubicin in cancer therapy. Pegylated liposomal doxorubicin has a polyethylene glycol (PEG) layer around doxorubicin-containing liposome as the result of a process known as pegylation. Non-pegylated liposomal doxorubicin (NPLD) was developed to overcome the drawbacks associated with previous formulations. Nudoxa® (NPLD) with its unique drug delivery system offers the benefit of pegylated liposomal doxorubicin without hand foot syndrome as the major side effect. nudoxa® (NPLD) with its unique drug-delivery system is a breakthrough in cancer therapy as it offers the benefit of pegylated liposomal doxorubicin without its major side-effects like HFS. Further, it decreased the toxicity and other adverse events such as nausea, vomiting, and alopecia.

Keywords: Liposomal, Nonpegylated, Nudoxa, Pegylated

H-178

Telehealth - Boom in the Management of Non Critical Emergencies in Health Sector

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Abstract:

With the escalating costs of health care, issues with recruitment and retention of health practitioners in rural areas, and poor economies of scale, the question of delivering people to services or services to people is a dilemma for health authorities around the world. People living in rural areas have poorer health outcomes compared to their urban counterparts, and the problem of how to provide health care and deliver services

in rural locations is an ongoing challenge. Telehealth services can efficiently and effectively improve access to healthcare for people living in rural and remote areas of India. However, telehealth services are not mainstream or routinely available in many rural and remote locations. A systematic literature review of peer-reviewed and grey literature was undertaken. Electronic databases were searched for potentially relevant articles. Reference lists of retrieved articles and the grey literature were also searched. Searches identified 970 potentially eligible articles published between 1988 and 2015. Studies and manuscripts of any type were included if they described telehealth services (store-and-forward or real-time videoconferencing) to provide clinical service or education and training related to health care in rural or remote locations of India. Data were extracted according to pre-defined criteria and checked for completeness and accuracy by a second reviewer. Any disagreements were resolved with discussion with a third researcher. All articles were appraised for quality and levels of evidence. Data were collated and grouped into categories including clinical speciality, disciplines involved, geographical location and the role of the service. Data relating to the success or sustainability of services were grouped thematically. Inclusion criteria were met by 116 articles that described 72 discrete telehealth services.

H-179

Role of Clinical Pharmacist in Adverse Drug Reaction Monitoring and Reporting

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Abstract:

Clinical pharmacists often work in collaboration with physicians, nurse practitioners, and other healthcare professionals. For safety medication (ADR) monitoring is required throughout its life cycle, during development such as pre-marketing including early stages of drug design, clinical trials, and post-marketing surveillance.The main goal of clinical pharmacist is to decrease the interaction between the drugs, provide the safer medication.The objective of the study was to measure role of clinical pharmacist in ADRs reporting .The cross sectional study, survey of 300 people on public awareness towards ADR has been done in Saudi Arabia on 2017 had the result obtain (73.2%) believed that the medical team, rather than consumers should report of the ADR.(48.5%) believed that patients do not know whether the ADR is from the medication or not,(46.1%) stated that the reason was because patients don't know about the Pharmacovigilance Center,(40.7%) think that patients don't know about the importance of ADRs reporting, and (36.3%) responded that patients probably don't know.The study concluded that With regard to attitudes toward ADR reporting, all clinical pharmacists showed a positive attitude, with much more knowledge. These results suggest that targeted educational interventions and a well-defined policy for ADR reporting may help increase ADR reporting and support the implementation of a fully function.

Key words: ADR, Clinical Pharmacist

H-180

Effect of Registered Medical Practitioner Treatment (Rmp) on Rural Area Population-A Pharmacovigilant Approach

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Abstract:

In developing countries like India, majority of healthcare is borne to private sector, resulting that most of the people levy on local /available unrecognized medical practitioners. The RMP's are very popular in the rural areas and urban slums because they are the primary contact in the medical emergencies that leads to some drug related errors, adverse effects and interactions. The quality of life in developing countries can be improved by enhancing the standards of medical treatment at all levels of the health care delivery system. This can be achieved through interventions, continuous medical education programs, effective implementation of therapeutic strategies. Our investigation is to study about the impact of RMP's treatment and to ensure the drug safety by clinical pharmacy services in rural India.

H-182

Guillian Barre's Syndrome

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Abstract:

Guillian barre's syndrome is also known as acute inflammatory non-myelinating multiple neuropathic syndrome. It is

one of the post infectious auto immune disease and may also be accompanied by auto immune disorders. The syndrome is generally characterized by sudden and unpredicted onset of symptoms such as stinging sensation and may lead to paralysis which usually starts in the lower extremities that would ascend to upper limbs towards the torso. according to epidemiological data the prevalence of syndrome is between 1or 2 in100 000 with slightly, more male individuals affected than females. In neurological studies we generally observe loss or decreased tendon reflexes. In the poster i am going to present a case study of 51 years old female patient admitted with the complaints of inability of walking since 4 days, weakness , altered sensorium, right bell's palsy, etc. The patient underwent CSF examination and nerve conduction studies and diagnosed to have guillian barre's syndrome.

Keywords: Neuropathic Syndrome, Stinging Sensation

H-183

Breast Cancer Pain Management - A Review of Current and Novel Therapies

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Abstract:

Breast cancer is one of the most prevalent cancers amongst women in the world. Unfortunately, even after adequate treatment, some patients experience severe pain either due to disease progression or due to treatment related side effects. Current ration pain management is patient-centered and requires a through psychological assessment. Usually adequate analgesia is achieved by adopting the WHO's three step analgesic ladder. This necessitates the administration of opiods and adjuvant analgesics to the breast cancer patients experiencing severe pain. These factor worsen the psychological state of patients and deteriorate their quality of life. Hence there is need to develop therapeutic modalities to provide adequate analgesia with minimum side effects.

Keywords: Best Cancer, Pain, Deteriorate, Deteriorate, Analgesia, Side Effects

H-184

Direct and Indirect Cost of Schizophrenia in Outpatients Treated in A Tertiary Care Psychiatry Unit

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Abstract:

To estimate the direct and indirect cost of care incurred by patients with schizophrenia attending a tertiary care psychiatry unit in Guntur. Study was carried out at the St.Joseph Hospital of Guntur . Systematic sampling selected every second patient with an ICD-10 clinical diagnosis of schizophrenia presenting to the clinic during a two month period. Sample consisted of 91 patients. Direct cost was defined as cost incurred by the patient (out of pocket expenditure) for outpatient care. Mean cost of a clinic visit was Rs. 500. Of the clinic visit cost, highest proportions were travel cost (39.8%) and medication (26.4%). Sixty four (70.3%) had received informal care. The mean cost of informal care during the entire course of the illness was Rs. 33, 540. Mean indirect cost was Rs. 150,190. Despite low direct cost of care, indirect cost and cost of informal treatment results in substantial economic impact on patients and their families. It is recommended that economic support should be provided for patients with illnesses such as schizophrenia, especially when patients are unable to engage in full time employment. There is a need to educate the public regarding higher cost of care by traditional healers and other informal modes of treatment compared to Western medical care.

Keywords: Schizophrenia, Cost Analysis, Cost of Illness, Andhra Pradesh

H-185

The Role Community Pharmacist in Identifying, Preventing, Treatment Diabetic Retinopathy

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Abstract:

The combination of educational materials and ongoing patient counseling can go far toward detecting and preventing safety issues. For example, diabetes patients often suffer from other debilitating conditions, such as high blood pressure, high cholesterol, and obesity. These conditions may require additional medications along with a patient's diabetes regimen. Pharmacists play a key role in ensuring that patients understand the interplay of medications that help manage diabetes. The

pharmacist seeks to collect and integrate information about the patient's drug history, clarify the patient's understanding of the intended dosage regimen and method of administration, and advises the patient of drug-related precautions, and in some countries, monitors and evaluates the therapeutic response. Diabetic retinopathy is the most common diabetic eye disease and a leading cause of blindness in American adults. It is caused by changes in the blood vessels of the retina. In some people with diabetic retinopathy, blood vessels may swell and leak fluid. In other people, abnormal new blood vessels grow on the surface of the retina. The retina is the light-sensitive tissue at the back of the eye. A healthy retina is necessary for good vision you have diabetic retinopathy, at first you may not notice changes to your vision. But over time, diabetic retinopathy can get worse and cause vision loss. Diabetic retinopathy usually affects both eyes. There is no cure for diabetic retinopathy.

H-187

Role of Clinical Pharmacist on Chemotheraphy (Paclitaxel)

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Abstract:

In current scenario of our world cancer is one of the major emerging disease, were we clinical pharmacist also have an important role on handling of those chemotherapy to give the right drug in the right time were all the cytotoxic drugs are narrow therapeutic drug which are to be monitored closely for patient care. Here we can discuss about the infusion of chemotherapy and major role of clinical pharmacist on it. Although antineoplastic agents are critical in the treatment of cancer, they can potentially cause hypersensitivity reactions that can have serious consequences. When such a reaction occurs, clinicians can either continue the treatment, at the risk of causing a severe or a potentially fatal anaphylactic reaction, or stop the treatment, although it might be the only one available. The objective of the present work was to evaluate the effectiveness of methods used to prevent and treat hypersensitivity reactions to platinum- or taxane-based chemotherapy and to develop evidence-based recommendations. Premedication with antihistamines, H2 blockers, and corticosteroids is not effective in preventing hypersensitivity reactions to platinum salts.

Keywords: Paclitaxel, Premedications, Antihistamines, Pharmacist

H-189

Awareness about Health Among Agricultural Workers in Haryana

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Abstract:

Safe working conditions are essential for healthy living and for ensuring food security among agricultural workers in developing countries. There is limited research on this topic, and documentation is essential to understand and change patterns of human health and safety. Agriculture has been identified as one of the most hazardous sectors in the world, and it is estimated that of 335,000 fatal work-related accidents occurring worldwide every year, some 170,000 involve agricultural workers. Large numbers of the world's agricultural workers also suffer serious work-related injuries and diseases caused by machinery and chemicals. In August 2014, male and female agricultural workers working on different farms in Haryana were interviewed about their awareness and attitudes to agricultural risk factors, health, and safety. In addition, transect walks were conducted. Agricultural workers reported health and safety concerns, e.g., paronychia, coughs, fever, cuts, dizziness and poisoning symptoms from using different agrochemicals, and these are considered as occupational hazard. The most important was the use of agrochemicals. They experienced physically demanding and hazardous work tasks. Cuts and bruises were often treated at home or by a neighbour with specific knowledge of healing herbs. The Agricultural workers did not consider these injuries worthwhile noting, reporting, or seeking medical care for. They seldom visited medical clinics, probably because of low convenience, lack of access to transportation, lack of financial means to pay a medical doctor, lack of confidence in the medical services, or lack of adequate and available health care. The results obtained in this study indicate that agricultural workers interviewed had low knowledge and awareness of risk factors and health and safety issues relating to farming. Training on health i.e proper medication and safety in agricultural workers of Haryana is urgently needed.

Keywords: Agricultural workers, Risk factors, Agrochemicals, Health, Haryana

H-190

Study of Medication Errors & Compliances for Inclusion of New Drugs in Hospital Formulary

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Abstract:

A retrospective observational single centered study was performed to detect the medical errors and to evaluate success of medical error prevention programme, it doesn't involve any direct supervision of the patient files, the study involves the review of written prescription chart by physician, transcription sheet and medical administration record sheet to check giving of each dose by the nurses. The study protocol was reviewed and approved by Aggarwal Hospital, Patiala that provides in-patient treatment under mainly secure conditions for patients who have cardiac problems Medication errors result from the deviation from hospital policy, these medications errors are classified into two groups, actual errors and near misses, actual errors are administration errors which directly harm the patients while near misses includes prescription error, transcription error and documentation errors which directly do not provide any harm to patient safety. The retrospective study was undertaken to find out the medication errors in hospital in case of new drugs to be added in hospital formulary for the period of 6 month study includes 140 patients files.

Keywords: Retrospective study; Medication errors; Transcription sheet; Medical administration record.

H-191

Dietary and Therapeutic Interventions for the Management of Diabetic Neuropathy

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Abstract:

Diabetes and their associated complications like nephropathy and neuropathy has been identified as a worldwide problem. The epidemiological data revealed that there is upto 60% of patients suffering from diabetic peripheral neuropathy (DPN) which is associated with significant morbidity, including gait disturbances, amputations, anxiety and depression. Dietary restriction and nutrional therapy plays an important role in the prevention of these chronic ailments. Pre clinical and clinical researches provides a basis for the therapeutic exploration of new dietary interventions for the management of diabetes and their related complications which further help in translating these nutritional improvements for the betterment of health-care system. The aim of this review is to describe the various aspects of diet restriction or diet therapy for the management of diabetic neuropathy and nephropathy. It is clearly stated that improper and irregular dietary habits causes overwhelming effects on the progression of diabetes and associated complications. However, dietary supplementations and interventions act by normalizing the nerve conduction velocity, brain oxidative stress and by repairing the damaged neuronal cells and maintain the normal conduction pathways of the brain. Still there is a need to explore new insight mechanisms of dietary supplements for the treatment of diabetes associated complications of human health.

Keywords: Brain oxidative stress, Diabetic Neuropathy and Dietary Interventions.

I-1

Pharmaceutical Education: Role of Regulatory Bodies in the Current Scenario

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Abstract:

Pharmaceutical education is a dynamic professional education for the development of country, individual and with a view to protect public health. This article representcurrent scenario of pharmacy in India, lack of awareness about advanced pharmaceutical technology and industry institution interaction, scope for pharmacist in hospital, compounding, dispensing, consultancy, industry, internet, nuclear, veterinary. It emphasizes on current syllabus of pharmacy, drawbacks of current syllabus, requirement of industry and need to upgrade syllabus with respective advance technology in pharmaceutical industry. It also represents flaws in pharma and the remedy to solve such unlikely things. Pharmaceutical education is a dynamic professional education for the development of country, individual and with a view to protect public health. This article representcurrent scenario of pharmacy in India, lack of awareness about advanced pharmaceutical technology and industry institution interaction, scope for pharmacist in hospital, compounding, dispensing, consultancy, industry, internet, nuclear, veterinary. It emphasizes on current syllabus of pharmacy, drawbacks of current syllabus, requirement of industry and need to upgrade syllabus with respective advance technology in pharmaceutical industry. It also represents flaws in pharma and the remedy to solve such unlikely things. Pharmaceutical education is a dynamic professional education for the development of country, individual and with a view to protect public health. This article representcurrent scenario of pharmacy in India, lack of awareness about advanced pharmaceutical technology and industry institution interaction, scope for pharmacist in hospital, compounding, dispensing, consultancy, industry, internet, nuclear, veterinary. It emphasizes on current syllabus of pharmacy, drawbacks of current syllabus, requirement of industry and need to upgrade syllabus with respective advance technology in pharmaceutical industry. It also represents flaws in pharma and the remedy to solve such unlikely things.

I-2

Formulation & Development of Topical Gel of Quercetin for Wound Healing

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Abstract:

The present study is designed to improve the wound healing activity of drugs.Quercetin, calendula flower extract, was incorporated in topical gel to investigate synergistic wound healing activity.Quercetin, calendula flower extract, was incorporated in topical gel separately or in combination. Topical gel containing drug in combination and separately, gelling agent, preservatives and triethanolamine were prepared. Pullulan which is film forming agent and bioadhesive was also investigated as a gelling agent. Topical gel formulations were evaluated for different parameters such as appearance, Viscocity, pH,Spreadability, drug content,ex-vivo diffusion study, and drug deposition study. The in vivo wound healing activity was done using excision wound healing model using wistar rats. All the formulated topical gels showed good effect on wound healing activity. Combination of drugsin good effect on wound healing activity. Carbopol gel showed better effect on wound healing activity as compared to pullulan gel beause the hydration property of carbopol gel is more.

Keywords: Wound healing, quercetin, calendula flower extract, pullulan.

I-3

Comparative Knowledge Assessment on Nicotine Replacement Therapy among General Population in Jaipur, Rajasthan

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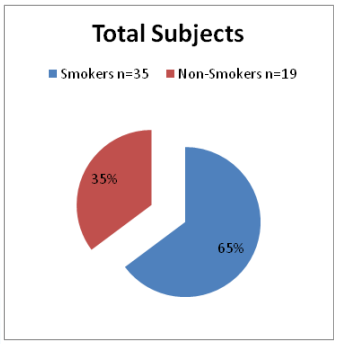
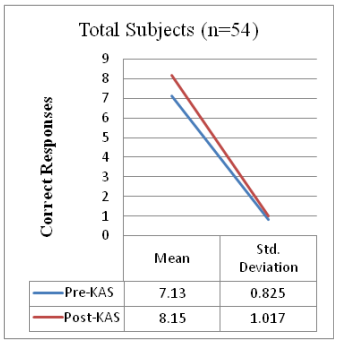
Abstract:

Introduction: World Health Organisation has estimated that tobacco use (smoking and chewing) is responsible for the 6 million premature deaths worldwide.[1] Nicotine Replacement Therapy (NRT) is medically approved way to take nicotine other than tobacco. This study was conducted among general population for the comparative knowledge assessment of NRT. Objective: In the present study, the goal was to evaluate the knowledge and perception of Nicotine Replacement Therapy

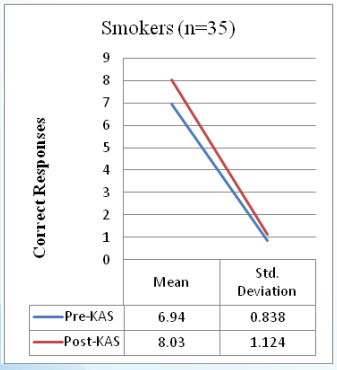
(NRT) among general population in Jaipur city, Rajasthan. The evaluation was done on the basis of pre-knowledge assessment survey and post-knowledge assessment survey. Materials and Methods: The study was performed within general population in Jaipur city, Rajasthan. A questionnaire based knowledge assessment survey was conducted. The survey was conducted in 3 major steps. The first one was a questionnaire based pre-knowledge assessment survey performed among the population. This survey contain 8 questions related to nicotine replacement therapy use, its side effects and recommendation. In second step knowledge regarding nicotine, nicotine replacement therapy were provided through leaflets and verbal. After providing the knowledge, the third step was a post-knowledge assessment survey. This questionnaire consisted of 9 questions. The correct answers given by the respondents were evaluated and statistical descriptive analysis was done using frequency distribution of responses. Result: Most of the people were unaware about Nicotine Replacement Therapy term and its forms. Among total respondents smokers were 65% and non-smokers were 35%.The evaluation is conducted on the bases of correct answers provided in pre-knowledge assessment questionnaire by total population mean was 7.13 with standard deviation mean obtain was 0.825 and in the post-knowledge assessment questionnaire mean was 8.15 and standard deviation was 1.017. Similarly separate analysed data of correct answers provided in pre-knowledge assessment questionnaire by smoker population mean was 6.94 and standard deviation mean of 0.838 and in post-knowledge assessment questionnaire mean was 8.03 with standard deviation mean of 1.124. And correct answers provided in pre-knowledge assessment questionnaire by non-smoker population mean was 7.47 along with standard deviation of 0.697 and post-knowledge assessment questionnaire mean was 8.37 with standard deviation 0.761.

Conclusion: Study results showed that the total population knowledge was improved after the assessment. Where smokers population and non-smokers population knowledge regarding nicotine replacement therapy, its uses, side-effects, its types and doses improved. It is concluded that by educating general population increases the awareness regarding Nicotine Replacement Therapy and smoking cessation.

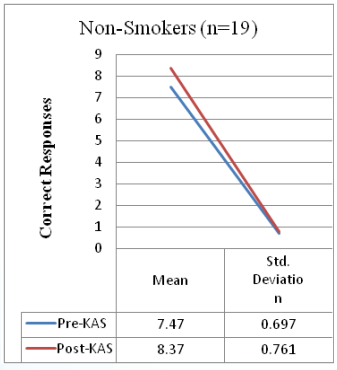




	Mean	Std. Deviation
Pre-KAS	7.13	0.825
Post-KAS	8.15	1.017



	Mean	Std. Deviation
Pre-KAS	6.94	0.838
Post-KAS	8.03	1.124



	Mean	Std. Deviation
Pre-KAS	7.47	0.697
Post-KAS	8.37	0.761

I-4

Assessment of Seeding & Enriching of Hard and Soft Skills in Buddy Pharmacy Professionals to Make and Serve the Quality Pill

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Abstract:

Present study deals with desired hard and soft skills in shaping pharmacy professionals into competent professionals through curricular and extracurricular contents. The challenges, nature of responsibilities and expectations varies as per area like Production, Marketing, Community, Research and Development, Export/Import, FDA compliance, Strategies planning, Clinical trials, Government Pharmacists, Quality Control etc. The present curriculum focuses on academic knowledge and hard skills. The development of soft skills varies from individual to individual and institution to institution. The enrichment of certain defined and well explained hard and soft skills leads not only to personal growth but can result into holistic growth of Pharmaceutical profession. The job responsibilities and expectations changes as per position like supervisor, manager, sales, planning, research and teaching etc. The skill awareness of Finance, Planning, documentation and administration makes the difference. Development of Analytical ability, creativity and decision making capability create upper edge. The positive attitude, respect to work discipline, approaches, scientific temperament, commitment, confidence, team spirit, objectivity, patience, initiative, courage, result/target orientation, stress manage-

ment, motivational ability, Global awareness, continue learning, visionary development, concern to social causes etc are some desired qualities fetching good prospects. The awareness and understanding of the relevant Government policies, schemes and subsidies, project formation become vital in start ups and self entrepreneurship. The incorporation of various modules and methodology in Curriculum being more interactive, more objective to inculcate the above skills should be effective. The training and orientation of teaching faculty to guide the disciples in becoming able to face the challenges in the career will support the theme.

Keywords: Hard and soft skill, Curriculum, Professional expectations, Quality, Pharmaceutical Industry.

