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DRUG DEVELOPMENT AND CLINICAL RESEARCH : CURRENT SCENARIO & OPPORTUNITIES

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- Track1: Clinical Pharmacology/Epidemiology/Pharmacoepidemiologic Studies
- Track 2: Drug Safety/Medical - medication errors
- Track 3: Public Health/Allied Health Research
- Track 4: Formulation Development/QualityAssurance/ Regulatory
- Track 5: Pre-clinical Studies - PharmaceuticalChemistry/ Pharmacagnosy/Pharmacology

INVITED SPEAKERS

Innovation to Commercialisation: A Roadmap for Life Science Projects

Prof. James F. Jordan

Camegie Mellon University, PA, USA

The Role of Data & Technology in Epidemiology Big Data and Visualization in Epidemiology

Kothandaraman Sridharan

CEO - Mindshare Learning Centre / Clever Insight

Health Research Methodologies - An overview

Dr. Alben Sigamani

Group Head - Clinical Research, Narayana Hrudayalaya Ltd, Bangalore

Trends and Opportunities in MedicalWriting Industry

Dr. Ananya Chakraborty

Professor, Pharmacology, Vydehi Institute of Medical Science & Research Centre, Whitefield, Bangalore

Development: Integrating Industry & Academia Efforts in Pharma Industry

Anirban Roy Chowdhury

Director & Principal Consultant, Arc Lifescience Consulting Group

Healthcare Innovation - Digital Health.IT & Predictive Analytics

Anusha Sridharan

Biomedical Research Capacity Strengthening at Individual and Institutional Level

Dr. Atiya Faruqui

Associate Profesor of Pharmacology,
St.John's Medical College, Bangalore

How important Analytics in Clinical Trial & Big Data Management

Bastin Robins J.

CTO / Chief Data Scientist, CleverInsight Inc., USA

Monitoring Product Safety Beyond Clinical Trials - Industry Practices

Dr. J. Vijay Venkataraman

CEO Oviya Medsafe Pvt. Ltd., Coimbatore, India

Good Clinical Practice guidelines-roles of various stakeholders in clinical trials,focus on sponsor and study monitor

Dr. Ramesh Jagannathan

Head-Clinical Development, Biocon Research Ltd., Bangalore

ICMR 'National Ethical Guidelines for Biomedical and Health Research involving Human Participants2017'

Dr. Roli Mathur

Head, ICMR Bioethics Unit, NCDIR, Bangalore

Clinical Trials - Indian Regulatory Scenario, framework and application procedures

Dr. Thirumalai Velu

Director, Regulatory & Scientific Affairs, Allergan India(P) Ltd

Operational Research for Diseases of Poverty: Scope & Opportunities

Dr. Uma Shankar S.

Chief Medical Officer, National Tuberculosis Center
Govt. of Karnataka & MOHFW, Govt. of India

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TRACK1: CLINICAL PHARMACOLOGY / EPIDEMIOLOGY/ PHARMACOEPIDEMIOLOGIC STUDIES

T101: RISK OF DEVELOPING DEPRESSION AND ITS IMPACT ON QUALITY OF LIFE IN PATIENTSWITH POLYCYSTIC OVARY SYNDROME (PCOS)

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ABSTRACT

Polycystic ovary syndrome (PCOS) is one of the most common reproductive endocrine disorders, affecting patient's psychological functioning and satisfaction with life. The present study was carried out owing of the fact that no such study was being orchestrated on this population. **AIMS:** Study was conducted to evaluate the prevalence of depressive disorders and its impact on quality of life in patients with PCOS and also to evaluate the determinants of depression in PCOS patients. Settings and Design: Tertiary care hospital-based case–control study was conducted. **METHODS AND MATERIAL:** Study was effectuated in 124 patients in total, including equal number of cases and controls.PHQ-9 was used to determine the depression based directly on DSM-IV diagnostic criteria for depression and PCOSQ was used to assess quality of life. **STATISTICAL ANALYSIS USED:** Data was examined using descriptive statistics, Spearman co-relation, and Chi-square test, F-test, and odds ratios (OR) with 95% confidence intervals (95% CI). **RESULTs:** The study shows an increased risk of depression in PCOS (76.96% of cases compared to 20.03% of controls), Odd's ratio 5.95 (95% confidence interval [2.67-1265]) and the depression was found to be having an impact on patient's quality of life. **CONCLUSIONS:** The care of individuals with PCOS should include the screening and possible treatment for depression in order to achieve and sustain treatment goals considering the fact that identifying depression early will further improve the quality of life of PCOS patients and also reduce the overall treatment cost, which are generally unaffordable by most individuals with this disease in India.