I-5

Comparative Study about Challenges of Influenza A (H1N1)

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Abstract:

The recent outbreak of a novel swine origin influenza A (H1N1) virus (S-OIV) which was 1st detected in April,2009 in California (USA), has now migrated to other parts of America, Europe, Australia and Asia. In India the 1st case of death had its epicenter in Pune. The word influenza was derived from the Italian word 'Influence'. Swine flu also called Hog or Pig Flu is an infection caused by any one of the several types of swine influenza virus (SIV) which is common throughout pig population worldwide. Human to human transmission of this virus occurs by inhalation of infectious droplets and droplets nuclei and by direct contact. This is facilated by air and land travel and social gatherings. The most frequent symptoms are fever, cough and sore throat. Detailed contact, travel histories and knowledge of viral activity in community are essential for prompt case detection by the health personnel. Real time reverse transcriptase-polymerase chain reaction analysis of throat swales or lower respiratory sample is a sensitive means of diagnosis. Use of oral Oseltamivir may be warranted for the treatment of severe illness.

Keywords: H1N1, swine, transcriptase-polymerase, (S-OIV), influenza.

I-6

Association between Socioeconomic Status and Diabetes in Rural Settings of India

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Abstract:

Background: The pattern of diabetes incidence is related to the geographical distribution of diabetes, rough estimates show that the prevalence of diabetes in rural population is one-quarter that of urban population for India and Indian subcontinent countries. Socioeconomic status (SES) determinants of health status refer to an individual's position within a hierarchical social structure. Objective: The 6 months prospective observational cross-sectional study in a sample of 100 diabetic's performed in a secondary referral health-care setting of India aimed at assessing the association of SES of an individual based on three variables of Kuppuswamy scale. Materials and Methods: Study included participants diagnosed with diabetes mellitus (DM) of age above 18 years who showed willingness to participate in the study, whereas pregnant women, children below 18 years of age and participants diagnosed with diabetes but showed no willingness was excluded from the study. Results: The prevalence of DM was found to be 0.0713 with period prevalence of 0.0571. In our study, 29% of the study population was under age group of 51-60 years, illiteracy was 71%, and marital status was 92%. Based on Kuppuswamy scale the score of SES in our study, 42% of individuals were documented under Class IV, which shows a study relationship of household income, occupation, and education with diabetes between age group of 30 and 70 years. Conclusion: These findings concluded an inequality of health according to SES in the younger population.

Keywords: Diabetes mellitus, observational study, prevalence, prospective, socioeconomic status.

I-7

Impact of Use of Mobile Phone on Students Learning and Health- A Survey Study

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Abstract:

Now a days smart phone usage among the college students have been rise drastically. Rise in the excessive mobile phone use affecting the students learning and health. Prior research suggested that there might be a relationship between excessive use of mobile phone and lack of daily sleep and other health problems. Also there might be a relationship between excessive use of mobile phone and student's lack of concentration and dedication for the study. The present survey based investigation is conducted on usage of mobile phone among the pharmacy students of Kalsekar Technical Campus of New Panvel, India by using online tool surveyplanet.com. The result of survey showed the ill effect of excessive use of mobile phone on student's education, health and family life.

I-8

Pharmacy Education: Scope and Global Opportunities for Pharmacist in Future

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Abstract:

Pharmacy is an evolving profession. When considering the role of pharmacist, many people envision someone in a white coat behind a counter filling and dispensing medication, and counseling patients. While retail pharmacy is the most popular employment choice for pharmacists, it is definitely not the only choice. The pharmacy field is continually growing and pharmacists are a more fundamental part of the health care system. Pharmacy profession was choice for many people and they completed the course with lots of dreams. But, recently we have been hearing a lot of negative remarks on the opportunity and scope of the profession in our country. Over the years pharmacists have found new ways to leverage their status as experts in medication therapy to create new pharmacy careers that have significantly improved patient care and advanced pharmacy profession. Pharmacists have more than 22 career jobs and 11 additional careers in global health care system. With respect to academics, we are not providing the training to the professionals as required by current system of opportunities and failure to provide the required skills and knowledge to take up challenges in opportunities. This article focused on to provide quality education in pharmacy profession to get more opportunities in both local and international platforms in future. "WHERE THERE'S A WILL; THERE'S A WAY"

Keywords: Pharmacists, Pharmacy Education, Opportunities, Quality Education.

I-9

Need of Major Revision in Pharmacy Curriculum to be in line With the Rapidly Changing Pharmaceutical World

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Abstract:

The objective of this paper is to create attention for the up gradation of pharmacy curriculum to cope up with the rapidly changing pharma world. New information, technology and research are the growth drivers of pharma industry. The upcoming advanced technology has served as a pillar of pharma world. Technologies like artificial intelligence are ready to change the face of pharma world. These advances promotes the development in research for new drug molecules. This will transform whole method of clinical trials as well as method of treatment of diseases. Development in biotechnology, 3D printing technology, medical devices, advanced nanotechnology, use of supercomputers, changes in clinical trial method, use of Nano robots is the future of pharma industry. These technologies may have advantages as well as some drawbacks. The technology is developed such that it is able to overcome the problems associated with the existing methods. It is the need of the hour to include the latest technology & new knowledge in our curriculum. However, it is disappointing to note that all these latest technology & related information is missing from pharmacy curriculum of most of the universities in India. Recently Pharmacy Council of India came up with new uniform syllabus across the country for UG & PG courses. However, most of the recent technologies are not included in latest PCI curriculum. To satisfy the current requirement in the world the change in face of pharmacy profession is required. This can be achieved by making some major changes in the curriculum and syllabus at different levels to be in line with the rapidly changing pharmaceutical world.

Keywords: Advanced technology, curriculum, artificial intelligence.

I-10

Development and Evaluation of Novel Oral Pulsatile Release of Gliclazide from Core-in- Cup Tablet

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Abstract:

The Core-in- Cup matrix tablet of Gliclazide was prepared by wet granulation technique by using hydrogenated castor oil (HCO) and hydroy propyl methyl cellulose. Of the different trial formulations, the optimized formulation F1 followed zero-order kinetics of drug release. The drug and Excipient compatibility studies were subjected to FT- IR. The results show that no significant changes were observed. The final tablets were evaluated for weight variation, hardness, friability, drug content determination. In-vitro dissolution studies were carried out using USP Type II dissolution apparatus. The result showed a release of 99.89 % of drug at the end of 12 hours. It was concluded that the drug release followed zero-order kinetics with both erosion and diffusion as the release mechanisms and improved the patient complaince.

I-11

Psychotropic Drug Utilization in Psychiatric Outpatient Department of a Tertiary Care Teaching Hospital in India

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Abstract:

Background: Although psychotropic medications have had a remarkable impact on psychiatric practice that legitimately can be called revolutionary, their utilization and consequences on real life effectiveness and safety in actual clinical practice need continuous study. Methods: The current retrospective study of six months duration was designed to assess the utilization of antipsychotics and its prescribing pattern in a tertiary care hospital of south India, which included prescriptions of patients suffering from a psychiatric illness with atleast one psychotropic drug of all ages and both sexes. Results: Out of 150 cases reviewed, 46% were of schizophrenia, where male (60.67%) at higher incidence of psychiatric illness, and maximum patients were under the age group of 29-39 years (54.67%). In present study of 355 prescribed drugs 72.67% were psychotropic medications. As per World Health Organization/International Network for Rational Use of Drugs (INRUD) drug use indicators average number of drugs per prescription (2.37%), average number of psychotropic drugs per prescription (1.72%), psychotropic drugs prescribed as Fixed Dose Combinations (FDCs) was 26.36%, and percentage of drugs prescribed by generic name (91.08%). In our study, 48.09% of psychotropic drugs were utilized the treatment of schizophrenia, diazepam (17.06%) was the only psychotropic medication distributed in the management of all three observed psychiatric disorders and the study showed higher utilization of psychotropic drugs as FDCs (25.98%) in the management of schizophrenia. Conclusions: The study advocated an overall rational utilization of psychotropic drugs with a fewer deviations due to socio-economic status of patients and prescription practices of healthcare providers.

Keywords: Drug utilization, INRUD, Prescribing pattern, Psychotropic medications, Retrospective study, WHO indicators.

I-12

Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP): Quality Medicines Available At Affordable Prices for All

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Abstract:

It is well known that due to market led consumer awareness and availability, branded medicines are sold by the drug manufacturer at higher prices than their unbranded generic equivalents which are as good in therapeutic values. The objective is making quality medicines available at affordable prices for all through exclusive outlets "JAN AUSHADHI MEDICAL STORE" so as to reduce out the pocket expenses in healthcare. Accordingly, a task force of senior officers of the Department Of Pharmaceuticals, CEOs of pharma CPSUs representatives of pharma industries, NGOs/charitable representative organizations, state governments, and most importantly doctors from reputed National level institutions like AIIMS, Maulana Azad

Medical College & RML hospital was constituted to implement the objectives of making available affordable medicines for all. Senior representative of WHO was also invited to the deliberations. The task force held extensive discussions & unanimously decided to launch a Janaushadhi campaign starting with sale of generic medicines through dedicated sale outlets in various districts of the country. It is ironic that even through Indian pharma companies rank among the top performers in the global generic market, offering quality medicines at affordable price to patients across the world. The scheme will be implemented and executed with due care that the end customer does not land up with fake or spurious drugs. However, there is no doubt that the scheme should be implemented on a war footing so that the rich and the poor alike are able to avail quality health care for a better life.

Keywords: Janaushadhi medical store, Unbranded generic medicines, Affordable prices, Quality medicines, Quality and care.

I-13

Development of Formulation and Preclinical Evaluation of Niosomes Co-Loaded With

5-Fluorouracil and Leucovorin

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Abstract:

In the present study, niosomes co-loaded with 5-Fluorouracil and Leucovorin was prepared and evaluated for their characterization, *in vitro* drug release and *in vivo* anticancer efficacy in Dimethyl hydrazine (DMH) induced colon cancer. Formulation of niosomes was optimized for highest percentage of drug entrapment. Microscopic observation confirmed that all particles were uniform in size and shape. The *in vitro* release studies of drug from niosomes exhibited a prolonged drug release observed over a period of 12h. The negative values of zeta potential indicated that the 5-Fluorouracil and Leucovorin loaded niosomes were stabilized by electrostatic repulsive forces. Results from stability study have shown that the drug leakage from the vesicles was least at 4°C followed by 25°C and 37°C. The mechanism of release of 5-FU and LV was found to be Non-Fickian and Fickian diffusion respectively. Colon cancer was induced by s.c injection of DMH (20 mg/kg b.wt) for 15 weeks. The animals were divided into five groups and the treatment was carried out for 15 weeks. At the end of the study period the blood was withdrawn and serum was separated for haematological, biochemical analysis and tumor markers. The colonic tissue was removed for the estimation of antioxidants and histopathological analysis. The results showed that DMH intoxication elicits altered haematological parameters, elevated lipid peroxidation and decreased antioxidants level, elevated lipid profiles, tumor markers (CEA and AFP) and altered colonic tissue histology. Treatment with 5-FU + LV niosomes significantly restored the altered biochemicals parameters in DMH induced colon cancer mediated by its anticancer efficacy. 5-FU + LV niosomes showed marked efficacy as that of the 5-FU + LV market formulation and 5-FU-alone. These improvements in 5-Fluorouracil and Leucovorin niosomal formulation may be useful in developing a more effective combination for cancer therapy.

Keywords: 5-Fluorouracil, Leucovorin, niosomes, colon cancer.

I-14

Design and Characterization of Lansoprazole Microparticles Compressed Tablet

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Abstract:

Objective: The present study aims to design oral compressed tablets of lansoprazole microparticles and to improve the chemical stability of acid-sensitive drugs. Materials and Methods: Chitosan and surfactant like span 40 were selected as carriers for the preparation of lansoprazole microparticles by o/w emulsion evaporation method with different drug polymer ratios. These microparticles were then compressed into tablet using methyl cellulose, magnesium stearate and talc as excipients. The prepared compressed tablet containing lansoprazole microparticles were evaluated for the drug excipients interaction studies, particle size, surface morphology, entrapment efficiency, drug content, in vitro release and stability. Results: From the dissolution studies, it is confirmed that lansoprazole microparticles showed that drug release is not affected by change in pH of medium and agitation of the dissolution medium, thus developed formulation shows independent drug release with respect to pH. The FTIR studies revealed that there is no interaction between drug and excipients. Accelerated stability study showed that formulation is stable after 3 months of stor-

age, as weight variation, drug content and percentage cumulative drug release were found stable after 3 months of storage. Conclusion: The combination of microparticles technique with compressed tablets using chitosan polymer is a promising approach for protecting the drug from acidic environment. It is found to be effective and better drug release.

Keywords: Microparticles, Compressed Tablet, FTIR.

I-15

Formulation Development and Characterization of Pregabalin Niosomes for Improved Anticonvulsant Activity

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Abstract:

The need for present study is to encapsulate the drug Pregabalin in the niosomal vesicles for effective Central Nervous System drug delivery for prolonged period of time. Objective of this study is to treat epilepsy with Pregabalin Niosomes .We aimed at formulating Pregabalin niosomes, thereby minimizing the dose and also to achieve sustained release for a prolonged period of time and to compare the anticonvulsant activity of Pregabalin Niosomes with a marketed tablet formulation. Pregabalin Niosomes were prepared by Thin film Hydration Technique. Three formulations F-I [Pregabalin, Cholestrol, Span 40], F-II [Pregabalin, Cholestrol, Span 60]and F-III [Pregabalin, Cholestrol, Span 80]were prepared and evaluated for various parameters. Using Optical Microscopy and SEM vesicle Diameter of Niosomes was determined and found that all the three formulations comply with niosomal size range of 100 – 300 nm. Drug Entrapment Efficiency and *Invitro* Studies showed that F-II has the better drug entrapment (76.61%) and sustained release (93.71%) . F-II was selected for further studies. Stability studies as per ICH guidelines revealed that all formulations were stable. From the studies, it was concluded that Pregabalin Niosomes showed Prolonged release and longer duration of action thereby achieving sustained release. Anti -convulsant activity of Niosomal Pregabalin(F-II) was compared with a marketed tablet formulation. The results revealed that niosomal Pregabalin exhibits better Anti -Convulsant activity at a lesser dose than that of the marketed tablet formulation. Thus, the objective of minimizing the dose of Pregabalin was achieved with Pregabalin niosomes.

Keywords: Pregabalin, niosomes, anti-convulsant, span 40, span 60.

I-16

Formulation and Characterization of Linagliptin Niosomal Drug Delivery System

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Abstract:

In the present study, niosomes loaded with linagliptin was prepared and evaluated for their characterization and *in-vitro* drug release. Formulation of niosomes was optimized for highest percentage drug entrapment. Microscopic observation confirmed that all particles were uniform in size and shape. The entrapment efficiency was optimized using different concentrations of cholesterol and non-ionic surfactants. The *in-vitro* study of drug from niosomes exhibited a prolonged drug release as observed over a period of 19hrs. Niosomes can be formulated by optimized process parameters to enhance linagliptin entrapment efficiency and sustainability of release. These improvements in linagliptin may be useful in developing a more effective formulation in treating diabetes mellitus.

Keywords: Linagliptin, Niosomes, Diabetes mellitus.

I-17

A Paradigm Stratagem of a Pharmacist with Current Insights towards Patient Centered Practices in Guntur District, Andhra Pradesh

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Abstract:

Patient-centred Practices (PCP's) are the centrepiece of primary care transformation in India. They are intended to improve care coordination and communication, enhance health care quality and patient experiences, and lower health care costs by linking patients to a physician-led interdisciplinary health care team. PCP's is widely supported by health care as-

sociations, payers, and employers. Health care accreditation organizations have created performance measures that promote the adoption of PCP's core attributes. Evidence-based prescription, medication adherence, medication use coordination, and systems to support medication safety are all necessary components of PCP's. Pharmacists have unique knowledge and skills that can complement the care provided by other PCP's team members. Their experience in drug therapy assessments, medication therapy management, and population health has documented benefits, both in terms of patient health outcomes and health care costs. Through collaborative care, pharmacists can assist physicians and other prescribers in medication management and thus improve prescriber productivity and patient access to care. Pharmacists are engaged in PCP's through both employment and contractual arrangements. There is growing support for pharmacist integration into PCP's; however, more convincing cost-effectiveness data, as well as performance measures requiring the unique skills of pharmacists, may be needed before pharmacist-provided PCP's services become more widely adopted. Given the continued evolution of the PCP's model of care, ongoing opportunities exist for pharmacists to create an optimal care model that is suitable for PCP's and rewarding for their profession.

Keywords: Patient-centred practices, multidisciplinary care, medication safety, Pharmaceutical care, patient health outcomes.

I-18

Development and *In-Vitro* Evaluation of Floating Microspheres of *Metoprolol Tartrate* by Emulsion Solvent Diffusion Method

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Abstract:

The present study deals with formulation of floating microspheres of Metoprolol tartarate using Eudragit S 100 by emulsion solvent diffusion method. Floating drug delivery systems have a bulk density less than gastric fluids and so remain buoyant in the stomach without affecting gastric emptying rate for a prolonged period of time. Metoprolol tartrate is selective β1 receptor blocker used in hypertension with short half life of three to four hours. The short half life of metoprolol tartrate and multiple administration doses make metopralol a very good candidate for formulation of floating drug delivery system. The floating microspheres were evaluated such as micromeretic properties, particle size, percentage yield, *In-vitro* buoyancy, incorporation efficiency and *In vitro* drug release of microspheres. The micromeretic properties was found to be good and scanning electron microscopy confirmed their hallow structure with smooth surface. Formulation F3 prepared with Eudragit S 100 drug: polymer ratio of 1:3 which exhibited excellent micromeretic properties, percentage yield, In-vitro buoyancy, incorporation efficiency and percentage drug release 61.61 % at the end of 12 hours. Results showed that increase in drug: polymer ratio better in the percentage yield, buoyancy, *in vitro* drug release of microspheres. The data obtained in this study suggest that floating microspheres of Metoprolol tartrate are promising for sustained drug delivery.

I-19

Recent Advancement in Glucose Monitoring in Diabetic Patients

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Abstract:

According to world health organization, diabetes is the sixth most death causing disease worldwide. In 2014, 422 million cases of diabetes were reported globally and in India this number was observed to be 69.1 million. According to the global diabetes community, over 30 million cases have now been diagnosed with diabetes in India. For diabetes management by insulin therapy, proper monitoring of glucose is essential to avoid the risk of hyperglycemia. For this purpose, techniques like self monitoring of blood glucose (SMBG) with glucometer, and continuous glucose monitoring (CGM) can be used. By allowing a constant peek at blood sugars, the CGM is becoming one of the most powerful, life-changing pieces of technology people with diabetes have ever seen. CGM is medically indicated for patients with frequent, severe, or nocturnal hypoglycemia. With this device, in every five minutes, glucose readings are transmitted from a glucose sensor to the insulin pump, which displays about 288 readings a day. The first CGM device MiniMed was approved by food and drug administration (FDA) in 1999 for use in USA. Till 2005 no patient oriented CGM was released in the USA. With the speeding the FDA approval process for diabetes technology, the first closed loop CGM system MiniMed 670G hybrid closed-loop system (Medtronic) got approval in April, 2017. The technique has been evolved in past

few years. Google is also developing a smart contact lens to measure glucose in tears continuously using a wireless chip and miniaturizing glucose sensor. Use of CGM in conjunction with an insulin pump with automated suspension of insulin infusion in response to actual observed or predicted hypoglycemia, is expected to enhance the clinical utility and utilization of CGM. The race for the next generation of painless and reliable glucose monitoring for diabetes mellitus is on.

Keywords: Diabetes, self-monitoring of blood glucose, continuous glucose monitoring, hypoglycemia, closed-loop system.

I-20

Pharmacare App – Your Digi Assistant

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Abstract:

"Pharmacare-app" project is based on implementation of digital tools by a pharmacist to create awareness among the society regarding the appropriate use of medicines. It is a compass to locate ones nearby pharmacy. This app assists in diagnosis of an individual's disease and maintains the complete health record (PMR), also useful in situations of emergency. It reveals the best options for generic medicines with special case drugs, drug-drug interactions, drug-food interactions, contraindications, adverse effects etc. It also emphasizes on an individual's dos and don'ts with personal reminder. This app proves useful when no personal assistance is available. It is the best key to maintain transparency and delicate relationship between the patient and the health care system. And at last but not the least "Pharmacare-app" is a major contribution to the "Digital India" and "Pharma Vision-2020".

I-22

A Study on Attitude and Interest of Postgraduate Students' In Teaching

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Abstract:

Lecturing is the most common method of teaching. It hardly interests students and students are often hesitant to interact.Small group teaching by postgraduate students might interest undergraduate students and may contribute tobetter learning for both. The present study was undertaken to identify whether postgraduate students will be interested in teaching. A structured questionnaire was prepared, validated and used for collecting the responses from students about their interest in teaching.A surveywas conducted among 98 postgraduate students (from 11 different specializations)who are currently in first semester MPharm at Manipal college of Pharmaceutical Sciences, Manipal University, Manipal. Majority (75.5%) of the students opined that postgraduate students could be utilized for undergraduate/diploma teaching.They were interested in teaching both diploma and undergraduate pharmacy students. About 10% had a formal training in teaching and about 20% had prior teaching experience. 95% of the students said that it improves self-learning. The subjects they were interested to undergraduates varied largely. Interestingly, a few students were interested to teach foreign languages and a few non-pharmacy subjects. About 30% students were apprehensive about teaching and reasons, to name a few, stage fear, not eligible to teach, don't like teaching etc., Overall, majority of the students have expressed their interest in teaching. Involving postgraduate students in undergraduate students may promote active learning for both.

Keywords: Teaching, Learning, Postgraduate, Undergraduate, Self-learning.

I-23

Preparation of Aloe Vera Cosmetic Herbal Hydrogel

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Abstract:

Aloe vera (AV) is a perennial, drought-resisting, succulent plant belonging to the Liliaceae family and historically, has been used for a variety of medicinal purposes. The leaves which are lance-shaped with sharp points contain an essentially clear viscous gel known as aloe vera gel (AVG). The present study was conducted to formulate a suitable AV cosmetic herbal hydrogel

formulation. The aloe vera cosmetic herbal hydrogel have been formulated using inner part of aloe vera leaf, acacia, hydroxy propyl methyl cellulose (HPMC), carbopol 934, glycerine, tartaric acid, potassium sorbate and sodium benzoate. Aloe vera gel was prepared by heating at low temperature and the hydrogel was prepared by simple dissolving method of other ingredients in a specific manner. The formulation was evaluated for percentage moisture content, transparency, smoothness, weight on drying, viscosity and pH. The present study showed smooth and effective formulation. Therefore, on the basis of evaluation of AVG, it can be used for cosmetic purpose as herbal preparation.