KEYWORDS: PCOS, depression, quality of life.

T102: A COMPARATIVE STUDY OF METFORMIN PLUS SULFONYLUREAS VERSUS METFORMIN ALONE FOR ITS EFFICACY IN TYPE 2 DIABETES PATIENTS

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ABSTRACT

The objective of the study was to compare the efficacy of combination containing Metformin plus Sulfonylureas-Glimepiride/Glibenclamide (MET+GLI/ GLIB) and to determine whether the combination of Sulfonylureas had clinically remarkable benefit over MET alone in patients with Type 2 Diabetes. This is a single-centric, open labelled, prospective study, involving 70 Type 2 diabetes patients between the age group of 18-75 years old. Data of only Type 2 diabetic patients who were pre-scribed with MET 500 mg,

MET+GLI (500+2) mg and MET+GLIB (500+5) mg were included in the study. Efficacy was evaluated based on changes in Random Blood Sugar (RBS) and Fasting Blood Sugar (FBS) at every follow-up of one month for totally 3 months. Total of 70 patients were enrolled in the study but 6 patients lost follow up in MET Group and 2 patients in MET + GLI Group. Therefore 24 patients in MET, 18 patients in MET + GLI group and 20 patients in MET + GLI group completed the study. A statistically significant reduction in RBS and FBS was seen in all the groups. MET+ GLI treatment showed a statistically significant reduction in RBS at third month as compared to other groups. Study demonstrated that combination of MET+ GLI treatment was more effective than MET + GLIB and MET alone in reducing FBS and RBS. Thus, Combination therapy of MET + GLI seems to be a better treatment in patients having Type 2 diabetes.

KEYWORDS: Type 2 diabetes, sulfonylureas, metformin.

T103: A RETROSPECTIVE DRUG UTILIZATION REVIEW ON PROTON PUMP INHIBITORS'

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ABSTRACT

BACKGROUND: Drug Utilization Evaluation is an essential part of pharmacoepidemiology as it describes the nature, extent, and determinants of drug exposure. This study aims to find the drug use pattern of Proton Pump Inhibitors (PPIs) in a tertiary care hospital, thereby to improve the rationality of prescription with PPIs. **METHODOLOGY:** In this retrospective observational study, Data of 100 patients were collected from the medical records department, who were diagnosed with various diseases from General Medicine and Gastroenterology, admitted in the SRM Medical College and Research Hospital, Chennai during a period of one month. A structured data collection form was used to obtain information on demographics of the patient, presenting complaints, provisional diagnosis, laboratory test report and PPI therapy given. The obtained data were thoroughly analyzed for the prescribing pattern of PPIs and the appropriateness of the prescribed PPI using FDA guidelines. **RESULTS:** A total of 100 cases were collected from the gastroenterology and general medicine department respectively. The gender-wise distribution of PPI prescribed, reported that a greater number of male patients (52%) were prescribed with PPIs than female patients (48%). The most commonly prescribed PPI was found to be Pantoprazole (92%) in which oral form of Pantoprazole (52%) was prescribed more than the IV form (40%). Following that, (8%) of the prescriptions contained esomeprazole and (1%) had rabeprazole and omeprazole. Out of all the PPIs prescribed, 63% of the PPIs were pre- scribed once daily and 37% were prescribed twice daily. Age of 40-50 was administered the greatest number of PPIs (25%) followed by age of 50-60 (23%). 23% of PPIs were pre-scribed among the age group of >60. 32% of the prescriptions are found to be irrational. **CONCLUSION:** It is the duty of the clinical pharmacist to promote the rational use of drugs in clinical settings. This will ultimately benefit the patient by reduction in medical cost and to avoid the potential adverse effects. When prescribing PPIs physicians should consider both their benefits and their harms. Majority of the PPIs are prescribed without proper indication. Some are found to have inappropriate frequency and dosage. PPIs should not be prescribed unless there is a specific indication that necessitates its use. There should be awareness among physicians to avoid the long-term use of PPIs, especially among geriatric patients.