Keywords: AVG, HPMC, Hydrogel.

I-24

Need to Introduce Exit Examination for Registration as a Pharmacist: An Effective Measure to Maintain Quality of Qualified Pharmacist in the Country

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Abstract:

As per the provisions of Section 32(2) of the Pharmacy Act, the registration as a pharmacist is granted by any State Pharmacy Council (SPC) to a person who have attained the age of 18 years, reside or carry on the business or profession of pharmacy in the state and have passed an approved examination or possesses a qualification approved under Section 14 of the Act or if he or she is a registered pharmacist in another state. Any SPC cannot deny reregistration of candidates satisfying above criteria. Once the students is registered as pharmacist he or she may engage themselves in community pharmacy services or academics. However, it has been reported that, there are several institutions in the country who are registering the candidates for either diploma or degree program & awarding them degree without attending regular academics.There are incidents where candidates obtained diploma certificates in pharmacy through illegal means and managed to register themselves with state pharmacy council.Such type of corrupt and malpractices is damaging the overall quality of healthcare sector in the country. The exit examination after the completion of the course and before the registration of pharmacist will significantly reduce the entry of persons in the profession with such fake degree or diploma certificates. This could be the effective way to restrict the entry of such persons in the pharmacyprofession to minimize further dilution of this noble profession.Several western countries havesuccessfully adopted this type of system. Thus it can be concluded that, PCI must introduce exit examination for students passing out diploma or degree in pharmacy which will make them eligible for registration with state pharmacy councils.

I-25

Role of Continuous Glucose Monitoring In Improving the Quality Of Life of Diabetic Patients

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Abstract:

Diabetes mellitus is a chronic disease that necessitates continuing treatment and patient self-care education. Monitoring of blood glucose to near normal level without hypoglycemia is a challenge in diabetes management. Although self monitoring of blood glucose (SMBG) can provide daily monitoring of blood glucose level and help to adjust therapy, it cannot detect hypoglycemic unawareness and nocturnal hypoglycemia. In recent years, meters for continuous monitoring of interstitial fluid glucose have been introduced to help people with diabetes mellitus to achieve better control of their disease. Dexcom G5 Mobile, the first CGM system approved for adults and pediatric patients two years of age and older. It provides real-time glucose readings for diabetic patients every five minutes. CGM systems usually consist of a glucose sensor, a transmitter, and a small external monitor (which may be built-in to an insulin pump or a stand-alone device) to view the glucose levels. Quality of life (QoL) is one of the key advantages of these devices along with other useful effects. As studied in DIAMOND trial, the CGM device showed improvement in overall QoL of diabetic patients when compared with SMBG. While it has been studied for many years, the *"added value"* of health related QoL is still a topic for debate among researchers. By evaluating the QoL, the overall balance between tolerability and efficacy can be assessed and for determining the overall therapeutic efficacy of a treatment, it can be considered to be an important factor. QoL can be considered as one of the major usefulness of CGM and studies can be conducted further in this direction.

Keywords: Diabetes, self monitoring of blood glucose,

glucometer, continuous glucose monitoring, quality of life.

I-26

Nanogel for Dermal Application of the *Glycyrrhiza glabra* for Anti-Acne Treatment

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Abstract:

The objective of present study was to formulate stable *Glycyrrhiza glabra* nano-gels intended for topical delivery with enhanced skin benefits. Gly-G nano-suspensions were prepared using via high-pressure homogenization technique (Remi Motor, Remi Elektrotechnik Ltd, Vasai, India) at 8000 rpm for 10 min using PVP K30, lecithin and tween 80, as stabilizer, followed by gelation using carbopol 940. Nano-gel was evaluated for organoleptic acceptability, homogeneity, pH, viscosity and spreadability. Long term and accelerated stability study of nano-gel were carried out at 25 ± 2 ℃ & 60 ± 5 % RH and 40 ± 2 ℃ & 75 ± 5 % RH. In order to confirm the advantages of Gly-G nano-gel for dermal application, anti-microbial test using well diffusion method were performed and compared with Gly-G powder carbopol gel. It was observed that Gly-G nanogels were homogeneous with acceptable organoleptic characteristics. The pH, viscosity and spreadability of Gly-G nanogels were found 6.3 ±.6, 17035 ± 4 centipoises and 6.3 ± 0.3 g.cm/s, respectively. Antibacterial activity of Gly-G nanogels was significantly superior ($*p < 0.05$) as compared to Gly-G powder carbopol gel which indicated its enhanced anti-acne efficacy for skin benefits in topical drug delivery. The Gly-G nanogels acquire improved therapeutic effect for anti-acne activity compared with Gly-G powder carbopol gel, which illustrated that nanogels are suitable and convenient mode of dermal drug delivery for skin friendly herbs.

Keywords: *Glycyrrhiza glabra,* **nanogel, high-pressure homogenization technique.**

I-27

Perceptions of Punjabi Pharmacy Students about Drugs and Alcohol: A Questionnaire-Based Survey

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Abstract:

Introduction: In Punjab, lots of students are using drugs and alcohol and its number is increasing day by day. The exact reason why these students are motivated towards these things is not fully understood. Thus, this study is designed to find out the Perceptions of Punjabi Pharmacy students about drugs and alcohol. Material and Methods: A questionnaire based survey was conducted in ISF college of Pharmacy, Moga, Punjab, covering all kind of students to assess the perceptions about the use of drugs and alcohol. Results and Discussion: Three hundred students have completed the survey. Majority of students have shown positive perception toward the use of drugs and alcohols. Some of them think, these things may be increase performance in learning and memory. While, some of them think these things give pleasure to human. The use of these things might be increase in case of examinations and other stress like conditions. Conclusion: Overall, the result of current investigation has find attraction of Punjabi Pharmacy students towards the use of drugs and alcohols. With an increasing number of students who are using drugs and alcohol, pharmacy institutes need to evaluate the adequacy of drugs and alcohol education in their curriculum.

Keywords: Pharmacy Students; Drugs; Alochol; Perception.

I-28

Exposition Relationship between White Poisons Induced Diseases - A Pilot Study

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Abstract:

Introduction: Like all that glitters are not gold, everything white is not always good or angelic.Nutritionists say there are four white poisons salt, refined sugar ,maida and pasteurized milk. White poison poses indeed place a heavy burden on the health care system as it leads to large number of diseases directly attributable to obesity, heart problems, diabetes etc Aim :To report on the dietary consumption of Refined Salt, Re-

fined Sugar, Maida and Pasteurized Milk collectively called as 'White poisons' and its association with Diabetes and Hypertension in a population of Chennai and Thiruvallur and also aimed to create awareness about hazards of white poison by effective patient counselling. Study Design: Pilot study. Methodology: A simple questionnaire was prepared in English and Tamil language. Data was collected regarding their identifications, disease conditions, food pattern, medicine usage, sedentary life style and their attitude and knowledge towards White Poison for the period of six months. Results and Discussion: On viewing the overall report of the surveyit was found 92.36% of patients were diabetic and 59.63% patient where hypertensive due to consumption of sugar (28.36 %), salt (37.45%), maida (37.81%), milk (12.75 %). Both diabetic and hypertensive patients had little basic knowledge about how their daily foods turns to poison and pose health hazards. Conclusion:The study presents a worrying picture of increases in unhealthy food habits leading to hypertensive and diabetic patients more across most places and reveals that concerted action is needed to reverse this trend. Due to patient counselling wecreated awareness on these issues for a better health.

Keywords: White poison, Refined sugar, Maida, Diabetes, Hypertension.

I-29

Technology Detrimental To the Quality of Life of Pharmacy Student

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Abstract:

Access to all information is just within the fingertips of our hand due to the mobile technology. This wireless communication has raised as one of the fastest diffusing mediums on the planet that speaks as much with thumbs as it does with tongues. These wide ranges of mobile technology have often ribbed the question about health hazards in human. People using cell phones are susceptible to high blood pressure and other symptoms such as hot ears, burning skin, headaches and fatigue.This survey was conducted to check population at risk due to health hazards caused by the excessive usage of mobile phones. In this studyan online questionnaire was used to collect the data from the multitude. The responses which have been received was assessed and interpreted. From the data containing 35.32% of females and 63.58% of males, 38.04% of total participants are using mobile phones more than 3 hours. Among these 41.42% of multitude are having neurological symptoms like headache, lack of concentration and problems with thinking or memory. The excessive usage of mobile phones more than 3 hourshave also shown various side effects likesleep disorders, headaches, memory loss, deafness, migraines, hot ears, burning skin and fatigue. The effect of mobile phone radiation on human health is a matter of interest and study worldwide. Therefore a detailed and further accurate study has to be done in this field.

Keywords: Mobile technology, Health hazards, Neurological symptoms.

I-30

Antibiotic Resistance- Need Awareness or Scope

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Abstract:

Antibiotic resistance is one of our most serious life threatening problem in society, can be occur in anybody. The emergence and spread of antimicrobial resistance is a growing problem in both developing and developed countries.Different type of serious infections– such as pneumonia, tuberculosis, blood poisoning and gonorrhoea – are becoming harder and sometimes impossible, to treat as antibiotics become less effective.Antibiotic resistance is increasing due to misuse and overuse of antibiotics and also due to low maintenance of proper hygiene condition and unhealthy lifestyle.Behavioural changes such sanitisation, hand washing, good hygiene, good lifestyle and preferring safer sex are some changes to decrease the chances of decreasing chances of infections, thus decreasing the use of antibiotics leads to decrease in antibiotic resistance. This type of more infections are growing day by day due to lack of awareness of antibiotic resistance.Consequences of antibiotic resistance are higher medical costs, prolonged hospital stays, and increased mortality. An approach for the restraint of resistance needs to be developed, applied and evaluated. Such approaches should focus on improving rational use of antimicrobials and reducing opportunities for spread of resistant organisms. Implementation requires education and training, surveillance, technical developments, research, and statutory regulation.

Keywords: Antibiotic resistance, costly, Infections, antibiotic overdose, awareness.

I-31

Pharma 4 All: e- learning Platform Pharmacy Professionals

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Abstract:

The beginning of pharmaceutical education in India was initiated at Banaras Hindu University in 1932 by Professor M. L. Schroff. From there it has been a long journey of almost 80 years for this profession in this country.Increasing population in India demands survival of peoples by any way. Everybody is trying to get admission to professional courses like Medical, Pharmacy, Veterinary, Engineering, Polytechnique to withstand their future. Many bureaucrats have commercialized the education by establishing the private education system.Majority of such system are lacking of quality education because the admission candidatesare either of poor quality or financially weak. Formal pharmacy education leads to a degree began in 1937, with the introduction of a 3 year industry oriented Bachelor of Pharmacy course (B. Pharmacy) latter on the course duration extended to 4 year. There is no doubt that currently there is enormous gap existing between education and practice of pharmacy. Most of the academic institutions providing education in pharmacy are away from practice environment and lacking of quality study materials.India is one among the leading country in world considering the mobile use and place 2nd rank in internet use. Keeping the view of this achievement a user friendly application "**PHARMA 4 ALL"** was propose for the benefit of active learners of pharmacy graduates, educators and the pharmacy professionals for theiroverall development. The key features of the app, to availthe conceptual study materials to all active learners and in same, it will also provide a platform for the educators to deliver the course content in web based design. Besides all this the benefits ofthis app will have a significant role in the society in respect to health awareness. It gives them a wide angle description regarding various diseases along with their sign and symptoms and their treatment.

I-32

Awareness Regarding FDA Updates in Pharmacy Students

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Abstract:

Food and drug administration (FDA) is a federal agency of the US department of health and human services.Laws, regulations and guidance issues governing drugs, biologics and devices for human use are advancing with time. FDA inspectorates in India, data integrity and contamination issues have become a growing concern for Indian manufacturers. Pharmacy student experiential programs provide opportunities to learn multi-disciplinary processes of FDA domain addressing public health structural framework involving drugs, biologics (medicines), and medical equipment. Relevant FDA knowledge, skills and abilities are beneficial for aspiring successful professionals. The overarching goal of the foundation of awareness through pharmacy curriculum is a conscientious reformation coupled with educational policies and structures at all levels.Expanding National *Awareness through* cross-*curricular* programs between pharmacy centers of educational excellence for sharing of knowledge produced also adds immense merit. So an online survey was conducted among pharmacy students in order to check whether they are being updated with FDA website or not. From the data collected, we observe that out of 156 responses, 88.5% of pharmacy students are not being updated with the FDA website, only 11.5% of students are updated. So there is a need to create awareness regarding need of FDA updating in medical professional in order to improve public health through rational therapy.

Keywords: FDA updates, awareness, improve public health.

I-33

Android App to Reform Pharmacy Education and Meet Professional Challenges

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Abstract:

Pharma sector facing various challenges; hence role & opportunity of pharmacist is increasing; but traditional teaching educations have limitations. Main objective of work is to understand need to development of Android App to reform pharmacy education to meet professional challenges; (1) determine student's needs and desirable App features (2) Understand relationship between variables (3) Develop prototype

Android App. The comprehensive survey of pharmacy students (n=200), professors (n=40), administrators (n=10), industry executives (n=15) community pharmacists (n=20) has been done; by using response sheets comprising MCQs and open-ended question. The data generated was analyzed to find out the significance of Android App. **Healthcare professional agrees that; there is scarcity of online educational materials in pharmacy, hence Android App will play significant role for students. Response sheet reveal that students also excepting infographics, video lectures, animations, MCQs, medicinal information, current affairs, industrial processes in App.** App will ensure activity based learning (ABL) and better understanding. It will empower students with current advancements & bridge gap between industry and institute & ensure output based learning. It is useful to cope up new PCI syllabus by using IPQC tools quality culture can be developed. App will be fast, economic and easily available and helpful in examinations. It is concluded that Android App in pharmacy education can catalyze learning and understanding. It will help them to keep pace with the advancement and hence it will ultimately helpful to reform pharmacy education to meet professional challenges.

Keywords: Android App, Education, ABL, Quality culture.

I-34

Impact of Innovative Teaching Learning Methodologies in Pharmaceutical Education

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Abstract:

Education is a very powerful instrument for social change and transformation. Students must be empowered to be able to withstand the global challenges of the 21st century. The problems which society faces are essentially the problems of educational institutions which are required to be innovative as they teach new skills and develop new insights and approaches for solving social problems which the nation faces. Therefore, innovative teaching learning practice is the only way to facilitate learning, or the acquisition of knowledge, skills, values, beliefs and habits which directly enhance the quality of our education system. However, teaching must include two major components *i.e.* delivering and receiving information. Teachers may provide instruction in literacy and numeracy, craftsmanship or vocational training, arts, religion, civics, community roles, or life skills. Formal teaching tasks include preparing lessons according to agreed curriculum, giving lessons and assessing pupil progress. Ultimately, a teacher tries his best to impart knowledge as the way he understands it. So, any communication methods that serve this purpose without destroying the objective could be considered as innovative methods of teaching. The use of innovative methods in educational institutions has the potential not only to improve education, but also to empower people, strengthen governance and galvanize the effort to achieve the goal of human development. The purpose of this paper is to explain various innovative teaching learning methodologies and to evaluate the usefulness of these methods over traditional methods of teaching.

I-35

Forumulation Development and In-Vitro Evaluation of Controlled Release Matrix Tablet of Losartan Potassium

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Abstract:

Losartan Potassium Contolled release matrix tablet were formulated by wet granulation method by using HPMCK 100M,Ethyl cellulose,xanthan gum as polymers in the ratio of 1.25,1.5,1.75. The tablets were punched by using 8mm diameter flat faced punches.The drug excipient compatibility study was satisfactory with respect to physical characteristics. The final tablet were evaluated for weight variation hardness friability,disintegration time.The in vitro dissolution studies were carried out using USP TypeII dissolution apparatus.It was found that formulation f8 was released 90.68% at the end of 10th hour. The stability studies were carried out on optimised formulation.The results were confirmed that the formulated tablet were stable.

Keywords: Losartan Potassium Contolled release Matrix Tablets, HPMCK 100M.

I-36

Requirement of Education and Training for Pharmacists as a Global Health Care Professionals: Work Force and Training Task Force

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Abstract:

Pharmacists are the third largest healthcare professional group in the world, behind physicians and nurses. In many countries, an expansion of pharmacist responsibilities to a more consultative, patient-focused role has increased workforce demand and highlighted the need for educational reform. Among the countries reviewed in this report, pharmacist workforce density varies from a low of 3 per 10,000 population (Singapore) to a high of 11 per 10,000 (France). The US is second to France with approximately 9 pharmaceutical personnel per 10,000. The UK, Germany, Australia and Canada ranged from 5 to 8 personnel per 10,000 population. The number of pharmacists are increasing in many countries, in part due to a rise in the number of accredited pharmacy programs and other training options, such as distance learning programs. The pharmacist supply (full- and part-time) in the US is expected to grow from 226,000 in 2004 to 305,000 by 2020. However, government data showed an estimated shortfall of approximately 10,400 pharmacists (5%) in 2004, and a 10% workforce shortage is predicted by 2020. Another estimate puts the projected shortfall of pharmacists in the US much higher, at approximately 150,000 by 2020. Other countries are facing similar trends. A projected pharmacist shortfall of approximately 10,000 is predicted in Australia by 2010, and Canada's shortfall was approximately 10% in 2000.[6] A number of factors contribute to the pharmacist workforce shortage experienced in many countries, including an aging global population, an increase in the number of prescriptions, the changing role of pharmacists, increasing administrative burdens within healthcare payment systems, and more women entering the profession only on a part-time basis. Imbalances in the distribution of pharmacists between rural and urban areas also create geographical shortages within countries. The majority of pharmacists are employed in community pharmacy settings, followed by hospital, industry, research/academia, and regulatory agencies. European countries have the highest percentage of pharmacists working in community pharmacy settings; the Western Pacific and Southeast Asian regions, which include Australia and Singapore, have a higher percentage of their pharmacists working in industry settings compared to other regions. The International Pharmaceutical Federation has partnered with UNESCO and World Health Organization to establish a Global Pharmacy Education Task Force with an Action Plan for promoting comprehensive education development and achievement of competencies in global pharmacy practice. The Task Force is leading a number of initiatives, including recommendations for improving academic workforce capacity and educational institutions, developing a framework for quality assurance of pharmacy education programs, and developing a competency framework for the pharmacy workforce.

Requirement	**US**	**UK**	**France**	**Germany**	**Australia**	**Canada**	**Singapore**
Previous	No , but generally 2	No	No	No	No	No	No
under-graduate degree	years of pre-						
required	pharmacy						
	under-graduate						
	course-work						

Years of pharmacy	4	4	6-9	4	4 (Bachelor's); 2	5 (Bachelors); 7 (PharmD)	4
school					(accelerated		
					Master's)		
Degree Title	Doctor of Pharmacy	Master of	Doctor of	Bachelor of	Bachelor of	Bachelor of Science in	Bachelor of Science
	(PharmD)	Pharmacy	Pharmacy	Pharmacy	Pharmacy; Master of	Pharmacy (B.Sc. Pharm);	in Pharmacy (B.Sc.
		(MPharm)	(PharmD)		Pharmacy	Doctor of Pharmacy	Pharm)
						(PharmD)	
Clinical/ residency	Clinical training	Optional 1-4	18 months	1 year	1 year post-grad	16 weeks during study; 4	12 weeks during
training	during study;	weeks during	– 4 years	during study		months post-grad; optional	study; 1 year
	Optional post-grad	study; 1 year	during			1 year residency	post-grad
	residencies and	post-grad	study,				
	fellowships		depending				
			on path				
Specialty training	Optional	Optional	Optional	N/A	N/A	Optional	Optional
			(by exam,				
			extended				
			program)				
Licensing/	National exams	National exam	National	National	National exams	National exams	National exam
Certification/			exams	exams			

Registration							
Re-licensure	Requirements vary	Process under			Annual, requirements	Annual (fee)	Every two years
Requirements	by state	development			vary		
Continuing education	Generally required,	No (may be	Policy in	No	No	Mandatory program, but	Mandatory for
required for renewal?	varies by state	linked to	developme			limited enforcement	re-licensure
		revalidation	nt				
		process					
Prescribing authority	Limited	Yes	No (except		Limited	Limited to full, depending	No
			emergency			on province	
			contracep-				

I-37

Analysis of the Use of Pharmacy Graduates in Task-Shifting as an Alternative Management Strategy in Healthcare Organizations

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Abstract:

The shortage of health care professionals and large patient load in developing countries like India, leads to large burden in healthcare system, resulting in impediment to optimum patient care.This leads to degradation in healthcare service quality. Based on our analysis, the data collected from 532 subjects reveals that only 7.01% of the subjects have received counselling always, 59.65% thinks counselling should be given and only 41.66% are satisfied with current healthcare system. This concludes that there is a scarcity of optimum patient care in the country for many chronic diseases. Hence a quick optimum solution is needed to address the critical shortage of trained healthcare professionals and it is found

that Task shifting is an optimum alternate solution to address such acute shortage of professionally qualified healthcare workers in developing countries. In Task-shifting model, task acceptors should be a paramedical or pharmacy professional who can be trained quickly to treat the patients. In India, Pharmacists being ignored professions in healthcare system have crucial role to play between the prescriber and the patients. Pharmacy graduates could be used as medicine prescribers asin other developed countries as addition rather than substitution. This paper contains the analysis of the advantages, benefits, constraints, and disadvantages of the use of pharmacy graduates for task-shifting by healthcare organizations as alternative survival strategy. Factors influencing the various determinant issues of task shifting according to identified key attributes under four constructs are derived and the critical constituent elements (CCE) of these factors are listed and analysed.

Keywords: Task shifting in healthcare organization, Pharmacy graduates, Alternative strategy, Optimum patient care, Factor and elemental analysis of Task shifting.

I-38

Pharmaceutical Industry Workers: From Improving the Health of Others to Deterioration of Their Own

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Abstract:

The pharmaceutical industry is an important component of the healthcare systems throughout the world. It is comprised of many public and private organizations that discover, develop, manufacture and market medicines for human and animal health.. Some manufacturing processes in the pharmaceutical, biochemical and synthetic organic chemical industries are similar, however the greater diversity, smaller scale and specific applications in the pharmaceutical industry are unique since the primary purpose is to produce medicinal substances with pharmacological activity. Many agents in the pharmaceutical and manufacturing are hazardous to workers. Proper control measures should be implemented to protect workers from industrial chemicals and drug substances during manufacturing and quality control operations. The data collected reveals that most of the pharmaceutical industry workers aren't satisfied with their work environment. Although utmost care is taken in maintenance of drug quality control there is no safe environment provided for the workers' health. Only 23% of the total workers surveyed have health and safety policies. A lot of workers are exposed to all harmful chemicals without any safety gear. Health providing industries are themselves facing health issues. Just 27% of the total surveyed workers are receiving regular health checkups. This clearly calls for a need of immediate measures to be undertaken in the pharmaceutical industry sector to promote safe work environment and ensure good health. From the study we conclude that most of the pharmaceutical industry workers are subjected to unsafe occupational environment. Hence further research is needed on this scenario.

Keywords: pharmaceutical industry, health policies, work environment, control measures.

I-39

Design and Evaluation of Bilayer Tablets of Efavirenz, Emtricitabine and Tenofovir Disoproxil Fumarate Tablets 600/200/300mg

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Abstract:

Bi-layer tablets of Efavirenz, Emtricitabine and Tenofovir disoproxil fumarate tablets 600/200/300mg were formulated by using microcrystalline cellulose, Hydroxy Propyl Cellulose, Croscarmellose Sodium. The combination of these drugs in a single dosage form will enhance patient compliance and exhibits antiretroviral activity. Efavirenz was prepared by wet granulation process and Emtricitabine Tenofovir disoproxil fumarate were prepared by dry granulation process. The tablets were

prepared by using Povidone and Sodium Stearyl Fumarate. The Drug-Excipient Compatibility study was satisfactory with respect to physical characteristics. The final tablets were evaluated for weight variation, hardness, friability, disintegration time. In-vitro dissolution studies were carried out using USP Type II dissolution apparatus using 2% sodium Lauryl Sulphate. It was found that formulation F8 has 95 % released within 30min. The stability studies were carried out on optimized formulation. The results were confirmed that the formulated tablets were stable.

I-40

Contaminated Currency Notes: A Major Threat to Human Health

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Abstract:

A paper currency note is widely exchanged for goods and services in countries. In India, on 31, March, 2016 total notes in circulation valued to ₹ 16.42 trillion, of which 86% of 500 and 1000. Lower the index value (5, 10, 20, 50) higher the chance of contamination because the exchange rate of these are very high when compared to high index denomination notes. The objective of this study was to know about the microorganism contaminating the currency notes, how and upto which extent. The major cause of contamination can be the unhygienic condition an individual living in, the unhygienic habits like improper hand washing after using the toilet, counting paper notes using saliva, coughing and sneezing on hands then exchanging money and placement or storage of paper notes on dirty surfaces and which may act as a major carrier of bacteria to contaminate the hands of the next user. Currency notes which are handle by a large number of people under a variety of personal and environmental condition, thus increase the possibility of acting as environmental vehicle for the transmission of potential pathogenic micro-organism. The commonly observed bacteria in currency notes in circulation are E.coli, Klebsiella pneumonia, Staphylococcus aurous of which most are resistant to commonly used antibodies, therefore it represents risk and public health hazard to the community. Several studies has been carried out to determine the level of contamination in currency notes in various countries and from the available data, it was observed that almost 100% currency notes in India are contaminated, compared to 69% in Mexico, 80% in UAE and 91% in Colombia. Considering this a serious issue, the govt. of India is taking steps to avoid the risks of contamination like minimizing the role of paper currency in its economy by the use of online transaction using credit card, and debit card. The replacements of cotton based bank notes by substrate material can play an important role in the reduction of bacterial contamination.

Keywords: Currency, contamination, micro-organism, hygiene, E. coli, antibodies.

I-41

Nanoparticles: Boon in Cancer Therapy

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Abstract:

Richard Feynman proposed nanotechnology which has been now used in the field of pharmaceutical sciences worldwide due to the newest possibilities which has emerged in the treatment and diagnosis various dreadful diseases such as cancer. The uncontrolled cell division and an abnormal change in the normal cell division is termed as cancer. The use of nanoparticles in the treatment of cancer have proved to be very advantageous. Nanoparticles along with chemotherapeutic agents enhancessolubility and stability of anticancer agents causing tumour elimination and reduces toxicity. Types of nanoparticles such as carriers, nanoparticles,dendrimers,quantum dots, micelles are part for the treatment of cancer and are used in preclinical stages currently. These nanocarriers improve the pharmacological effects. Their exclusive properties and surface volume ratio, and property to bind and absorb with RNA and DNA proteins. Nanoparticles have the advantage of overcoming the biological barriers and show localised action on the targeted sites. Nanomedicines like Abaxane (for metastatic breast cancer), Doxil (for metastatic ovarian and breast cancer) , zinostatinstimalamer (for hepatocellular carcinoma) and various other preparations are used to treat diseases. Thus nanoparticles are being used as novel drug delivery system for treating cancer.

I-42

Perception and Preferences of Teaching and Learning Methods Among M. Pharm Students: A Questionnaire Based Survey

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Abstract:

Introduction: Currently, the way of teaching is dramatically changed specially due to use of computer. Mostly, to teach post graduate students, now days, teachers are using Power Point Presentation but effectiveness of these methods is still unclear. Thus, this study was undertaken to assess the perception and preferences of teaching and learning methods among M. Pharm Students. Material and Methods: A questionnaire based survey was conducted in ISF college of Pharmacy, Moga, Punjab, covering all postgraduate students of different branches to assess the perception and preferences of teaching and learning methods. Results and Discussion: There were 10 different parameters/data points for which the data was collected from all Master degree students of ISF College of Pharmacy, Moga, Punjab. Descriptive statistics were used for analysis of data. Total respondents were 100. Among them 55 were females (55%) and 45 were males (45%). Majority of students have preferred Chalk and board method as compare to Power Point Presentation method. However, some of students preferred PPT method specifically in case to understand pathogenesis of diseases. Conclusion: Overall, Chalk and board teaching remains the best preferred teaching aid which can be supplemented with PPT to improve medical teaching.

Keywords: Teaching Methods; Chalk and board; Power Point Presentation.

I-43

Teaching: A Path to Quality Education in Education Industry

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Abstract:

The 21st century learner is referred to as "empowered digital native". With the "Digital India" programme's vision to transform India into a digitally empowered society and knowledge, the education sector in India is poised to witness major growth in the years to come. Technology-led reach and easy access will bring about a socio-economic difference in the lives of Indian learners. Teaching and learning are natural processes. Teaching is a profession, an art, a gifted talent with which only a few are born, and that it is a complex process requiring years of specialized university training. Increased teacher training and credentialing, requirements are methods for controlling the teaching 'profession' and feeding the machinery of the education industry. Teaching methodologies including best practices in teaching, assessment-tracking protocols, design documents are currently the monitoring tools for the evaluation of teaching innovations. The essential qualifications of the sage remain unchanged: knowledge, good communications skills, patience, dedication, integrity and leadership. Traditional teaching techniques, has come a long way from clay to blackboard to white board based which was teacher centered which still is useful, but education today revolves more around encouraging the student to awaken their curiosity and desire to learn. There is need of empowering and liberating students, giving them opportunities to excel in the classroom and beyond. Modern methods of teaching require different types of multidimensional teachers from motivators to analyst to organizer to consultant etc. Some of the innovative approaches which we feel is required for enhancing academic competence are reciprocal teaching, cooperative learning, constructive, integrated, collaborative approaches, design thinking, self-learning, research based approach, metacognitive approach, social media, free online learning tools etc.

Keywords: Teaching, learning, methodology, assessment, innovative teaching strategies.

I-44

Artificial Intelligence: The Future of Healthcare and Pharmaceutical Industries

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Abstract:

Although pharmaceutical industries and pharmacies play a key role in the healing process, the revolution in medical technology which has tumbled down the clear-cut roles of singular actors in the healthcare system, may require these to redefine their place in medicines also. The drug discovery process also requires a fundamental shift from its usual pattern for meeting the needs both of patients and society and this can be implemented using artificial intelligence (AI). AI is the branch of computer science emphasizing on creating intelligent machines that work and react like humans and pharmaceutical industry is one of the few top domains which can be benefited the most from emergence of AI. Using AI and machine learning, the pharmaceutical industry get an opportunity to do R&D differently, improving the success rate at the early stages of drug development. Industry is currently said to spend over

$1 billion per drug. Even after going very far in drug discovery process both in terms of time and money, the chances of the compound to make its way through to the market are less than 1 in 10. The drug discovery process can be greatly aided by the latest innovations in AI and machine learning technology. BenevolentBio, has been doing research into amyotrophic lateral sclerosis (ALS) with AI embodied in the company's judgement correlation system (JACS) which can review billions of sentences from a number of literature. The USFDA has also approved an epilepsy drug called Spritam that is made by 3D printers. It prints out the powdered drug layer by layer to make it dissolve faster than average pills. We are only just scratching the surface when it comes to the uses of AI and machine learning in drug discovery. To sum up, the basic concept of the future pharmacist covers the ancient mediwitch combined with the 21st century tech-guru and scientific professional. However, even at this early stage, the technologies are proving to be tremendously promising when it comes to giving new mechanistic insights to disease and thereby helping to identify promising targets.

Keywords: Pharmaceutical industry, pharmacy, drug discovery, artificial intelligence, machine learning.

I-45

Review on Hypertension in Diabetes

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Abstract:

Hypertension affects over 600 millions in the world. Over 3 millions in USA have diabetics. With hypertension (htn), with a diastolic BP of 95mm of mercury as the Cut of Point. Community hypertension evaluation clinic (CHEC)study in USA showed the overall prevalence of hypertensions more than 11%.Epidemilogical study have revealed the hypertension is twice as common in diabetics as compared to non diabetics. There is increased incidence of hypertension and obesity in diabetics among Indians and American Indians. Hypertension is a independent risk factor which influences morbidity and mortality from serious cardio vascular and cerebral vascular events.

I-46

Recent Trends in Nanomaterials and Nanotechnology in Drug Discovery and Development

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Abstract:

Nanotechnology is the fastest-growing technology in the world, and it is also called the Industrial Revolution of the twenty-first century. Many research, development, and manufacturing methods have been used globally to develop better and safer nanomaterials for various applications. Nanotechnology teaches us the critical properties of day-to-day materials and structures. The invention of the scanning tunneling microscope , carbon nanotubes , and fullerenes laid a path toward nanotechnology because atomic- and molecular-level studies could be performed using the STM and nanomaterials. Today this technology is employed in various fields such as engineering, technology, applied sciences, biomedical, pharmaceuticals, food and agriculture, and construction industries. The number of technical articles and patents related to nanotechnology and nanoproducts has been continuously increasing for nearly two decades. Within 10 or 15 years, it is expected that the industrial production of nanotechnology will be worth over $1 trillion. Thus, this technology will drastically change science, education, manufacturing, and the lifestyles of people around the world. Nanotechnologies are applied to cross industrial problems and are a general purpose technology that acts as both a basis for technology solutions or at the convergence of other enabling technologies, like biotechnologies, computational sciences, physical sciences, communication technologies, cognitive sciences, social psychology and other social sciences.

I-47

Policy and Professionalism in Pharmacy Education

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Abstract:

Pharmacy as a profession in the INDIA is on a path of significant change with legislative and policy changes to practice happening or on the horizon. The INDIAN government review of the regulation of health professionals will have a major impact on the profession of pharmacy and thus on the education of pharmacists. For many pharmacy academics there is also an

interesting dual professional identify; academics have an occupational identity from being a teacher but their identity as a subject specialist comes from their professional background. This essay will explore the impact of policy and professionalism on these dual identities in the context of pharmacy higher education.

I-48

Improving Communication Skills and will to make & Serve Quality pill of Pharmacy Students through Effective Precepting

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Abstract:

Pharmacy students should be given opportunities to learn and practice interpersonal communication skills during their community advanced pharmacy practice experience (APPE). Preceptors have the responsibility of setting the stage for the pharmacy students during their initial encounter. During this orientation to the site, students should become familiar with the history of the practice, the types of services provided, and the staff members. Once the orientation is completed, preceptors can develop strategies for incorporating the students into the practice's patient care activities. Students should participate in patient counseling, interviewing, and educational sessions. Also, students should participate in collaborative work with other health care providers. To ensure the development of communication skills in pharmacy students, preceptors can incorporate the teaching process "see one, do one, teach one" into their teaching activities. By following these strategies, preceptors can effectively and positively impact the communication skills of their students.

Incorporating the Student into Patient Care Activities

Once students understand the history, philosophy, and values of the pharmacists and staff members, they will be prepared "to approach/to communicate with patients and physicians" within the pharmacy setting. Communication strategies can differ for each type of relationship that is established with patients and other health care providers. Both written and verbal communication skills will be needed for establishing positive and productive relationships.

Establishing the Pharmacist-Patient Relationship

Pharmacists in all practice settings have opportunities to interface with patients, whether it is through counseling, interviewing, or educating. These sessions provide excellent training opportunities for students to develop therapeutic relationships with patients. This relationship is built on the foundation of trust and an open exchange of information; it is a *collaborative* relationship

Keywords: community pharmacy, advanced pharmacy practice experience, communication skills, preceptor.

I-49

Emulsions: Emerging liquid dosage form

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Abstract:

Emulsion is a mixture of two or more immiscible liquids. In these one liquid is dispersed in other liquid, one is dispersed phase and other continuous phase. Nowadays the dosage forms that are available in market have some limitations which can be overcome by emulsions. Unpalatable oils can be administered through emulsions. Aqueous phase can easily be flavoured. Some oily sensation caused by other dosage forms can be covered by emulsions. These can be easily and readily absorbed in skin. One of the most important advantages is that we can include two incompatible ingredients, one in each phase of emulsions. Oil in water emulsion is convenient for oral dosing, to cover unpleasant taste, to increase oral absorption. Emulsions are also used for external use to be applied topically on skin. There are microemulsions that are thermodynamically stable and optically transparent. Some emulsions available in the market are Biafine; used for dressing and management of wounds, Voltaren; used for relieving pain associated with muscles and joints, Dolowhite; used to relieve muscle stiffness, Cleviprex, used to lower blood pressure. Further research is going on this dosage form to get better formulations in future.

Keywords: Emulsions, advantages, research.

I-51

Factors Effecting Job Satisfaction among Pharmacist

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Abstract:

Pharmacy is the profession that links with health science with chemical science; it is committed to ensure the safe and effective use of pharmaceutical drugs. Job satisfaction is a feeling that an individual has about his/her job and the extent to which these feeling are satisfied in the workplace.Job satisfaction can influence the quality of work produced. Job satisfaction plays a vital role in job retention, motivation andimproved health system performance. A survey was conducted among the pharmacists using a pretested questionnaire in English with 9 questions. The questionnaire was on the basis of analysis, we found out that from 110 responses only 92% are satisfied with their profession and 7% are not satisfied with their profession. The factors which affect the job satisfaction found to be pay & promotion (58%), fairness (24%), job security (40%), work condition (57%), relationship with co-workers (33%), relationship with immediate supervisor (30%).From the study we can conclude that most of the pharmacists are satisfied in their profession. As the sample size was small the data collected was insufficient. Further studies can be carried out on this topic.

Keywords: Job satisfaction, Pharmacist, Work Condition, Health Sector.

J-2

Global Perspective of Regulatory Systems Pertaining to Spurious, Adulterated and Not of Standard Quality Drugs and to Recommend Measures for their Effective Eradication in the Indian Regulatory System

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Abstract:

There is a dire necessity to address the issue of Not of Standard Quality drugs in India as the same has acquired a pandemic situation. The Mashelkar Committee report has highlighted the need for & suggested ways to strengthen the drug regulatory system in our country. The Department-Related Parliamentary Standing Committee which submitted the 59th report on "The functioning of the CDSCO" is highly critical about the functioning of the CDSCO due to obvious reasons of skewed priorities and perceptions, shortage of staff and infrastructure, etc. The present Indian Regulatory set up is parallel type of a set-up, wherein we have the CDSCO and State Drugs Control Departments functioning parallel to each other with obvious disadvantages and demerits inherent of such a system. The biggest problem that is required to be tackled is that of non-uniformity in implementation of the Drugs and Cosmetics Act, 1940. The present regulatory system is functioning with an average of 40 to 50 % of sanctioned strength. The sanctioned posts are just 20 to 30 % of the actual strength required. Hence, the ineffectiveness of the regulatory system is obvious. The most important criteria for India to emerge as global leader in Pharmaceuticals is to have a robust drugs regulatory mechanism in the country. This study is aimed at evaluating the present Indian Regulatory system and suggest measures that can be implemented in a short time so as to effectively eradicate the menace of not of standard quality, spurious and adulterated drugs.

Key words: Regulatory System, Not of Standard Quality, Non-Uniformity, Changes, Merger.

J-3

Haemovigilance-Evaluation of Adverse Donor Reactions Reported in the Blood Banks of Kerala

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Abstract:

A retrospective review of all the no of donor Reactions reports of 19 blood banks of Kerala from 01/01/2014 to 31/12/2015 was done with the objectiveto describe the various adverse donor reactions and determine the frequency of their occurrence in whole blood donors.The total number of donations were 246092(94.34%) and the Donors rejected were14752(5.66%)1174(0.48%) had an adverse reaction of which 999(0.41%) were vasovagal related and 175(0.07%) were needle injuries. Mild vasovagal reaction contributes to 377/100000 (95% CI: 353-401), Moderate-24/100000 (95% CI: 18-30) and severe contributes to 7/100000 (95% CI: 3-10). Local complications caused by insertion of the needle, occurred with a rate of 71/100 000 donation (95% CI: 61–82). Most of the complications were vessel injuries with hematoma (49/100000 donations, 95% CI: 40-57) and extravasations (18/100000, 95% CI: 13-23). The remainder consisted of nerve injuries (5/100000 donations, 95% CI: 2–8). Donor safety is an essential prerequisite to increase voluntary blood donation. AE analysis helps in identifying the blood donors at risk of AE, applying appropriate motivational strategies, pre-donation counseling, and care during and after donation, developing guidelines and hemovigilance programme in countries with limited resources. Thus, it can be concluded that this study can be beneficial for the attainment towards the goal of safe donation and for establishing an effective donor hemovigilance system.

Keywords: Blood Donations, Blood Donors, Adverse Reactions.

J-4

Collation, Compilation and Comparison of GLP Compliance Requirements for Regulatory Approvals in Europe, Singapore and India

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Abstract:

Good Laboratory Practice (GLP) is defined in the OECD Principles as "a quality system concerned with the organization-

al process and the conditions under which non-clinical health and environmental safety studies are planned, performed, monitored, recorded, archived and reported". The aim is to ensure the quality, reliability and integrity of studies allowing the reporting of verifiable conclusions and the traceability of data. The present study activity to shed light on to the role of the GLP inspections which is helps to overcoming non-compliance activity. The objective of the present study is to identify the GLP inspection and understanding the underlying concepts for GLP compliance for licenses pertaining to Pre-Clinical study. The study compared and contrasted the GLP requirements and their inspection procedure of the regulatory authorities in India, EU & Singapore.

Keywords: GLP, Inspection, Compliance, Pre-Clinical Study.

J-5

Documentation for GMP Compliance of Herbal Products in India and Canada: Regulatory Overview and Perspectives

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Abstract:

In India, herbal product includes the traditional systems of practices of Ayurveda, Siddha and Unani medicines (ASU medicines) whereas in Canada, it includes the Natural Health Products (NHPs). The Drugs and Cosmetics Act, 1940 (D & C Act) contains the regulatory provisions with regard to ASU drugs in India and it is Natural Health Products Regulations (NHPR) in Health Canada.Manufacturing of herbal products are regulated under Good Manufacturing Practices (GMP) both in India and Canada. Schedule T of the D & C act lays down the GMP practices for the manufacture of ASU drugs in India. Even though the GMP procedure differs in both countries, documentation is a common and important activity during manufacture of herbals for GMP compliance. Good documentation practices are always followed by the developed countries during manufacturing of herbal products to maintain its quality and standards. Though the documentation practices described under Schedule T overrides in many aspects, acceptable changes may be adopted to strengthen the regulatory mechanism in India. It also helps to improve the quality and standards of ASU drugs and widen its influence in the international market. The aim is to study and analyze the documentation practice followed under GMP in both countries during manufacturing of Herbal Products and discuss the scope for inclusion of better acceptable methods in Indian regulations.

Keywords: Herbal, ASU drugs, NHPs, GMP, Documentation.

J-6

Registration of Utility Models in India: Need of the hour

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Abstract:

A Utility model is a type of intellectual property right to protect inventions, defined or described as second-class patents, petty patents etc. A legal monopoly granted for a slender time in exchange for an inventor providing appropriate information about the innovation. Utility models differ from patents in aspects such as the requirements for acquiring utility models are less stringent as compared to patents, protection is provided for a shorter duration of time, registration and examination of utility models is simpler and faster, and are more economical. China, Germany & Russia have the highest utility model grants globally their GDP's are 11,218,281 M$, 3,466,757 M$, 1,280,731 M$ respectively .The GDP's of China and Germany are greater than that of India (2,256,397 M$), the main reason for this is the absence of utility models in India and this affects the MSME's (Micro, small & medium enterprises), because these enterprises possess inventive capabilities but lack the technical and legal support to pursue patents, or their inventions fail to cope up with the stringent patentability criteria thus the inventions are not protected and the inventor suffers economic loss. These MSME's are an important component of the Indian manufacturing sector and contribute to stable monetary growth.Although India has well framed patent laws but still the MSME'S cannot avail the benefits of these legislations, thus employing utility models in India is the need of the hour to boost the growth of these MSME's and encourage more innovations, fueling greater economic growth and employment.

Keywords: Utility model, GDP, MSME's.