KEYWORDS: PPIs, prescribing pattern, rational use.

T104: NEED AND ASSESSMENT OF CLINICAL PHARMACIST INTERVENTION: HEALTH CARE SECTORS OF INDIA

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ABSTRACT

Medicines are an integral part of health care system. But the best therapeutic outcome will result when the patient receives right medication at right time with correct dose. An aforementioned outcome is provided by the involvement of clinical pharmacist as a member of healthcare team for monitoring drug interaction, reporting Adverse Drug Reactions (ADRs), therapeutic drug management, community ser-vices, patient counselling, and optimization of therapy, clinical research and during ward rounds in hospitalized patients. This helps in the identification and prevention of drug-related problems which will help to rationalize drug therapy and improved patient care. Unfortunately, the Indian health care system is not utilizing the service of a pharmacist as it really required. Reason for this is a poor encouragement to the clinical pharmacist for their professional activities. Now the clinical pharmacist profession is in a blossoming stage as the Indian government

determined to strengthen the pharmacy practice system through the start of the Pharm D program in Indian pharmacy education. The main objective of the program is to provide rational therapy to the patients which reflects a reduction in medical expenditure and the disease burden on patient by preventing the drug-related issues like side effects or any adverse drug events. Hospitals have started distinguishing the importance of clinical pharmacy and have taken initiatives for making it possible although at a developing stage. The Pharmacy Council of India needs to initiate more visionary measures in creating clinical pharmacy jobs for Pharm D graduates in India and promote the Pharm D degree to gain international status, as in the United States. So, an online survey was conducted in general population in order to check how safe and effective treatments are provided in India with poor pharmacist intervention and what are the consequences will be faced by a single Indian citizen who is opting poor or no pharmacist intervention from the Indian health care system. From the data, 65% of 200 people are not counselled by the pharmacist in a hospital. The pharmacist should be encouraged to receive a prescription and provide drug information for improved health service. 60.8% of 194 peoples prescription is not taken by the pharmacist after doctor prescribe the medicines.

KEYWORDS: Clinical Pharmacist; Indian health care system; Pharm D

T105: A STUDY ON PREVALENCE AND RISK FACTORS OF TYPE 2 DIABETES MELLITUS IN PCOD PATIENTS IN A TERTIARY CARE HOSPITAL

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ABSTRACT

BACKGROUND: In recent years Polycystic Ovarian Disease (PCOD) or polycystic ovarian syndrome (PCOS) is a globally emerging endocrine or metabolic abnormality among women. The clinical manifestations of the disease include oligomenorrhea or amenorrhea, hirsutism and frequent infertility. Most of the PCOD patients affected with insulin resistance can cause Type 2 Diabetes mellitus (Type 2 DM), which may be due to a number of comorbidities including metabolic syndrome. Normally the prevalence of Type 2 DM in PCOD patients is found to be 20%, in this study it is 15%. **OBJECTIVE:** The aim of the study is to analyze the prevalence and risk factors of Type 2 DM in PCOD patients in a tertiary care hospital. **METHODOLOGY:** A Prospective observational cross-sectional study was conducted in both out-patients and in-patients of gynecology and general medicine department for a period of 6 months with the aim, to study the prevalence, risk factors of Type 2 DM in PCOD patients in a tertiary care hospital. Based on the inclusion and exclusion criteria, the number of subjects enrolled in the study was 160. **RESULTS:** The prevalence of Type 2 DM in PCOD patients in our sample was found to be 15%. Insulin resistance is the most major risk factors of PCOD. The most common risk factors in our study were food habit 52.65%, 32.40% of the participants shows a family history of the disease, 31.25% of the participants show a low physical activity in their lifestyle and 31% of participants were having high BMI. In our study setting 89% stick to non-surgical treatment. Based on the studies PCOD is cured by Lifestyle modifications and Pharmacological therapy. Only complicated cases like removal of cyst from ovary leads to surgical interventions. **CONCLUSION:** Our study investigated the prevalence and risk factors of type 2 Diabetes mellitus in PCOD patients. In our study the prevalence of type 2 Diabetes Mellitus is less and it varies from the duration of the disease and lifestyle changes of the patients. Since PCOD is not a complicated disease it can be prevented by following a healthy lifestyle. The treatment option also follows non-surgical treatment except for the complicated cases.