J-7

Comparative Study of Active Pharmaceutical Ingredients (API) Supply Chain in India, China and United states

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Abstract:

This study was the result of the examination API supply chain in India, China and United States countries.During this study, the information was collected through secondary media, i.e., the official Websites of the respective regulatory authorities, research article and the knowledge gained by interaction with various industrial and Govt. professionals in the field of regulatory affairs. APIs can be of two types: APIs consisting of single chemical substances which fall under the category of fine chemicals and APIs consisting of two or more chemical substances and Analysis of trends in exports and imports of Indian pharma sector. Chinese and Indian active pharmaceutical ingredient suppliers are striving to become global players. Expansion strategies have included having their plants inspected by the US Food and Drug Administration, and by alliances with, and acquisitions of, US in this market. Although the API industry in China is continuing to develop rapidly, it still lags behind its Indian counterpart. Today, China continues to be mostly a supplier of older, off-patent molecules, while Indian API manufacturers often focus on newer, still-patented molecules. As a result of the introduction of product patents in India. However, we see increased interest in older molecules by Indian API manufacturers, though the full impact of this change is difficult to determine at this time. A number of the fast-growing "second wave" of Indian generic companies and API manufacturers have continued to forge alliances with generics in the U.S., with an increasing number of the Indians focusing on supplying the finished dosage form as opposed to just the active ingredient.

Keywords: Active Pharmaceutical Ingredients, India, China, United States.

J-8

Investigative Approach in Resolving Regulatory Issues in Indian Pharmaceutical Sector

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Abstract:

India has been continuously evolving as a potential market in the pharmaceutical sector with an expected CAGR of over 15% per annum to reach USD55 billion over 2020. Indian Pharmaceutical sector accounts for about 2.4% in value terms and 10% in volume terms of the global pharmaceutical industry.20% of the global generic exports comprises of the Indian generics. However, it is disappointing that 35% of the world counterfeit drugs come from India occupying a drug market of Rs.4000 crore. 20% of the drugs sold in India are counterfeit drugs. Over 2, 00,000 brands marketed by over 10,000 Pharmaceutical companies in India are creating a load on the regulatory agencies making it very difficult to exercise control over each and every product. Why can't we assure use of quality medicines in our own country? Why such double standards when it comes to sale of medicines in India and other markets such as USA, European etc.? There is a realization that an attitudinal change is required from both the QA subordinate end and the investigator's end to ensure a better teamwork in providing quality medicines. Training and development of the subordinates in handling or responding to regulatory queries and other important aspects shall be one approach in overcoming this problem. Further, a keen knowledge based rational investigation is a must in order to reach to the root of the problems and ultimately resolve the issue. Training of the students in academic institutions for investigative approach in resolving knowledge based issues is highly recommended.

Keywords:Counterfeit Drugs, Substandard Medicines, Regulatory Issues.

J-9

Rationale and Regulations for Therapeutic Ingredients in Cosmetics: India versus World

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Abstract:

The trend of using cosmetics as a vehicle for therapeutic ingredients has increased exponentially in the recent times, not only because the expectations of consumers is for a value-

added product but also due to cut throat competition in the open market. The rationale behind it is to deliver nutritional and functional ingredients topically, but it is also being exploited by many manufacturers to bypass regulatory clutches. Though India is clear on its stand regarding regulations for cosmetic vis medicated topical product in comparison to those nations where these medicated cosmetics enjoy the status of either quasi drugs or OTC drugs. But with the incorporation of many herbal actives and nanotechnology driven active ingredients in cosmetic formulations, there is a need to revisit the regulations of the cosmetics. Though some products claim to contain unique botanical extracts or some rare ingredients with magical skin altering properties, most of them use ingredients such as peptides, retinol, ceramides, alpha lipoic acid, alpha hydroxy acids, beta hydroxy acids, aloe vera, panthenol and vitamins in their formulations.This concept of therapeutic ingredients in cosmetics have been especially used by a number of skincare companies endorsed by dermatologists, to claim that the products contain more effective or more biologically active ingredients than just ordinary cosmetics. This paper throws light on the rationale behind adding therapeutic ingredients in cosmetics, regulatory status enjoyed by such products in various countries and reasons for India to review its present cosmetic regulations in changing paradigms.

Keywords: Medicated Cosmetics, Anti-Aging, India, Regulatory Aspects.

J-10

Regulatory Requirements forMedical Devicesin European Union

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Abstract:

A medical device is an instrument, apparatus, implant, *in vitro* reagent, or similar or related article that is used to diagnose, prevent, or treat disease or other conditions.Since, the 1990s, regulation of the medical device industry in Europe has been relatively unchanged. Recent incidents, such as the breast implant crisis and the hip replacements, have now prompted urgent regulatory and compliance reforms to the industry. Most significant of these are the European Commission's 2012 proposals for regulation on medical devices (EU MDR) and in-vitro diagnostics (EU IVDR). With the formal publication of guidance imminent, the proposals will give national regulators much more control and oversight of the medical devices industry—with adoption mandatory. If companies do not comply with these upcoming changes then this could possibly result in a company losing its license to operate. The impact of this regulation can dramatically alter the operations of medical device manufacturers and even impact the composition of their existing as well as future portfolios. Cost of compliance will most likely be significant. It is critical that businesses take action now—to gain stakeholder buy-in, prepare their organizations, and start implementing changes. This review looks to understand the range of impacts the EU MDR will have on the industry—from change management to portfolio reviews to product labelling. This study explores regarding taking charge of the new medical device regulatory environment: From complex regulation to impactful change.

Keywords: European Union, Medical Device, EU MDR, EU IVDR.

J-11

Electronic Medical Device Reporting (eMDR) In USA

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Abstract:

Medical devices play an increasingly vital role in health care delivery around the world. Pharmacovigilance of medical device is close monitoring of any undesirable occurrence resulting from a medical device by means of having a system in place which comprises identifying, collecting, reporting, and estimating undesirable occurrences and reacting to them, or safety corrective actions after their post-marketing phase. For example, due to malfunctioning of medical devices like babies being burnt to death due to short circuits in incubators, or hip implants causing blood poisoning so medical devices has to be watched carefully for possible danger or serious adverse events or difficulties has to be reported to safe guard the health of the people. For this USFDA had developed the pharmacovigilance programme, MDR (medical device reporting). Medical device reporting is a procedure for the food and drug administration to get significant medical device adverse events information from manufacturer, importer and user facilities so these institu-

tions can be detected and corrected quickly. The MDR is meant to monitor medical device adverse events to create awareness among healthcare professionals about the importance of MDAE (Medical Device Adverse Event Reporting) reporting and to monitor the benefit-risk profile of medical devices. It is also meant to generate independent, evidence-based recommendations on the safety of medical devices and to communicate the findings to all key stakeholders. Medical device reporting programme reduces the likelihood of recurrence of the harmful incidents elsewhere, thereby improving medical devices quality.

Keywords: Medical Device, Adverse Events, MDR, Pharmacovigilance.

J-12

Regulatory Aspects of Personalized Medicine

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Abstract:

Personalized medicine is a type of medical care in which treatment is customized for an individual patient on the basis of specific characteristics, including age, gender, height/weight, diet, environment, etc. Basically, the purpose of introducing personalized medicine is to develop the new therapies and optimize the right dose of drug at a right time. For achieving these, we need to overcome numerous numbers of scientific challenges, which include; determine biomarker that have the most clinical significance, limiting the off-target effects of gene based therapies and also need to conduct clinical studies to identify genetic variants that can correlate with a drug response. The success of personalized therapy depends upon the accurate diagnostic tests to identify patients, who can be benefited from target therapies. The future of personalized medicine lies in the therapy of disorders which emerges due to genetic mutation like cancer,*Alzheimer's etc.*Various regulatory agencies are working to ensure the accuracy of these medicines, so that the patients and clinicians can receive more accurate test results. United *States* Food and Drug Administration (USFDA) has drafted some guidance related to the NGS (i.e. Next Generation Sequencing) tests. NGS tests having a capability of identifying or sequencing large sections of a person's genome and are important advances in the clinical application of personalized medicine. Physicians and researcher can use these tests to find genetic variants that help them in the diagnosis, treatment and help them to understand more about human diseases.

Keywords: Personalized Medicine; Biomarkers; Target Therapies; Next Generation Sequencing Tests (NGS); Precision Medicine.

J-14

Role of Regulatory Affairs in Branding of Medical Devices and its Future Scenario

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Abstract:

Therapeutic treatment based on the medical devices (MDs) is providing technologically advanced solutions for the management of several diseases, which is continuously growing day by day. However, the treatments based on the medical devices also carry significant risk with them, which if neglected can lead to life threatening accidents and can cause severe consequences. Therefore, certain rules and regulations are required for monitoring the entry of such devices into the market and a complete successful clinical trial before entering into the market. Regulatory bodies or also known as government bodies have come up with certain guidelines for the import, manufacture, sales and distribution of these devices and for the safeguard of public health as well as to ensure that effective and technologically advanced inventions reach out patient regularly. Every country has its own regulatory body for the fulfilment of public health safety purpose. The regulatory bodies relay on a number of core principles and concept such as product safety, effectiveness and quality of devices. When it comes to branding, branding is not only about getting your target market to select your product over the competition but about getting your prospects to see you as the sole provider of a solution to their problem or need. Brand gives something to believe in, something to stand behind and help to understand the purpose of the organization. Choosing the right brand name for a new medical device is becoming increasingly important in a world where having the right name for a product can make the difference between a blockbuster hit and a flop. Thus, it can be concluded that how regulation should be presented and applied for device safety and how branding play an important role for marketing of medical devices.

Keywords: Medical Devices, Regulatory Bodies, Branding, Marketing.

J-15

Vaccine Adverse Event Reporting System (VAERS) In USA

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Abstract:

The pharmacovigilance of vaccines is defined as the science and activities relating to the detection, assessment, understanding, prevention and communication of adverse events of immunization, or any other vaccine, or issues related with immunization.The strengthening of pharmacovigilance is very important in every country because it helps professional health care workers to avoid the problems with immunization, protect the health of people from adverse events during immunization. The USFDA has developed the valuable tool for post-marketing safety surveillance for Vaccines, VAERS (Vaccine Adverse Event Reporting System). VAERS reports are monitored carefully by the Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA). Adverse drug reaction is fourth to six leading cause of death among hospitalized patients, and reporting and prevention of the adverse effects are more important in case of vaccine.The success of the immunization system is reducing morbidity and mortality related to the vaccine. The vaccines are biological products used to prevent infectious diseases, but sometimes the vaccines can cause some AEFI (Adverse Events Following Immunization). The detection of adverse events following correct immunization is one very important step for prevention of problems in the immunization system.

Keywords: VAERS, Pharmacovigilance, Adverse Event.

J-16

ANDA Submission - Rejection to Acceptance

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Abstract:

The generic drug user fee Amendments of 2012 requires more stringent criteria for ANDA. So, the review period needs several cycles of response by FDA. Hence, this compilation is intended to guide applicants preparing to submit to the Food and Drug Administration (FDA) abbreviated new drug applications (ANDAs), and prior approval supplements (PASs) to ANDAs for which the applicant is seeking approval of a generic drug product. The guidance highlights different factors or parameters of prior approval supplements (PASs), major and minor deficiencies that may cause rejection to acceptance an ANDA by FDA. This guidance identifies certain deficiencies and certain recurrent deficiencies that in FDA's experience have led FDA to rejection-to-acceptance an ANDA. This guidance also describes how FDA will assess deficiencies identified during FDA's filing review to determine whether an ANDA should be received. We note that industry is aware of many of the standards described in this guidance because FDA has historically applied many of these standards in its rejection-to-acceptance determinations.

Keywords: FDA, ANDA, Rejection-to-Acceptance.

J-17

Annual Safety Report: A Comparative Study of USA and EU

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Abstract:

Annual safety report shall submit by the sponsors, once a year throughout the clinical trial or on request safety report to the competent authority, Ethics Committee of the concerned Member States, considering all new available safety information received during the reporting period.The aim of the annual safety report is to describe concisely all new safety information relevant for one or several clinical trial(s) and to assess the safety conditions of subjects included in the concern. The annual safety report should be the same for the competent authorities concerned and the Ethics Committee concerned trial(s). The new version of Annual safety report is DSUR (The Development Safety Update Report) and is intended to be a common standard for periodic reporting on drugs under development among the ICH regions. U.S. and European Union (EU) regulators consider that the DSUR, submitted annually, would meet national and regional requirements currently met by the U.S.

investigational new drug application (IND) annual report and the EU annual safety report, respectively and can therefore take the place of these existing reports. DSUR provides an outline of points to be considered in its preparation and submission. Finally, it concludes how risks have been managed in the trials and any additional actions that should be taken to address emerging safety issues.

Keywords: Annual Report,ASR, DSUR, US, EU.

J-18

Regulatory Requirements for Biological Products in Australia

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Abstract:

The Australian Regulatory Guidelines for Biologicals (ARGB) provide information for manufacturers, sponsors, health professionals and the general public on the legal arrangements in Australia for the supply of goods derived from human cell and tissues, and living animal cells, tissues and organs (collectively defined as 'biologicals'), this explains which products are included in the new Biologicals Regulatory Framework, and why. It describes transition arrangements that apply for up to three years to allow all biologicals to meet the new arrangements. The TG Act defines a biological as an item made from, or containing, human cells or human tissues, and that is used to, treat or prevent disease or injury, diagnose a condition of a person, alter the physiological processes of a person, test the susceptibility of a person to disease, replace or modify a person's body part(s). An item can also be specified as a biological by the Secretary. The Secretary is the person who is the Secretary (i.e. the chief executive officer) of the Australian Government Department of Health and Ageing. The Biologicals Regulatory Framework allows for four classes of biological based on the risk posed by the products, which are in turn related to the methods used to prepare and process the products during their manufacture and whether their intended use is the same as their usual biological function. Therefore, our aim is to give information about regulatory requirements for biological products in Australia.

Keywords: ARGB, TG, Australia.

J-19

Challenges in Approval Process of Class 1 Medical Device in ICH Countries

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Abstract:

The Regulation of medical devices involves competing goals of assuring safety and efficacy while providing rapid movement of innovative therapies through the investigative and regulatory processes as quickly as possible. Assessing medical devices (MDs) raises challenges which require us to reflect on whether current methods are adequate. Major features of devices are: (i) device–operator interaction can generate learning curve effects; (ii) incremental nature of innovation needs to be addressed by careful identification of the alternatives for comparative and incremental costeffectiveness analysis; and (iii) broader organizational impact in terms of training and infrastructure, coupled with dynamic pricing, requires a more flexible approach to costing. The United States and the European Union approach these challenges in different ways. Japan's approval process is getting faster and is now roughly equivalent to the US. Japan has reduced regulatory timelines and introduced a number of favourable initiatives for fast tracking and premium price acquisition. The European Union regulates medical device approvals through a network of centralized and decentralized agencies throughout its member states. Japan is a large and potentially profitable market. The environment for market entry is improving. This study explores some of the challenges facing in European regulation and U.S. Regulation Medical devices each.

Keywords: Device approval, European Union, Regulatory Timelines.

J-20

Regulatory Pathways for Vaccines for Developing Country: India

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Abstract:

The challenges faced in delivering lifesaving vaccines to the targeted beneficiaries need to be addressed from the existing knowledge and learning from the past. This review documents the history of vaccines and vaccination in India with an objective to derive lessons for policy direction to expand the benefits of vaccination in the country. A brief historical perspective on smallpox disease and preventive efforts since antiquity is followed by an overview of 19th century efforts to replace variolation by vaccination, setting up of a few vaccine institutes. The early twentieth century witnessed the challenges in expansion of smallpox vaccination, typhoid vaccine trial in Indian army personnel, and setting up of vaccine institutes in almost each of the then Indian States. In the post-independence period, the BCG vaccine laboratory and other national institutes were established; a number of private vaccine manufacturers came up, besides the continuation of smallpox eradication effort till the country became smallpox free in 1977. The Expanded Programme of Immunization (EPI) (1978) and then Universal Immunization Programme (UIP) (1985) were launched in India. The intervening events since UIP till India being declared non-endemic for poliomyelitis in 2012 have been described. Though the preventive efforts from diseases were practiced in India, the reluctance, opposition and a slow acceptance of vaccination have been the characteristic of vaccination history in the country. The operational challenges keep the coverage inequitable in the country. The lessons from the past events have been analyzed and interpreted to guide immunization efforts.

Keywords: Eradication, India, Smallpox, Vaccination, Vaccines.

J-21

Outsourcing Clinical Trials on Foreign Soil: Strategies and Implications

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Abstract:

Outsourcing clinical trials has been a subject of both controversy and relevance in the pharmaceutical community. It is an important part of drug development that not only reveals the effectiveness of new medications, but it also brings on such a powerful effect on public health. The statistics on the economics of clinical trials are astounding. Approximately one-third of the trials registered on clinicaltrials.gov are now conducted exclusively outside the US; over half of all study sites are now outside the US.Scientific issues related to the 'outsourcing' of clinical trials include the need for transparency with regard to access to data, and publication rights for investigators from developing countries who might be inexperienced in trial design, implementation, and analysis (and consequently may have little marketing or intellectual clout with the sponsor). A brief historical overview, prevalence, business strategies, and need for transparency in conduct of foreign clinical trials are discussed.

Keywords: Clinical trials, Good Clinical Practices, Health Care.

J-22

Indian Pharmaceutical Pricing Policy and Control: An Overview

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Abstract:

Pharmaceutical sector is playing a key role toward the wellness of the people and economic development of India. The innovation, development, production, and marketing of medicines are accountable to the pharmaceutical industry. It is the duty of the government to ensure the availability of the lifesaving drugs at reasonable prices by considering the interest of both the producers and the buyers. To safeguard the public health, the National Pharmaceutical Pricing Authority (NPPA) is the supervisory body in India, which controls the prices of drugs. The main objective of this study is to ascertain the various roles played by the NPPA, to control the prices of the drugs in India. To ensure the affordability of medicines along with the pricing policy, the Indian government may look and concentrate on the other important areas of pharmaceutical sectors. In liaison with NPPA, the pharmaceutical companies will reduce the expenses in order to make affordable drugs to comply with the government drug pricing policy.

Keywords: Pharmaceutical Sector, Pricing, Drugs, Regulator, Drug Price Control Order.

J-23

Comparison between United States and European Union Drug Regulatory Process

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Abstract:

Regulatory agencies have a responsibility to ensure that high-quality safe, and effective medicines are made available to patients in a timely manner. Despite the fact that all regulators worldwide share the same aims, they do not adopt a consistent approach to drug approval, and as a result, medicines are often approved quicker in some countries than in others. The regulation of medical drugs and devices involves competing goals of assuring safety and efficacy while providing rapid movement of innovative therapies through the investigative and regulatory processes as quickly as possible. The United States and the European Union approach these challenges in different ways. Whereas the United States has always relied on a strictly centralized process through 1 agency, the Food and Drug Administration (FDA), the European Commission synchronized the regulations of 28 different countries as they combined to create the European Union. The FDA historically developed as a consumer protection agency, whereas the regulations from the European Commission arose out of a need to harmonize interstate commercial interests while preserving national "autonomy."Thus, whereas the FDA has the advantages of centralization and common rules, the European Union regulates medical drug and device approvals through a network of centralized and decentralized agencies throughout its member states. This study explores some of the similarities and differences in European and U.S. regulation of drugs and devices, and discusses challenges facing each.

Keywords: United States, European Union, Food and Drug Administration (FDA).

J-24

GDUFA: Implementation and the Latest Amendments

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Abstract:

The Generic Drug User Fee Act (GDUFA) is a law designed to speed the delivery of safe and effective generic drugs to the public and improve upon the predictability of the review process. Overall Purpose of the GDUFA is to help FDA to ensure that participants in the U.S. generic drug system comply with U.S. quality standards, and to increase the likelihood that American consumers get timely access to low cost, high quality generic drugs.In pre-GDUFA time due to limited resources, FDA was not able to keep pace with an increasing number of applications requiring review. However, with the enactment of the GDUFA User Fee Amendments of 2012, for the first time ever, FDA received funding from the generic drug industry to ensure the timely access to safe, high-quality, and effective generic drugs. GDUFA II was signed into law on August 18, 2017, in order to facilitate timely access to quality, affordable generic medicines and to address the issues related to GDUFA. Further, FDA agreed to review goals and procedures for the scheduling and conduct of post-Close Response Letter meetings.

Keywords: GDUFA, Amendments, GDUFA II.

J-25

Requirement of Strict Regulations to Monitor E-Pharmacy in India

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Abstract:

In our country, the sale of drugs and cosmetics is controlled by the Drugs and Cosmetics Act, 1940 and Rules, 1945, and Drugs and Magic Remedies Act, 1954. When these acts were framed, the internet was not existed. But today is the internet era & e-commerce has taken a front seat and pharmaceutical business is not an exception to it. Today there are several e-pharmacies dealing in the sale of drugs & cosmetics across the globe.Purchasing of drugs via online portal is an easy exercise for the customer, however; at the same time, it is a risky affair in case of potential drugs. Purchasing drugs or medicines via online portal is preferred by the Indian patients and consumers as it is easy & time saving. The sale of drugs via online portal where

there is no intervention of pharmacist may pose the danger of misuse of the drugs by patients. Number of online pharmacies increases due to this increase in trend of online medicine purchase. Indian laws are quiet on the issue of e-drug stores and don't have any regulation to monitor online selling of drugs. The common problems anticipated in e-pharmacy may include fake and illegal dispensing sites, drug abuse, medication errors, counterfeit medicines, substitution and Pharmacovigilance. Ethical conduct ensuring privacy and confidentiality of the patient is one of the corners tones of medical practice. Selling drugs over the Internet obviously necessitates the collection and use of confidential medical information. There is lack of proper regulatory checks and balances for exercising regulatory control over e-pharmacies. The objective of this paper is to create attention of regulatory authorities not only eliminate unlawful E-pharmacies, but also to make strict regulations for valuable addition to both the healthcare industry and e-commerce platform- the lawful e- pharmacy.

Keywords: E-pharmacy; Online Sell.

J-26

Cons and Pros of GST on Pharma Sector

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Abstract:

The cost of inputs is much higher than output, i.e., the raw materials are costlier in terms of duty than the finished product itself hence depressing investments from the manufacturer. India has slipped in 'business optimism' index to the 7th position in the September quarter, from the 2nd slot in the previous three months, showing clear signs of lag in the economy, says a survey. Profit margin has reduced to a lot. Pharmaceutical products will see 28 per cent GST as against earlier rate of 10 per cent. The healthcare sector will remain exempt from the GST however the inputs by the healthcare sector will be taxed at 18 per cent leading to rise in the operating costs. Lifesaving drugs like insulin have received fall in their price; whereas other generic drugs have increase in their price. Cosmetics have inflation in their price after approval of GST. Expired and out of stock medicines are being returned to industry with taxes. Four types of taxes are being implemented 5%; 12%; 18%; 28%. Payment of tax changed from quarterly to monthly for those whose turnover is more than 75lakh. A scheme applied to sale of medicines to the retailer from manufacturer is being implemented with taxes GST. Neither does the supply chain benefit in any way, as this business of input credit was available pre-GST too. In fact, manufacturers and traders will be filing returns every month and those small traders who are not computer savvy will need to become savvy or depend on competent persons for help. There is no obvious way, if one has followed the above analysis, how medicine prices can decrease if everybody at every stage maintains the same profit margins. We have seen the GST rates of 12% on formulation were about 2.3% more than the incidence of tax before GST.

Keywords: GST, Pharma Sector, Cosmetics.

J-27

Nanomaterials in Cosmetics: Current and Future Global Regulatory Aspects

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Abstract:

Nanotechnology draws its name from the prefix "nano". A nanometer is one-billionth of a meter (1 nanometer = 10^{-9} meter). It is the distance equal to 2 to 20 atoms laid down next to each other (depending upon the type of atom). The term Nanotechnology means manipulation of the structure of a matter on a particular length scale of having nanometers, interpreted by different people at different times. The matter size varies from 0.1 nm (by controlling the arrangement of individual atoms) to 100 nm or more (anything smaller than microtechnology). The global market for products that contain nanomaterials is predictable to reach $3.0 trillion by 2019. The use of nanotechnology has stretched across various streams of science, including electronics, medicine and cosmetics (pronounced as nanocosmetics). Nanotechnology field is growing enormously in many areas with more than 13% nano based products coming in the cosmetic industry. The use of nanoparticles in cosmetics formulations for different applications has led to various safety concerns worldwide, including skin particles which comes in direct or indirect contact to the environment, waste particles management etc. It is major issue which needs immediate attention. In this poster, main emphasis is made on the use of nano materials in cosmetics industry and definitions of nanoparticles in various countries like, United States of America, European Union, Canada, Japan, and Australia. Another emphasis is mainly on "Regulatory and Safety Aspects of Nanomaterials used in Cosmetics" in different countries like India, Europe, Brazil etc.

Keywords:Nanotechnology, Cosmetics, Regulatory and Safety Aspects, Health and Safety.

J-28

National Health Programs: Either on Papers or in Communities - A General Survey

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Abstract:

India's health system was designed in a different era, when expectations of the public and private sectors were quite different. India's population is also undergoing transitions in the demographic, epidemiologic and social aspects of health. There is an enormous capacity gap in health promotion and lack of sufficient resource material in India for effective implementation of the National Health Programs. There are various National health programs organized in favor of the general population. Few of them that we highlight in our study are Mission Indradhanush, National AYUSH mission and NPCDCS. We have carried out survey to collect data regarding the awareness, their attitude toward and assumptions of various National Health Programs among general population. Out of 224 subjects, only 4.91% males and 4.46% females are aware regarding the National Health Programs organized by the government of India. Our study revealed that 94.1% of the participants are not aware of the health programs started by the government accompanied by 96.54% from other non-medical occupational fields. Our study suggests the need for intensive awareness programs to create awareness among the general population as well as health care professionals and students regarding the health care programs, to maximize the benefits of the National Health Programs. This study also revealed the loophole in the implementation of various National Health Programs and root of failure of health programs to get implemented in various communities. This survey can increase the awareness of people in all parts of the country regarding National Health Programs.

Keywords: National Health Programs, Mission Indradhanush, National AYUSH Mission, NPCDCS.

J-29

Understanding the Root Cause Analysis of the Unmet Quality Standards using Right Metrics

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Abstract:

The objective of the study reveals the importance of data in the form of metrics used to gauge the site performance and to meet the maintenance or improving product quality, manufacturing quality and performance. Using the Leading indicators in the form of metrics to achieve the standards and regulation mechanism required for the pharmaceuticals products in Indian healthcare Industry as an Emerging Market in comparison to developed market – directly, by taking in account the no. of warning letters from last Five years (i.e. 2012-17) raised because of these leading indicators as - number of deviation, deviation per batch, No. of out-of-specification (OOS) by their regional as well as national Regulatory bodies of INDIA (CDSCO) and US FDA (CDER). Alternatively, another way to look on these deviations is by tracking the "Deviation past due" to mitigate the risk of recurrence and helps in determining the field of focus to meet the quality standards and came up with the result of the study with a conclusion of 5 top most root cause analysis with-in Indian Pharmaceutical Market.

KEYWORDS: CDSCO, CDER, NSQ, cGMP, GRP.

J-30

New Approach of Investigational New Drug Application for

Sponsor- Investigator in Pharmaceutical Industry as Per FDA Guidelines

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Abstract:

Investigation of new drug is a submission to food and drug administration (FDA) requesting permission to initiate a clinical study of new drug products. Clinical investigators invoke a number of specific regulatory requirements if their study includes use of a pharmaceutical agent. Studies using a drug that has not been approved by the Food and Drug Administration (FDA) or for indications not in the approved labeling may require filing an Investigational New Drug (IND) application with the FDA. If a study meets specific regulatory exemption criteria, then anIND may not be needed. Individual investigators may meet the FDA definition of a sponsor investigator, in

which case the application process is generally less complicated than for commercial sponsors, and this review addresses only this circumstance. The purpose of this article is to assist sponsor-investigators in preparing and submitting complete investigational new drug applications (INDs) to the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER) at the Food and Drug Administration (FDA). Sponsor-investigators seeking to do clinical research often do not have the regulatory knowledge or the resources to hire experts to help them with the IND submission process. Although not an exhaustive step-by-step instruction manual, this article highlights certain elements of this process to facilitate a sponsor investigator's successful submission of an IND. This article also discusses the IND review process and general responsibilities of sponsor-investigators related to clinical investigations.

Keywords:Investigational New Drug, Food and Drug Administration, Code of Federal Regulation, Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research.

J-31

Regulatory Requirements for Herbal Products in USA

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Abstract:

United States Food and Drug Administration (USFDA) Consider Herbal products as a Dietary Supplement which covered under Dietary Supplement Health and Education Act 1994(DSHEA). Unlike drugs DS do not have to be proved safe before going on the market. Federal Authorities can act to take them off the shelves if they are shown to be unsafe. Before drugs or food additives go in the market hundreds of research studies must be submitted to the FDA for review of the product's efficacy.A product taken by mouth that contains a 'dietary ingredient' intended to supplement the diet like vitamins, minerals, herbs, botanicals, amino acids, enzymes, extracts… It's neither food nor drug. These Supplements are not meant to replace foods, but to supplement diet to humans.Dietary supplements can be produced, sold, and marketed without first demonstrating safety and efficacy, as is required for pharmaceutical drugs. New Dietary Ingredient (NDI) Notification must be sent to the FDA within 75 days prior to marketing your Dietary Supplement that contains the NDI. No pre-market approval is required.Federal Trade Commission (FTC)regulates the advertisement related to dietary supplements.Understanding FDA regulations regarding Dietary Supplement is key to a successful product commercialization in the U.S.A. Knowing and abiding by FDA requirements for exporting Dietary Supplements in the U.S.A. will avoid unnecessary delays.

Keywords: DSHEA, FDA, NDI.

J-32

Comparison of Recommended Dietary Allowance of Vitamin in India, USA and Europe

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Abstract:

The present study was aimed towards the comparison of recommended dietary allowance in India, US and EU. Recommended dietary allowance means average daily level of intake sufficient to meet the nutrient requirements of nearly all (97-98%) healthy people. The purpose of this guideline is to inform you how much of a specific nutrient your body needs on a daily basis. It is important to meet your daily recommended dietary allowances so that your body gets everything it needs to function. Vitamins are a group of substances that are needed for normal cell function, growth, and development. Vitamins are grouped into 2 categories: fat soluble and water- soluble vitamins. Vitamins are considered essential nutrient. The nomenclature of vitamin and age division differs in every country. The most stringent and highest requirement of vitamin is found in Europe and USA compared to India.

Keywords:Recommended Dietary Allowance, Vitamins, Nutrition, India, EU, USA

J-33

Role of Pharmacovigilance in Drug Safety and its Future Aspects

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Abstract:

Pharmacovigilance is the science which is used for understanding and prevention of adverse reaction of medicines. The ultimate goal of pharmacovigilance is to improve safe and rational use of medicines for improving patient care and public health. Pharmacovigilance is helping to ensure patient safety for both newly released drugs and those that are well established in the market. It plays a vital role in ensuring that physician together with the patient have enough information to make a decision when it comes to choosing a drug for treatments. The current articles deal with some salient features and future scope of Pharmacovigilance.

Keywords: Pharmacovigilance, Adverse Reaction, Safety.

J-34

Technology Solutions in Clinical Pharmacy

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Abstract:

Electronic technologies have created remarkable applications in all industries even in Clinical Pharmacy. Some of the technology solutions are briefed in this paper for better use of electronics to reduce the time consumption, to overcome classical method disadvantages, to maintain reviews, history, data accuracy, to reduce waiting time, to minimize repitions, elimination of the paper storage costs, to achieve effective communication. Some of the technical solutions are electronic medical records systems like(CPOE, Inpatient computerized provider order entry systems), outpatient CPOE systems, Real time monitoring systems that provide a work queue of the patients needing of reviews and possible interventions. Automated systems to notify pharmacists, when medication serum concentrations or other clinically important laboratory values fall outside of a therapeutic or normal range. Use of a bar code technology during an inventory, preparation, compounding and dispensing process. Bar coding minimizes medication errors, wrong dispensing, strength, dosage. System which efficiently captures Pharmacy metrics and outcome data'.E-prescribing, like any new technological development, comes with advantages and disadvantages. Some of the most appealing benefits include enhanced patient safety and decreased medication errors, reduced drug costs with FDS software, increased access to patient medication records, and improved pharmacy workflow. Some of the most notable disadvantages are introduction of prescription errors, poor design features of e-prescribing software, and disruptions in pharmacy workflow. Last but least is telecare.

Keywords:Electronic Prescribing, Bar Coding, EMR, OEMR,EDPA, CPOE, Telecare.

J-35

Loan Licensing in India: The Golden Era of Pharmaceutical Industry

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Abstract:

Loan licensing is the method of getting manufactured own products in others premises. According to Drugs and Cosmetics Act 1940 and Drugs and Cosmetics Rules 1945 , a loan licensee in a manufacturer of drugs who may be a company, a unit, a body corporate or any other establishment having no drug manufacturing facilities ,but who intends to avail himself manufacturing facilities owned by a licensee in Form – 25. Loan license was granted in India so that the branded companies and manufacturing companies would come under Memorandum Of Understanding (MOU) and increase the generic market in India. In order to increase manufacture of drug products in India, the rule of the loan license was sanctioned first in 1965 and the first firm was carried out was for supply of 3,00,000 tablets of Isonicotine acid hydrazide (100 mg)by Manorama Raje T.B.Hospital Indore to Messrs. Cadilla Laboratories Ahmedabad, Gujarat. According to Indian Drug Manufacturing Association (IDMA) , loan licensee consist of 40 – 50% of the manufactured product out of the total manufactured product in India. As per Pharmaceutical policy of 2017, a scrap on loan licensing was announced. The draft policy appears to have great effect on the future of pharma industry, as some of the steps such as eliminating third-party manufacturing and loan licensing can hit the industry as well as the availability of medicines. To increase the importance of the Indian marketed products at the global level this decision is taken. But a severe negative response is seen from the pharma field. The loan license companies are given more 3 years to continue manufacturing and to show the positive results from it to the government.

Keywords: Loan Licensing, Indian Drug Manufacturing Association,

J-36

E-Health in INDIA: Opportunities and Challenges

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Abstract:

E-Health, broadly defined as the use of Information and Communication Technology (ICT) in health, can make a world of difference in all developed and developing countries. Most notable attribute of e-Health is that it is enabling the transformation of the health system from one that is narrowly focused on curing diseases in hospitals by health professionals, to a system focused on keeping citizens healthy by providing them with information to take care of their health whenever the need arises, and wherever they may be. Hospitals and hospital associations need to be aware of, prepare for, and properly manage, this transformation. It will change, forever, the role of hospitals in the business of producing health. It will make them more efficient, improve quality and strengthen processes. But it will also remove them as the centre piece of the health-care system, and give hospitals a more forward-looking and progressive role. Public health service run by Government is overburdened and collapsing. Large geographical size, increase population density, lack of transport, in accessibility, illiteracy, poverty, poor nutritional status, low budget for health, lack of funds and coordination and diversity in food habit and life style are various challenges that have triggered down trend in health services. The present paper discusses the challenges and opportunities in ICT implementation in health care specific to Indian scenario.

Keywords: Information and Communication Technology (ICT), E-Health, Public Sector.

J-37

Conformité Européenne, (CE) Marking for Various Classes of Medical Devices

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Abstract:

Conformité Européenne, meaning European Conformity (CE) appear on many products traded on the extended Single Market in the European Economic Area (EEA). They signify that products sold in the EEA have been assessed to meet high safety, health, and environmental protection requirements. When you buy a new phone, a teddy bear, or a TV within the EEA, you can find the CE mark on them. There are two main benefits CE marking brings to businesses and consumers within the EEA, Businesses know that products bearing the CE marking can be traded in the EEA without restrictions and Consumers enjoy the same level of health, safety, and environmental protection throughout the entire EEA. CE marking is a part of the EU's harmonisation legislation, which is mainly managed by Directorate-General for Internal market, Industry, Entrepreneurship and SMEs. The CE marking for Restriction of Hazardous Substances is managed by Directorate-General for Environment. Comprehensive guidance on the implementation of EU product rules can be found in Blue Guide. CE Marking Medical Device - Most manufacturers in medical electronics, medical software, active medical device, Implant(s), Large medical equipment's go for CE Certification. The CE Mark Certificate is a proof of compliance with essential requirements of the various classes (I-III) of Medical Device Directive (MDD).The Notified Body is permitted to assess whether a Medical Device meets certain standards and issue CE Certificate. Medical Device CE Mark is widely accepted across doctors and healthcare practitioners across the globe as a The Cost of CE Marking certification.

Keywords: MDD, CE, EEA.

J-38

Challenges in Designing of Medical Device

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Abstract:

The design process for medical devices is highly regulated to ensure the safety of patients and healthcare workers. This paper/Poster will present a review of the design process for medical devices. A common observation was that current device development has a tendency to be performed in the serial manner of requirements capture, design and then test. Within this serial approach, the captured requirements were often inadequate, there were frequent difficulties over deciding what

to test or how to test and there was confusion over device and process validation. It will cover the main stages of Feasibility, Design reviews, Design, Intellectual property (IP), Design verification, Manufacture, Design validation, Design transfer and Design changes. Few of the challenges that the Medical Device faces in design process and dealing with challenges are addressed.

Keywords – Validation, Intellectual Property, Feasibility.

J-39

FDA's Jumpstart Program: A Vital Tool to Accelerate Drug Approvals

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Abstract:

As pharmaceutical developers and manufacturers submit electronic product applications in ever greater numbers, the applications have also grown in complexity. In turn, CDER's workload has increased, and digital tools used to analyze large amounts of data are critical to consistent, reliable, and expeditious assessments of drug safety and efficacy. The scientists and physicians who serve on CDER's review teams, although experts in their respective specialty areas may have difficulties and spend valuable time navigating the digital intricacies of electronic drug product submissions. Jumpstart, a vital new service in CDER's portfolio, is meeting this challenge. The Jumpstart service is modernizing the drug review process; medical reviewers are using this service to quickly and thoroughly assess data from drug clinical trials, ensuring safe and effective products are approved for public use. Jumpstart runs a series of drug clinical trial data analysis early in the review process to assess data composition, quality, analyses options, and tools for the analysis, so reviewers better understand the data and have the information to conduct an effective evaluation of the drug product data submission. It is an effective test bed for new tools and technologies to determine best practices and how they could be broadened for use in the scientific regulatory review process.

Keywords: Jumpstart, CDER, Digital tools, Safety, Efficacy.

J-40

Comparative Study of the Regulatory Requirements for Cosmetics in India,US and EU

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Abstract:

The cosmetic industry is growing up with an equal pace with other developing technologies as a result it has been diversified creating a way for huge market for cosmetic industry. The growth in global economies, rising demands of skin and sun care products encourages the growth of the market for cosmetics. Consumer safety is the top priority and manufacturers are committed to upholding strict regulations as required by the regulatory authorities. More than 11 billion personal care products sold each year globally and show few adverse experiences reported. The law requires that every cosmetic and personal care product and its ingredients be substantiated for safety before going to the market. The USFDA can take action against any company that markets an unsafe cosmetic product. The law provides severe penalties, including seizures, recalls, fines and bans, for the manufacturers that do not meet these strict safety standards. The FDA has wide ranging authority to regulate and ensure the safety of cosmetic products. However, the common goal: To protect the consumer by ensuring safe ingredients and finished products. Hence this abstract deal with the comparison of all the regulatory requirements for cosmetics in US,EU and INDIA.

Keywords: Cosmetics, Regulations, Safety.

K-4

Clopidogrel-Induced Thrombotic Microangiopathy- A Case Report

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Abstract:

Clopidogrel was administered to a 65-year-old patient to prevent the recurrence of cerebral infarction. Twelve weeks later, he was admitted to our hospital with acute renal failure, haemolyticanaemia and thrombocytopenia, and was diagnosed with clopidogrel-induced thrombotic microangiopathy. Clopidogrel was immediately discontinued and corticosteroid and plasma exchange therapy were administered simultaneously. Thereafter, the patient's condition gradually improved. The patient had a decreased serum complement C3 level. This suggests that the activated alternative pathway is related to thrombotic microangiopathy (TMA). TMA is a critical drug-associated adverse reaction that clinicians should always be vigilant about, because clopidogrel is widely prescribed.

Key words: Thrombotic Microangiopathy, Clopidogrel, ThromboticThrombocytopenic Purpura, PlasmaExchange, Corticosteroid

K-5

Comparative Study of Sulphonyl Ureas versus Gliptins with Metformin in Cardiac Patients with Type-2 Diabetes Mellitus

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Abstract:

In the current research, a study is carried out comparing the use of Dipeptidyl peptidase-4 inhibitors (Gliptins) treatment versus sulfonylurea (SU) treatment in participants with type 2 diabetes mellitus (T2DM) along with cardiac complications. The objective behind the research was to examine the efficacy, weight variations and side effects of adding Gliptins or Sulfonylurea in the treatment regimen of patients having cardiac complications as comorbidity with type 2 diabetes mellitus. It was a prospective observational study conductedon about 40 patients each in sitagliptin and glimepiride group, in the department of Internal medicine, Endocrinology and cardiology, in KIMS hospital. Glycated haemoglobin (HBA1c) was the primary measure of efficacy. Safety was assessed by checking weight gain/loss, hypoglycaemia episodes and other laboratory investigations. The HbA1c level after 12 weeks and 24 weeks of treatment was significant compared to each other or from baseline. Both HbA1c and FPG decreased from baseline with each treatment, with no statistically significant differences between treatments. Concluding that a significantly lower incidence of reported hypoglycaemia was observed with Gliptins compared with sulfonylurea. Body weight decreased significantly with Gliptins but not with sulfonylurea. Significantly more patients on sitagliptin than on sulfonylureas achieved a composite endpoint of >0.5% HbA1c reduction with no reported hypoglycaemia or increase in body weight.The efficacy of sitagliptin was comparable. Gliptins had superior adverse effect profile with less chances of hypoglycaemia and weight gain.

Keywords:Type 2 Diabetes Mellitus, Cardiac Complications, DPP4 Inhibitors, Sulfonylurea.

K-6

Are Bachelor Students of Pharmacy Aware About Their Role in Pharmaceutical Industries

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Abstract:

The confusion and dilemma among Students (Undergraduates mainly) about their role in pharmaceutical industry as well a profession of pharmacy was evaluated in various pharma institutes of Anand District with the series of questionnaire. Around 400 questionnaires were distributed among students and Pharma companies with intention of receiving a better feedback about their views and the questionnaire was mainly dealt with how students are not aware about their role in profession of pharmacy and problems faced by pharmaceutical industries regarding hiring of fresher's. Based on evaluation of the questionnaire and 1on1 interviews with student, we found that most of the students did not have any idea about application of their academics and scope of pharmacy in industry as well as their role as a professional. This scenario can undergo a change if there is change in system of academics where teachers act as facilitators instead of just instructors. This scenario can change if we can refer to digital connection between the phar-

maceutical industries and students. There should also be side by side problem solving approach for students to get enlightened about their role. Students should be exposed to practical application of their academics through digital program.

Keywords: Pharmaceutical Industries, Bachelor Students.

K-7

Evaluation of Price Disparity among Generic Medicines Procured and Supplied through Government Schemes in India

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Abstract:

Even though the generic medicines are considered to be a cheaper option compared to the branded medicines in India, there is a need to study the price disparity among the generic medicines. Hence the present study aims to evaluate the price disparity in generic medicines under Government scheme in India. It was found that there were 101 generic medicines were approved with fixed price for procurement under the Central Government Health Services scheme. The prices of these medicines were searched for their availability as well as for current price in Bureau of Pharma PSUs of India (under Jan Aushadhi scheme) website. The major category of the generic medicine were antibiotics (53.45%) followed by NSAIDs (10.89%) and cardio-vascular (6.93%) drugs. It was clearly evident from the result obtained by comparing the prices across categories, that there were both positive as well as negative deviations. It was very much evident from the results of the mean differences that even though there are fixed price contracts being in place there is a price disparity in the generic drug prices seen under Government Scheme.

Keywords: Generic Medicine Price, CGHS, Jan Aushadhi, India.

K-8

Pathogenic Role of mobile phones in Germ thriving communities

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Abstract:

Mobile phone is part of human accessories and used in every moment in social life but are normally not cleaned properly. They serve as main source of transmission for many pathogenic disorders. The present study seeks to identify the bacteria present on the mobile phones used by 200 volunteer students, Cleaners, Workers and Staff of Hindu college of Pharmacy. The surface of phones was swabbed with sterile sticks and immediately streaked on three plates each of Nutrient agar. The petriplates was incubated in an inverted position at 37°C for 24 hours. Following incubation, the microbial colonies were isolated and identified. Thus, the purpose of this study was to investigate microbiological colonization on mobile phones and to suggest that the importance of following proper hygiene habits of using phones as they prove to be potential transmission vehicles for microbial populations responsible for several diseases.