KEYWORDS: Type 2 DM, lifestyle, PCOD.

T107: DRUG USE EVALUATION AND PHARMACOVIGILANCE OF ANALGESICS AND ANTIBIOTICS USED IN ORTHOPEDIC DEPARTMENT AT A TERTIARY CARE HOSPITAL

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ABSTRACT

Introduction: Drug Use Evaluation is a performance improvement method that focuses on improving and evaluating medication-use processes with the goal of improving the outcome of the patient. The aim of drug use evaluation is to facilitate the rational use of drugs in population. The rational use of a drug implies the prescription of a well- documented drug at an optimal dose, along with the correct information, at a reasonable price. To discuss about the rational use of drugs, it is necessary to have knowledge about how drugs are being prescribed and used which helps to improve prescribing habits. **AIM & OBJECTIVES:** To evaluate the drug use and

pharmacovigilance of analgesics and antibiotics used in the Orthopedics department at a tertiary care center. Objectives of the study were Prescribing pattern of antibiotics and analgesics, incidence of adverse drug reactions, average drug encounter per prescription, the percentage of antibiotics and analgesics use and cost per prescription. **METHODOLOGY:** It was a prospective observational study. Patients who have been admit- ted in orthopedic wards of NRI General Hospital from December 2015 to May 2016 were included. Exclusion criteria include patients who are not willing to participate in the study, patients who are HIV positive, patients using immunosuppressant and with malignancy. **RESULTS:** Out of 343 patients, the incidence of use of antibiotics was found to be 97.66%. The month wise use of antibiotics and analgesics were 98.87%, 99.98% respectively. The use of antibiotics was higher in the age group of 18 - 29 years while it was least in patients aged 80 - 89 years. In our study, 96 (28.65%) patients received combination therapy while 239 (71.34%) patients received monotherapy. **CONCLUSION:** There is a great need for the adoption of various strategies to prevent/minimize the inappropriate use of antibiotics and analgesics in order to improve the quality use of medicines. As many numbers of significant interactions were found, designing and implementation of mechanisms which constantly monitor the potential interactions and adverse drug events are needed.

KEYWORDS: Rheumatoid Arthritis, Antibiotics, Prescribing indicators.

T108: A STUDY ON MONITORING, DETECTION, ASSESSMENT, REPORTING AND MINIMIZATION OF ADRS ASSOCIATED WITH CORTICOSTEROIDS IN DERMATOLOGICAL DISEASES

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ABSTRACT

BACKGROUND: Pharmacovigilance is the science of collecting, monitoring, researching, assess-ing and evaluating information from healthcare providers and patients on the adverse effects of medications, biological products, herbalism and traditional medicines. It mainly includes Identifying new information about hazards associated with medicines and preventing harm to patients.Most common dermatological diseases like leprosy, pemphigus vulgaris diseases and allergic contact dermatitis. **AIM:** To improve patient care and safety in relation to the use of corticosteroids in dermatological diseases. **MATERIALS AND METHODS:** This study was approved by the ethical committee of Rajiv Gandhi Institute of Medical Science, Kadapa. It was a Prospective and interventional study con-ducted in the dermatology department for 6 months. A total of 40 patients were recruited during the study period. Patients of all age groups with both genders and who are diagnosed with skin diseases and on treatment with systemic and topical corticosteroids were included. Patients having past history of HTN, DM, Gastric ulcers, other drug-induced skin diseases and renal impairment were excluded. To serve and review the patient therapy and adverse drug reactions (ADRs) we used various materials like Patient data collection Performa, Patient informed consent form, ADR Reporting form, Naranjo scale, WHO scale, Severity scale, Preventability scale. RESULTS: A total of 40 patients were recruited, in that 23 (57.50 %) were males and 17 (42.50 %) were females. Majority of patients were recruited in the age group of 51-60. Out of all observed patients 25 (62.5%) ADRs were identified. Most cases had reaction time between 24 to 32 days. The most common age group diagnosed as having ADRs was 51-60 years and higher incidence rate was observed in male as compared to females (M:F = 1.27:1). Glucocorticoids like predisolone (42.50 %), betamethasone (17.50 %) and dexamethasone causing highest number of ADRs (42.50 %). After detection of adverse drug reactions with glucocorticoids, complete data pertaining to event was collected and causality assessment, severity, preventability, predictability was done by using scales, finally reaction management and reporting to regulatory authorities was done. **CONCLUSION:** Our study concluded that ADRs commonly affect patient's quality of life, increas-ing hospital admissions, length of hospital stay and cost of care. Prednisolone is the most common drug and cardiovascular system was the most commonly affected organ system associated with the ADRs. Clinical pharmacists can contribute to improved patients outcomes by monitoring, identifying, assessing and prevention of ADRs and can also promote rational use of drugs.