Keywords: Mobile Phones, Micro Organisms, Disease, Transmission, Hygiene.

K-9

Change in Inflammatory Proteins in Tears due to Corticosteroid Treatment in Dry Eye Disease Patients

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Abstract:

The tear protein biomarkers can predict the effects of topical steroid treatment and desiccating stress in patients with dry eye disease (DED). To identify this concept, a randomized controlled clinical trial with 41 patients was done. The patients were treated topically with 0.1% fluorometholone (FML) or polyvinyl alcohol. Tear samples were collected in a controlled environment chamber using 1 µl glass capillaries at recruitment into the study and after a 3-week treatment period, both before and after 2 h exposure to desiccating stress. Ocular surface integrity (corneal and conjunctival staining and conjunctival hyperemia) was selected as the key DED-related sign and analyzed with proteomic data. Many proteins were

identified and relatively quantified from each tear sample. Analysis revealed 9 differentially expressed proteins between FML and PA treatments after 3 weeks and 7 after desiccating stress ($P < 0.05$). We also identified several differentially expressed proteins at the initial collection, which could be used to predict changes of conjunctival and corneal staining and conjunctival hyperemia after FML treatment and after desiccating stress. These proteins include complement C3 and calmodulin like 5, which could also differentiate the severity of DED at baseline.The identified proteins could be further used as biomarkers to identify patients most benefiting from FML treatment.

Keywords: Corticosteroid, Dry Eye Disease, Tear Fluid, Desiccating Stress.

K-10

Murine Lupus Nephritis: Daily Moderate Exercise is Beneficial and Social Stress is Detrimental to Disease Pathology

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Abstract:

In the current research, daily moderate exercise (DME) and stress management are underemphasized in the care of patients with lupus nephritis (LN) due to a poor comprehensive understanding of their potential roles in controlling the inflammatory response. To investigate these effects on murine LN, disease progression was monitored with either DME or social disruption stress (SDR) induction in NZM2410/J mice, which spontaneously develop severe, early-onset LN. SDR of previously established social hierarchies was performed daily for 6 days and DME consisted of treadmill walking (8.5 m/min for 45 min/day). SDR significantly enhanced kidney disease when compared to age-matched, randomly selected control counterparts, as measured by histopathological analysis of H&E staining and immunohistochemistry for complement component 3 (C3) and IgG complex deposition. Conversely, while 88% of non-exercised mice displayed significant renal damage by 43 weeks of age, this was reduced to 45% with exercise and significantly decreased deposits of C3 and IgG complexes. Further examination of renal infiltrates revealed a macrophage-mediated inflammatory response that was significantly induced with SDR and suppressed with DME, which also correlated with expression of inflammatory mediators. Specifically, SDR induced IL-6, TNF-α, IL-1β, and MCP-1, while DME suppressed IL-6, TNF-α, IL-10, CXCL1, and anti-dsDNA autoantibodies. These data demonstrate that psychological stressors and DME have significant, but opposing effects on the chronic inflammation associated with LN; thus, identifying and characterizing stress reduction and a daily regimen of physical activity as potential adjunct therapies to complement pharmacological intervention in the management of autoimmune disorders, including LN.

Keywords: Lupus Nephritis, Daily Moderate Exercise, Stress Management, Kidney Inflammation.

K-11

Fake Blood Cells Deliver Medicine

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Abstract:

Nanosponge delivery system was developed by Eva Harth, assistant professor of chemistry at Vanderbilt. Since 1950s, researchers have been trying to mimic the abilities of red blood cells. These flexible discs carry oxygen throughout the body, squeezing through the smallest capillaries to do so. In research, Proceedings of the National Academy of Sciences declared that these are biodegradable, biocompatible particles with the size, shape and flexibility of red blood cells. Such flexible, potentially long-lasting particles hold great potential for drug delivery. In 1966, similar particles with varied shape and size were made by Thomas Chang. By 1970s, it was observed that artificial blood particles work best at 200 nanometers or less than 30 times smaller than red blood cells. The active ingredients are added to vehicles in entrapped form since the nanosponges particles have an open structure the active substance is free to move in or out from the particles into the vehicle until equilibrium is reached when the vehicle become saturated. Once product is applied to skin, the active substance that is already in vehicle which will become unsaturated, therefore distributing the equilibrium. This will start low of active nanosponges particle into vehicle from it, to skin until vehicle is either dried or absorbed. Even after the nanosponges particles retain on the surface of the stratum corneum will continue to gradually release active to skin providing release over time.

Keywords: Nanosponge, Blood cells, Drug delivery.

K-12

Epharmacies Beginning of New Era in Healthcare

Industry

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Abstract:

The Indian pharmaceutical market in 2015-16 was Rs. 2,04,627.15 Crores. Of these the exports constituted Rs. 110, 5, 342.20 Crores and the domestic consumption was Rs. 98, 414.4 Crores. The Indian Pharmaceutical sector is largely fuelled by exports and is the 3rd largest foreign exchange earner for India. The industry has been growing at a Compound Annual Growth Rate (CAGR) of approximately 10% for the period 2010-11 to 2014-15. However, the growth rate is coming down from 14.36% in 2010-11 to 8.68% in 2014- 15.It employs about 2 Million work force across the value chain.Online pharmacies are expected to capture 5-15% of total pharma sales over the next few years, over 60 e-pharmacies start-ups have mushroomed in India in 2014 and 2015.So how does the online pharmacy model work. Customers go to the webpage or app, and upload their prescriptions through email or WhatsApp. Once the prescriptions are received, they are vetted by pharmacists. These are then digitized, and the orders are encrypted and transmitted electronically to fulfilment centers where they are decoded, packed and shipped. Every order is digitally timestamped and filmed to preserve a record of exactly what went into every package, Consumers can speak to customer service agents and pharmacists via voice over internet protocol and chat, they get push notifications and text messages on their mobiles, and messages on Facebook and Twitter. Another factor boosting the prospects of e-pharmacies is a steady rise of nuclear families. A report by BCG in 2015 estimated that more than 200 million households will have nuclear families by 2020. A rapidly ageing population, which curtails mobility, will also push online ordering. The share of individuals aged above 50 is projected to increase from 16% (roughly 190 million) in 2014 to 31% (approximately 506 million) by 2050. And those above 60 will grow from 8% to 18% of the total population during the same time.

Keywords: E-pharmacies, Pharmaceutical, Prescriptions.

K-13

Improving Energy Efficiency and Conservation in Pharmaceutical Manufacturing: Solar Energy

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Abstract:

Pharmaceutical industries face an increasingly competitive environment, they are looking for opportunities to reduce production cost without negatively affecting the yield or the quality of finished products. Energy conservation is an important way to reduce costs and to increase earnings. This presentation discusses few energy efficiency practices and energy efficient techniques that can be implemented at the instrument, process, system, and at organizational level too. The information in this Energy Conservation presentation is intended to help energy conservation in a cost-effective manner while using pharmaceutical instruments and maintaining the quality of products to be manufactured. Implementation of few energy saving techniques in pharmaceutical industries will play an important role in energy conservation.

Keywords: Energy Saving Technique, Solar Energy, Cost Effective.

K-15

The Roles and the Impacts of Principles of Material Management in Pharmaceutical Sector

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Abstract:

For many years, the primary focus of the pharmaceutical sector has been to provide patients with the best quality of medicine. Recently, with the increasing cost of supplies and the severe competition among pharmaceutical company, the pressure on material managers to operate more cost-efficiently without compromising the quality of medicine standards has significantly increased. The total material management activity starts right from selection of vendors for raw material and packaging material to dispatch of finished products to its destination. All incoming materials should be separately placed after received or processing, until they are released for use or distribution. Topics to be discussed include scope, problems, inventory control, objectives of inventory control, quantitative measurement of inventory control, and methods of inventory control, automated information systems, and quality assurance.

Keywords: Material Management, Raw Material, Packaging Material, Finished Product.

K-17

Need of Indian Drug Service (IDS) for Effective Management of Indian Pharmaceutical Sector

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Abstract:

The objective of this paper is to highlight the attention of Indian government for creation of Indian drug service (IDS) for better and effective management of pharmaceutical sector by bureaucrats of pharmacy discipline. The Union Public Service Commission is India's central recruiting agency & responsible for appointments to and examination for All India Services and Central Services. The Indian Pharmaceutical industry is growing at an enormous speed and expected to grow to US$ 55Billion by 2020, thereby emerging as 6th largest pharmaceutical market globally. As on today, most of the higher positions of pharmaceutical in government sector are governed by IAS officers. Most of the time these officers are not having any pharmacy & healthcare background and may not be aware with the quality parameters to be implemented for manufacture, import, sale & distribution of drugs. Few major challenges faced by the Indian pharmaceutical sector are non-compliance to c-GMP norms, hygiene, cleanliness around the premises of drugs warehouses and their maintenance by non-professionals or non-pharmacy professionals, sale of prescription drugs through unauthorized people and illegal online sales, counterfeit drugs in the market. Millions of rupees worth of medicines is getting wasted due to unprofessional management. Creation of IDS like other civil services could be the answer for effective governance of pharmaceutical sector in our country. Government has already taken an initiative by proposing to create IDS for the growth of pharmaceutical and health care sector. However, there is urgent need of IDS for induction of competent pharmacy professionals in key government departments regulating pharmaceutical sector.

Keywords: Indian Drug Service (IDS), Civil Service, Effective Management.

K-18

Newer Anaesthetic Agents with Neuro Protective Properties

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Abstract:

Based on preclinical evidence and clinical epidemiological observations there is a significant role of commonly used anesthetic agents in the development of neurotoxic effects. This evidence prompted the FDA to issue a safety warning for all sedatives and anaesthetics approved for use in children under three years of age. Recent studies have identified dexmedetomidine, the potent α2-adrenoceptor agonist, and xenon, the noble gas, as effective anesthetic adjuvants that both are less neurotoxic to the developing brain, and also possess neuroprotective properties in neonatal and other settings of acute ongoing neurologic injury. Dexmedetomidine and xenon appear to be less neurotoxic than other existing agents and possess potential neuroprotective properties in the neonatal and paediatric settings. Although results from recent preclinical trials and case reports have indicated the neuroprotective properties of xenon and dexmedetomidine, additionalrandomized clinical trials corroborating these studies are necessary. By reviewing existing preclinical evidence on the neuroprotective effects of dexmedetomidine and xenon, we hope to provide insight into the potential clinical efficacy of these agents in the management of paediatric surgical patients.

Keywords: Dexmedetomidine,Xenon,Neurotoxicity,Neuroprotection,Paediatric.

L-1

Economic Burden of Anti-Viral Therapy in Hepatitis-B Management-A Flexible Method of Approach

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Abstract:

Hepatitis-B has become a grave health concern due to its high morbidity and mortality rates as well as its expensive management options. Determining the Cost Effectiveness of the pharmacotherapeutic alternatives helps in improving the care of Hepatitis-B patients. But such data is sparse in India where the prevalence of Hepatitis-B is 4% and about 6 lakh patients die every year due to hepatitis-B. The main objective of this study is to evaluate the economic burden of anti-viral therapy in Hepatitis-B management and to scrutinize the Quality of life of the patients. A prospective Observational Cost-Effective Analysis was carried out for one year in Sai Tirumala hospital, Andhra Pradesh, India. Four Anti-viral oral therapies namely Adefovir, Lamivudine, Entecavir and a combination of Adefovir and Lamivudine have been evaluated economically. The follow-up of patients was done for one year and the Quality of Life was assessed based on the therapeutic response of the patients to the drugs. From this study we found out that the incidence of Hepatitis-B is higher in the age group of 41-50 years (37.0%) and most probably in male individuals (68.0%). The combination of Adefovir and Lamivudine proved to be most cost effective as it is shown to battle the anti- viral resistance at an Incremental Cost Effectiveness Ratio (ICER) of INR 12305.4 for one year. From our study, we found out that the fixed dose combination of Adefovir and Lamivudine (10mg+100mg) is the most cost-effective choice for the better management of Hepatitis-B infection.

Keywords: Hepatitis-B, Adefovir, Lamivudine, Quality of Life.

L-3

The Evaluation of Drug Utilization Pattern and Cost of Illness in Dengue Patients - A Prospective Study

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Abstract:

The aim of this study was to assess the drug utilization pattern in dengue and also to identify its signs and symptoms as well as to determine the cost of illness in dengue and to correlate that with the socioeconomic status of patients. Out of 126 patients, majority were females (52.4%), and in total pediatrics (55.6%) were affected more with dengue than adults. Illiterates (29.4%) and those who were staying in rural area (83.3%) were more affected with dengue. The most common symptom found was fever followed by headache, myalgia. Antibiotic therapy and fluid based therapy was given commonly. The mean cost of illness was found to be Rs. 7,816.3. Discharge bill and Total loss of productivity had negative and significant relationship with SES. Travelling cost had a positive and significant relation with SES. The study concluded that pediatric age groups, female gender, rural area of residence and poor literates were more prone for dengue. Dengue is becoming an economic burden to the society. Direct cost was found to be more than indirect cost in dengue patients. Development of a vaccine is becoming essential to face the disease.

Keywords:Dengue, Cost of Illness, SES, Vaccine.

L-4

Epidemiological Surveillance on RMP's in Northern Andhra Pradesh

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Abstract:

A large number of practitioners in the allopathic medicine have no professional qualification and no licence to practice any system of medicine. They practice on the basis of practical experience in hospitals and clinics. These unqualified medical practitioners are popularly known as RMPs or TMPs or they may call as Private Medical Practitioners (PMPs) in urban areas. The presence of large no of these unqualified medical practitioners in the rural areas and urban slums indicate that they provide most of out-patient services in private sector. About 70% of RMPs or other unqualified medical practitioner does not prescribe medicines on the basis of proper diagnosis. Majority of them have relatively 12 years of education. The huge quantum services provided by RMPs and their number,

the present study aims at improper prescription of medicines without proper diagnosis and their nexus with the qualified doctors through the case study of seven diseases in Vizianagaram District,AndhraPradesh, India.

Keywords: RMPs, Improper Prescription, Diagnosis, Survey.

L-5

A Comparative Study of Benefits and Drawbacks of Dispensing the Exact Number of Pills

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Abstract:

In the current research, Gwalior pharmacies replaced traditional pre-packed boxes by per-unit dispensing of pills in the exact numbers prescribed, for 14 antibiotics. A cluster randomized control trial was carried out in 10 pharmacies. 5 pharmacies counted out the medication by units (experimental group), the other 5 providing the treatment in the existing pharmaceutical company boxes (control group). Data on patients under the two arms were compared to assess the epidemiological, economic and health effects of this change in drug dispensing. In particular, adherence was measured indirectly by comparing the number of pills left at the end of the prescribed treatment. Out of the 1185 patients included, 907 patients got the personalized delivery and 278 were in the control group. The initial packaging of the drugs did not match with the prescription in 60% of cases. 13.1% of patients declared that they threw away pills. Finally, per-unit dispensing improved adherence to antibiotic treatment. Supplying antibiotics per unit is not only beneficial in terms of a reduced number of pills to reimburse or for the environment (less pills dumped in garbage), but also has a positive impact on adherence to treatment, and thus on both individual and public health and has significant epidemiological impact.

Keywords:Epidemiological Impact, Drug Dispensing, Economic, Pre-Packed Boxes, Per-Unit Dispensing.

L-6

Assessment of the Nutritional Behaviour among College Students- A Survey

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Abstract:

To assess the nutritional behavior among college students. A prospective observational survey was conducted randomly among college students in Guntur. A self-administered data collection form was designed to understand the nutritional behavior of the subjects. A total of 300 subjects were included in the study among them 225(75%) were females and 75(25%) were males. The survey revealed that most of them skipped their meals. A majority of 184(61.33%) students opted for high fat diet and 268(89.33%) opted for starch rich foods. A total of 222(74%) students usually eat four different varieties of vegetables but only 71(23.66%) of them eat fruits in each week. From this study it is evident that majority of students have poor dietary habits. Lack of awareness on balanced diet and due to their busy schedules, teenagers are not maintaining a proper diet. This can be reduced by bringing minimum awareness on dietary habits to them. Taking proper diet is very essential to reduce the risk of diseases in future and to improve nourishment.

Keywords: Balanced Diet, Nutritional Status, Improper Diet, Skipping Meals, Poor Nutritional Effects.

L-7

Economic evaluation of NSAID's in a Community Pharmacy: a Cost Minimization Analysis

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Abstract:

NSAID's are the most commonly used drugs in clinical practice. Cost minimization can only be used to compare two products that have been shown to be equivalent in dose and therapeutic effect. This was a retrospective observational study conducted in an urban community pharmacy for a period of one month. Top five of the prescribed drugs and top three of the OTC suggestions were chosen as examples to illustrate the cost difference between the branded drugs and alternatives. This study has shown a very significant difference of prices between branded with their alternatives. The cost of branded drugs used was 1.1 to 17.32 times more than the alternatives.

Keywords: Pharmacoeconomics, Generic Drugs, Branded Drugs, Cost Minimization.

L-8

Prevalence of Gross Hematuria

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Abstract:

To determine the prevalence of gross haematuria amongst healthy peoples living in Guntur and Vijayawada and to determine the associated risk factors as well as to create awareness among people and educate them on the consequences. This study was conducted in Guntur and Vijayawada from south India for the public between September 2017 and October 2017. A total of 300 peoples (20-70 years of age) were included in the study. A brief questionnaire was filled out for the specified studied peoples. We collected the data regarding the person's history, associated risk factors like renal and bladder stones, renal failure, past and present medication history, diabetes mellitus, prostate and bladder cancer, family history etc., analysed and reported. The percent of prevalence was found to be 9.66%. Among them haematuria was found in 44.82% with a male and 55.17% of female in the ratio of 0.82:1.2. About 3.66 % of peoples are aware of haematuria but, 6% of peoples are not. Hematuria was affected mostly in the peoples with the body weight in the range of 60-70kg with the prevalence of 44.82%. About 55.17% of the peoples are suffering from haematuria with the age group of 40-50 years. Diabetes mellitus (31.035%) and renal stone (17.24%) were found to be the most significant risk factors for haematuria.Untreated cases are double than treated cases due to their negligence. It was found that there is a positive correlation between the incidence of DM and haematuria in the elderly peoples. We found a prevalence of haematuria in women, aged around 40-50 years, body weight of 60-70kg is suffering more. Hematuria was also found to be high in the diabetic patients. Majority of the peoples are not aware of haematuria in the studied area. As a clinical pharmacist, we educated the peoples those who are in lack of awareness regarding the effects and control measures of haematuria. Screening with proper diagnostic tool and prevention programs are therefore recommended.

Keywords: Hematuria, Prevalence, Diabetes Miletus, Awareness.

L-9

Role of Pharmacists in Counseling of Asthmatic for Better Drug Compliance

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Abstract:

Multi-drug treatment is necessary for control of the asthma, but it can be well managed by diet, physical exercise and stress management, rational utilization of drugs and devices. Patient ignorance and poor compliance are the main hurdles in the management of asthma. There is a need to overcome these problems and increase the patient compliance by counseling about, diet, importance of yoga and exercise, stress management, impact of addiction, safe use of drugs and devices. The role of pharmacist in counseling of asthmatics for better drug compliance can also be achieved by patient counseling and educating the patients for proper and safe use of inhalers. The pharmacist should also monitor the safe use of drug. Certain drugs like Beta blockers (including eye drops), aspirin and NSAID, hypotonic nebulizer solution or solution with preservative, ACE inhibitors should be avoided as they can induce asthma. We found patient ignorance and poor compliance are the main problems in the management of asthma. Due to rapid civilization and modernization lifestyle of each individual is changing and furthermore environmental factors have a great deal of impact on asthma. Thus, the pharmacist is the person who can be actively involved in the counseling of asthmatics by guiding about diet, importance of yoga and exercise, stress management, impact of addiction, safe use of drugs and devices. In this way pharmacist can be a good counselor for asthmatic and can help to increase patient compliance.

Keywords: Beta blockers, NSAIDs, Asthma.

L-10

Prevalence and Predictors of Atypical Antipsychotic Use in Elderly Patients with Depression in the US Ambulatory Settings

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Abstract:

Little is known about utilization pattern of atypical antipsychotics in depression in the elderly.The objective of this study was to examine the prescribing practices and predictors of atypical antipsychotics in elderly outpatients with depression.This study used the National Ambulatory Medical Care Survey (NAMCS) and outpatient department component of the National Hospital Ambulatory Medical Care Survey (NHAMCS) data from 2010 and 2011. The study included elderly patients (age >=65years) with depression. Descriptive weighted analysis determined the prescribing practices of atypical antipsychotics and multivariable logistic regression analyses determined the predictors of atypical antipsychotics prescription.There were about 22 million ambulatory visits for depression during the study period; atypical antipsychotics were prescribed in 3.53% (95% CI, 2.02-5.04) of the visits. Among depression patients who were using antidepressants, 4.86% (95% CI, 3.07-6.04) used as an augmentation therapy. Commonly used atypical antipsychotics were quetiapine (1.44 %), aripiprazole (0.73 %), and risperidone (0.51 %). Multivariable regression analysis revealed that Hispanics (odds ratio [OR] =0.33; 95% CI, 0.12-0.90) was associated with decreased likelihood of antipsychotic prescription, whereas personality disorder (PD) and obsessive-compulsive disorder (OCD) (OR = 10.23; 95% CI, 2.80-37.40) were associated with increased likelihood of prescribing antipsychotics. Less than 4% of the elderly visits with depression were prescribed atypical antipsychotics. Both clinical and demographic factors contribute to their prescribing in the elderly.

Keywords: Depression, Atypical Antipsychotics, Augmentation therapy, Elderly.

L-11

Epidemiological Studies on Depression

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Abstract:

Depression is a mental health disorder characterized by persistently depressed mood or loss of interest in activities, causing significant impairment in daily life. Depression in adolescence and adulthood is common, affecting up to 20% of the population. Adolescent onset depression tends to be a particularly malignant and recalcitrant condition increasing the childhood, recurrence and chronic in adulthood. Our study is an observational, cross-sectional epidemiological study in paramedical students of age starting from 15-25 years. Total population for study is 300 and study was conducted in SIMS group of institutions, Guntur. By the study conducted among subjects, based on score we observed that females are more prone to depression than men. Among them females of age group 18-20 are mildly depressed. These studies are the valuable sources for public health measure and for shaping and research in the clinical and biological aspects of complex depression disorders.

Keywords: Depression, Adolescence, Epidemiology, Score.

L-12

Awareness and Prevalence of Dysmenorrhoea in Para Medicals

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Abstract:

Dysmenorrhoea is a common menstrual complaint with a major impact on women's quality of life, work productivity, and health-care utilization. Based on time of occurrence, dysmennorhoea is Primary dysmenorrhoea (Dysmennorhoea occurred immediately after menarche <6months) and Secondary dysmennorhoea (Dysmennorhoea beginning in the 20s or 30s after previously relatively painless cycles). Women's age, parity, use of oral contraceptives and high stress increased the risk of dysmenorrhoea. Our present survey is an observational, cross-sectional study which includes awareness and prevalence of dysmenorrhoea in para medicals. The study was conducted among 300 para medicals under 17-32 age groups. Among the subjects studied, 67.6% of people are dysmenorrhic and 32.3% are non- dysmenorrhic. Subjects under age group 19 are more dysmenorrhic i.e., 17%. Subjects under medication are 25% while, 75% are not. From the study it can be concluded that dysmenorrhoea is a very common problem among adolescent girls and they experience a number of symptoms associated with dysmenorrhoea. So, there is need for further research studies on dysmenorrhoea.

Keywords: Dysmennorhoea, Incidence, Prevalence, Awareness, Para Medicals, Survey.

L-13

Incidence of Polycyistic Ovarian Syndrome

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Abstract:

Polycystic Ovarian Disease(PCOD) is the most common endocrine disorder in women at reproductive age associated with hyper androgenic, hirsute, oligomenorrhea. PCOD, the most common cause of infertility due to an ovulation. There are no single criteria for the diagnosis of this syndrome. PCOS can have a significant impact on the quality of professional, social, emotional life. The prevalence of PCOS ranges from 2.2 to 2.6 %. PCOD was first described in 1935 by American gynecologist Irving Stein and Michael Leventhal. In olden days, PCOD was considered as a rare disorder but today most of the women are suffering from PCOD. According to world statistics from 1997 to 2017, the prevalence of PCOD was increased to 55%. Mostly affected women are under age groups 14-40. The prevalence of PCOD in Indian adolescents is 9.13%. This increase in prevalence was due to increasing stress, improper diet that leads to disturbances in metabolic,endocrine functions of the body that leads to irregular menstrual cycles and finally PCOD.

Keywords: Oligomenorrhea,Polycystic Ovaries, Hirsute, Ovulation.

L-14

Drug Utilisation Evaluation and Cost Analysis of Anti-Emetic Drugs Prescribed in Oncology Ward in a Tertiary Care Hospital.

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Abstract:

Drug utilization evaluation (DUE) is a system of ongoing, systematic; criteria based evaluation of drug use that will help to ensure that medicines are used appropriately (at the individual patient level). Drug utilization is defined by the World Health Organization (WHO) as the marketing, distribution, prescription, and use of drugs in society, with special emphasis on the resulting medical, social, and economic consequences, Types include, quantitative or qualitative. Quantitative study is done to obtain the variation of drug use and costs of drug therapy, from which medical and social qualitative consequences can be found. It also provides the base from which further qualitative research can be conducted. Our study emphasizes on knowing the drug utilization and cost included for antiemetics in patients undergoing chemotherapy in oncology ward. Total of 141 patients were studied, out of which 77(54.6%) patients were female and 64(45.4%) were male. Majority of the patients in this study belong to the age group of 40-49(29%) and 60 – 69 (20%) years. The comparison with the standard protocol was made according to the use of antiemetics in the patients. Out of which 137(97%) patient profiles were found to be deviating from standard protocol and 4(3%) patient profiles were found following the standard protocol because of including prochlorperazine which is not mentioned in the standard protocol. Deviation of cases without considering prochlorperazine was found to be 74% deviating and 26% not deviating compared to the results where prochlorperazine was included.

Keywords: Drug Utilisation Evaluation, Quantitavive, Anti-emetics, Chemotherapy, Prochlorperazine.

L-15

Awareness of Cervical Cancer among Girls Studying in a Medical Institution

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Abstract:

Carcinoma of the cervix is the second most common and life-threatening cancer in women. Human Papilloma Virus (HPV) is the principle causative agent of this type of malignancy. To assess the awareness of cervical cancer among paramedical students a survey was conducted among selected 150 girls of age varying from 17-22yrs studying in a medical institute. Girls mostly who are aware of this disease were at higher rate yet to most of them the screening methods were unknown. They were oblivious about the vaccination techniques provided the awareness about the preventive methods was high. Altogether the awareness of cervical cancer among the para medical girls was found to be significantly low.Lack of knowledge and awareness about cervical cancer in most screening programs contribute to high incidence of cervical cancer in most developing countries. Hence there is a need to create awareness among people especially girls who are liable to cervical cancer.

Keywords: Carcinoma, Human Papilloma Virus, Vaccination, Awareness.

L-17

A Study of Usage of Teriparatide in the Clinical Management of Osteoporosis

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Abstract:

Teriparatide is a recombinant DNA form of parathyroid hormone consisting of first 34 amino acids which is the bioactive portion of the hormone. It is manufactured using recombinant DNA technology.Teripatatide is an effective anabolic agent used in the treatment of osteoporosis and fracture healing. Its intermittent use activates osteoblasts which lead to increase in Bone Mineral Density.Teriparatide was used in 109 cases which were clinically diagnosed as Osteoporosis from period 2015 to 2017.The patients were diagnosed on the basis of observations noticed in the evaluation of Vitamin-D, Serum Calcium, magnesium, Para thyroid hormone and Bone Mineral Density. The cases were diagnosed as having osteoporosis when Bone Mineral Density is more than -2.5 as per WHO classification. The patients were treated with Teriparatide of 8 to 20 units subcutaneously around umbelicous or front of the thigh with a pre-loaded cartridge pen and also supplemented with Calcium, Magnesium and nano form of Vitamin D. After a period of 210 days of Teriparatide, Alendronate once in a month with an empty stomach for 9 months were given. Patients were evaluated at the end of the treatment. The pain scores were assessed by VAS scale. It was observed that the pain scores improved and BMD scores were brought back to normalcy. There was gross clinical improvement of life style of patients who had pain free life, able to get up, move around and walk on their own or with support. The results were analyzed and presented in this paper.

Keywords: Teriperatide, Osteoporosis, Alendronate, Parathyroid Hormone, VAS Scale

L-18

Efficacy and Safety of Pregabalin used in Painful Diabetic Peripheral Neuropathy: Meta-Analysis (MA)

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Abstract:

Painful diabetic peripheral neuropathy (DPN) is a highly prevalent disorder. It is managed with multi-drug treatment approach among that pregabalin is most effective treatment assessed with many Randomized clinical trials (RCTs). This study was aimed to perform meta-analysis to assess the efficacy and safety of pregabalin (300 mg, 600 mg) for managing pain associated with the DNP which provides better evidence for the treatment of painful diabetic neuropathy. A comprehensive data search was done in Medline (PubMed) and Cochrane databases till august 2017. Then we systematically reviewed the studies which assess the pregabalin used for DPN. Total of 934 participants were involved in 4 trials. Pooled analysis showed that pregabalin was significantly superior to placebo for improving mean pain score [Standard mean difference (SMD) -0.503, 95% CI -0.821 to -0.186], and also high doses of pregabalin causes mild adverse effects than the placebo [OR= 2.313, 95% CI 1.213 to 4.413]. This head to head comparison for the efficacy of pregabalin verses placebo shows that though it has mild adverse effect, pregabalin is beneficial for pain relief in DNP.

Keywords: Diabetic peripheral neuropathy, Meta-analysis, Standard Mean difference, Odds ratio

L-19

Epidemiological Study in Paramedical Students-Phobic Disorders in Community

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Abstract:

A phobia is a type of persistent, abnormal/ irrational fear of a specific thing / situation that compels one to avoid the feared stimulus. A usual onset of fear is rapid and duration upto 6months which leads to severe complication of suicide.in this paper we present a system that enables the identification retrieval of the key characteristics from the study on paramedical students for phobias related to medical profession. Our study was an observational, cross-sectional epidemiological study in paramedical students who expose to clinicals in a population of 300 in sims group of institution. By the study, we observed that females of age group 18-26 years asss re more phobic to medi-

cal conditions/ phobias than men. among the subjects 75% are phobic to needles ,65% are phobic to dentistry,55% are phobic to tuberculosis.These studies are the valuable sources for public health measure and for shaping of research questions in the clinical and biological aspects of complex phobias.

Keywords: Phobia, Irrational Fear, Epidemiology, Para Medical Students.

L-20

Study of Health-Related Quality of Life in Patients with Gastroesophageal Reflux Disease

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Abstract:

Gastro esophageal reflux disease (GERD) is a common problem worldwide with a wide range of clinical manifestations and potential complications like esophagitis, ulceration and stricture formation. It is a common disorder associated with substantial reduction in health-related quality of life. To assess the health-related quality of life in GERD patients.The study was conducted at Gastroenterology department (outpatient and inpatient) of JSS Medical College Hospital, Mysore. The study was a prospective interventional observational study conducted over a period of six months from December 2012 till April 2013. Patients Health Related Quality of life was assessed using SF12 questionnaire at the baseline. The patients were then counseled in a private area to ensure privacy and provided with education about GERD. The patients were followed up for 30 days and their HRQOL was re-assessed using SF12 Questionnaire and their scores were calculated and outcome was measured to assess improvement in HRQOL.A total of 80 patients were included in the study. 15 patients (13.07%) were considered as drop outs due to irregularity in follow up. Of the 80 patients who completed the follow up and considered for study, preference existed for the gender and GERD was found to be more prevalent among the males [n=54(67.5%)] then in females [n=26(32.5%)]. In the study it was found that GERD occurred in all age groups with an average age of 44 years. This study has helped to identify and track unmet health needs and disparities. This study concludes that improving patient knowledge about GERD by providing patient education can improve their overall health related quality of life.

Keywords: Gastro esophageal Reflux Disease (GERD), Health Related Quality of Life(HRQOL), Short Form Health Survey Questionnaire(SF-12), Patient Education.

L-21

Measuring Adherence in HIV Naive Patients an Assessing Self Efficacy Beliefs

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Abstract:

This study set to determine the influence of HIV adherence self-efficacy and beliefs about medicines on antiretroviral therapy adherence, with the aim of enhancing adherence through focused intervention on modifiable factors (duration, frequency, alcohol) from study variables that are strongly associated with ART adherence.The percentage of the participants who strictly followed the specific dosage schedule during past days was only 8%; while the remaining 36% partially followed schedule instructions. In fact, 39% of the participants never followed the given instructions.In the study, it was observed that around 64% of participants agreed that their current health is dependent on the regular antiretroviral medication and also agreed that their current and future health would depend on the ART medications adherence.

Keywords: HIV, ART, Medication Adherence.

L-22

Incidences of Daytime Sleeping in General Population

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Abstract:

In present times it is not uncommon to stay up late and fall asleep during daytime. A variety of factors are known to lead up to this, among which stress is the most prominent. Poor sleep is also known to cause increased tension, irritability, depression, confusion, and lower life satisfaction in general. It is also known to cause lifestyle diseases like obesity and diabetes mellitus. An online survey was conducted with the help of a questionnaire to assess the daytime sleepiness pattern in the general population. From a sample size of 143, data was collected and analyzed. The activity most associated with daytime sleepiness (high chance of dozing) was found to be lying

down in the afternoon (35.66%), followed by sitting after lunch (14.68%), sitting and reading (12.58%), and sitting as passenger in car (9.09). The activities less associated with the same were sitting inactive in a public place (8.39%), watching TV (3.49%), sitting in traffic for a few minutes (1.39%) and sitting and talking to someone (0.69%). In the age group of 19-21years, the incidence of daytime sleeping was found to be high especially while lying down in the afternoon. As the sample size was small, the data collected may be insufficient. Further studies can be carried out with this topic.

Keywords: Dozing, Daytime Sleeping.

L-24

Cost Analysis of Malaria Treatment inIndian Population

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Abstract:

Malaria is a disease caused by the infection of the red blood cells with protozoan parasites of the genus Plasmodium inoculated into the human host by a feeding female anopheles mosquito. Malaria is one of the major public health problems of the country. India reports around one million malaria cases annually.India with the huge population under middle economic class and with huge group below poverty line needs cost-effective treatment.This study helps to find out the cost-effective treatment for malaria. This study involved the collection of the patient profile forms from the tertiary care hospital, the data was collected, analyzed and recorded in the data collection forms and the pharmacoeconomical study was conducted. This study was conducted by observational analysis and no software was used. The patient profile forms were collected of patients confirmed having malarial infection.13 types of prescription patterns were seen. It was found out that the various brand names often prescribed can be substituted with a different brand of a lower cost such as Injection Falcigo (Artesunate) which is available as a vial of 10ml for ₹388.80 which can be substituted with Injection Larinate (Artesunate) which costs ₹282.66 for 10ml.There is a difference of ₹106.14 between both the drugs which is an unnecessary added burden for the patient and this can be easily avoided. Thus, this study helps in concluding the fact that the cost effectiveness of the various drugs used in the treatment of malaria may be improved helping form a better health care policy.

Keywords: Malaria, Cost-effective Treatment, Pharmacoeconomical Study.

L-25

A Survey to Estimate the Frequency of Medication Adherence in General Population

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Abstract:

Compliance, adherence, and persistence being the common terms used in the literature to relate medication-taking behaviours, refers to the extent to which a person takes medications as prescribed by their health care providers. Patient noncompliance is an expanding concern to healthcare systems, clinicians, and other stakeholders (e.g., payers) because of mounting evidence that is predominant and associated with unfavourable outcomes and elevated costs of care. We conducted a survey to assess the extent of compliance of patients to the medical regimen. Based on our analysis, the data collected from 321 subjects reveals that only 43% of the subjects forgot to take medications regularly, 57% among them discontinued the medication as they felt worse after taking it, 20% of the subjects feels hassled to stick to treatment plan reason being the high medication cost and high number of medications, 54.3% of them discontinued the medications because they felt that the symptoms were under control. Our data study shows that medication adherence is very low in India, which may lead to problems like decreased therapeutic outcomes for the patient, recurrent hospital and physician visits due to the retrogression of their medical condition, expand health care expenditure, and even overtreatment of a condition. And this becomes huge problems in developing countries like India where doctor to patient ratio is 1:1689. This study also opens the way for further care in this field.

Keywords: Medical Adherence, Patient Noncompliance, Treatment Regimen.

L-26

Effectiveness of Direct Antiviral Agents (DAAs) for the Treatment of Chronic Hepatitis C (CHC) With Severe Renal Impairment (SRI)

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machandran

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Abstract:

Introduction - Approval of DAAs showed a new direction for treatment of CHC in patients having glomerular filtration rate (GFR) <30ml/min/1.73m^2. The dosing of sofosbuvir is still questionable in this population due to limited evidence. This study was performed to assess the effectiveness of combination of sofosbuvir with ledipasvir (SOF+LDV) and daclatasvir (SOF+DCV) in CHC patients with SRI. This prospective observational study was conducted in out-patient setting at public teaching tertiary care hospital after approval from the Institute's Ethical Committee. Patients' data was collected in a predesigned case record form on enrolment, 4th, 8th, 12th week of treatment and 12 weeks after the end of treatment(ETR). Patients with <18 years of age and with missed follow-up were excluded. Effectiveness was assessed with sustained virological response(SVR12) with negative HCV-RNA 12 weeks after ETR. Data was analyzed by using SPSS software version 20.A total of 27 patients were included. 12/27 patients had GFR <30ml/min/1.73m^2. 11/12 patients were on hemodialysis(HD) and 14/27 patients were with renal-transplantation(RT). 18/27 patients were treatment-naïve(TN) and 4/27 patients were cirrhotic. HD patients(11/27) were prescribed with SOF200mg+DCV60mg once-daily(OD) irrespective of HCV genotype and 12/27 patients with HCV 1&4 genotype having GFR >30ml/min/1.73m2 were on SOF400mg/OD+LDV90mg/OD for 12 weeks. SVR12 was achieved in 26/27 (96.3%) patients. CHC relapsed in one TN cirrhotic HCV-1genotypic patient with SOF200mg/OD+DCV60mg/OD at ETR.This study showed 96.3% effectiveness of SOF200mg/OD+DCV60mg/OD in CHC-HD patients and 100% effectiveness of SOF400mg/OD+LDV90mg/OD in CHC-RT patients.

Keywords: DAAs, Hepatitis C, Renal Impairment, Effectiveness.

L-27

Anxiety Conquering Masculine Minds

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Abstract:

Anxiety is a feeling of excess nervousness on unthreatening situations.Feeling anxious is a normal response to stress. But if it oftenly get indulged in our daily lifethen it is called "Anxiety disorder". The aim of the study was to identify the prevalence of anxiety in general population and analyze the data according to gender. Participants of the study were candidates of the age of 18 -20years. Questionnaire was sent by means of various online services including social networking sites and software. Thequestionnaire used was the standard scale to assess anxiety "The Beck Anxiety Inventory". The data was collected and analyzed by Microsoft Excel and SPSS.558 candidatesparticipatedamong which 258 were female and 300 were male. After analysis of data we concluded that men have high level of severe anxiety but while takingindividual symptoms(feeling hot,shaking of legs, etc.) women show most of the symptoms in peak level. This study reveals the nearly equal chances of men in being anxious as women. Every fifth Indian suffers from anxiety disorder, or so goes the unwritten belief among the Indian psychiatrists. This study opens a platformfor more discussion. As the scientists are burning their head in finding out the presence of genetic cause for anxiety this data gives moreburden to them as there arises the need to find the reason for higher prevalence of anxiety in men in certain population. Overall the data have a strong point fordiscussion and discovery.

Keywords: Anxiety, Beck Anxiety Inventory.

L-28

Awareness Regarding the Use of Antibiotics as Over the Counter Drugs

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Abstract:

Antibiotics resistance is a global crisis threatening to reverse the astonishing health benefit achieved with antibiotics. One reason among this is the use of antibiotics as OTC drugs. Due to the over usage of antibiotics there is a rapid development of drug resistance. The worldis now lacking safer and effective antibiotics. The objective of the study is to assess awareness regarding the use of antibiotics as OTC dugs. An online survey was conducted among the general population with the help of a questionnaire to assess the awareness regarding the use of antibiotics as OTCdrugs and 206 responses were received and interpreted. Among this 14.2%of people are unaware about antibiotics and 45.3% people are taking antibiotics as OTC drugs;

21.7% use it because of suggestions from family and friends, 7.5% use antibiotics as OTC because of expensive consultation. 31.1% use these without a prescription. 9.4 % pharmacists dispense antibiotics without prescription. Therefore there is an alarming number of people who consume antibiotics without proper guidance or prescription. As the sample size was small there may be insufficient data. More studies can be conducted on this topic.

Keywords: OTC, Antibiotics, Resistance, Self-medication.

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Modern Healthcare and Pharmacoeconomics

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Abstract:

The objective was to study the impact of rising cost on modern healthcare.The rising cost of healthcare delivery systems is a major concern to all patients, healthcare professionals, and the government. The demand for and the cost of health care are increasing in all countries as the improvement in sophistication of health technologies. The increase in health care spending is mainly because of increased life expectance, increased technology, increased standard of living and increased demand in health care quality and services. Medicines form a small but significant proportion of total health care cost. As the affordability of new medical technologies continues to be the subject of heated debate, attention is also increasingly focused on providing quality and cost-effective healthcare. Economic evaluation of pharmaceutical products, or pharmacoeconomics, is a rapidly growing area of research. Pharmacoeconomic evaluation is important in helping clinicians and decision makers to make choices about new pharmaceutical products and in helping patients obtain access to new medicines. The limited financial resources, health economics, and particularly pharmacoeconomic analyses, are becoming a frequently used criterion for decision making in modern health care policy. The purpose is to provide an introduction of pharmacoeconomics, its various methods of evaluations such as cost minimization analysis, cost benefit analysis, cost utility analysis, cost effectiveness analysis and also discuss challenges, limitations and applications of pharmacoeconomics.

Keywords: ECHO model, Cost of illness, cost minimization, cost benefit analysis, cost utility analysis, cost effectiveness analysis.

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Probiotics and Prebiotics in Health and Disease: A Boon for Gut Health

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Abstract:

Probiotics are **microorganisms** that are believed to provide health benefits (especially gut health) when consumed. The term probiotic is currently used to name ingested **microorganisms** associated with benefits for humans and animals. The potential health effects of supplemental probiotics has included the molecular biology and **genomics** of **Lactobacillus** in immune function, cancer, and antibiotic-associated **diarrhoea**, travellers' diarrhoea, pediatric diarrhoea, **inflammatory bowel disease**, and **irritable bowel syndrome**, bacterial and yeast vaginosis, urinary tract infections. The first commercially sold dairy-based probiotic was **Yakult**, a fermented milk with added Lactobacillus casei in 1935. Since then, many more probiotic foods have come on the market, mostly in the form of **dairy products**. Recently, nondairy and unfermented probiotics have been produced, including **breakfast cereal** and **snack bars**, whereas other probiotic products include **kefir**, **yogurt**, **kombucha**, **kimchi**, **sauerkraut**, and other **fermented foods** and beverages. Prebiotics are substances that induce the growth or activity of microorganisms (e.g., bacteria and fungi) that contribute to the well-being of their host. These are mainly composed of carbohydrates ranging from small sugar alcohols and disaccharides to oligosaccharides (Fructooligosaccharides) and large polysaccharides. The global research data has clearly indicated and highlited the importance and prevalence of reduction the incidence C difficile associated diarrhea with the administration of Probiotic. Both the Probiotic and Prebiotic products are providing health benefits by different types of mechanisms in the body of the recipients. Present study is based on the data compiled from the authenticated and reliable sources available globally. Further an attempt has also been made to formulate and devise a tool for the use of both products to achieve therapeutic goal.