KEYWORDS: ADRs, glucocorticoids, dermatology.

T109: ANTI-EPILEPTIC ACTIVITY OF HEDYCHIUM CORONARIUM AGAINST PENTYLENETETRAZOLE (PTZ) INDUCED RATS

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ABSTRACT

Hedychiumcoronarium (Zingiberaceae) is a well-known plant which is being used in Indian traditional system which has been reported to have a num-ber of uses. But the role of rhizome of Hedychiumcoronarium in the treatment of brain associated disorders and epilepsy has not been evaluated. The methanolic extract of Hedychiumcoronarium (MEHC) were subjected to anti-epileptic activity on pentylenetetrazole (PTZ) induced rats. MEHC at both 200mg/kg and 400mg/kg exhibits significant anti-epileptic activity and delayed the onset of convulsions and also reduced the duration of convulsion. Thus the present work substantiates the use of Hedychiumcoronarium as potent anti-epileptic drug.

KEYWORDS: MEHC, epilepsy, convulsions, PTZ

T110: A CASE REPORT OF ADVERSE DRUG INTERACTION OF LITHIUM AND FUROSEMIDE – A SERIOUS INTERACTION

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ABSTRACT

INTRODUCTION: Drug interactions are said to occur when pharmacological activ-ity of one drug was altered by concomitant use of another drug or by the presence of some other substances. The drug whose activity is affected by such an interaction is called as the object drug and the agent which precipitates such an interaction is referred to as the precipitant. Drug interactions are mostly undesirable and rarely desirable. Lithium was the first drug used for the treatment of mania, it reduces the motor activity, decrease euphoria, relieves insomnia & stabilises the mood. It produces narrow margin of safety, it causes wide variety of adverse effects from GI side effects to coma, either by drug alone or by interacting with some other drugs. Furosemide is one of the most commonly and extensively used diuretic in treatment of hypertension, renal oedema, hepatic oedema, cardiac oedema, acute pulmonary oedema etc. **CASE:** A 45 years female patient was admitted in psychiatry ward with chief complaints of hyperactivity, uncontrolled thought and speech, excessive laughing since one week. Lithium was the first drug used for the treatment of mania. In our case, the patient was already known mania patient and she was on treatment with lithium and suddenly she developed pedal oedema and severe pain. So the patient was treated with Furosemide injection and NSAIDs for relieving pain and oedema. On day 3, the patient experienced symptoms like confusion, palpitations, and abnormal heart rhythms. **DISCUSSION:** As per scientific literature we have concluded that because of diure- sis the patient developed hyponatremia. For correcting sodium levels in the body, the sodium pump was activated in distal convoluted tubule and because of that the sodium reabsorption took place, as sodium is a monovalent cation and lithium also a monova- lent cation, the subsequent reabsorption of lithium also took place. Because of that on day 3, patient experienced symptoms similar to acute lithium toxicity. **CONCLUSION:** Better vigilance is necessary for the implementation of safe and effec-tive treatment for each individual patient. In order to prevent serious adverse drug interactions need to consider thorough drug history and patient risk factors, knowledge about actions of drugs, close monitoring during the treatment course, individualization of therapy, recognition of the problem, and careful management of all patients who experienced this type of interaction is essential.

KEYWORDS: drug interactions, diuresis, mania

T111: A PROSPECTIVE OBSERVATIONAL STUDY ON HEALTH RELATED QUALITY OF LIFE IN DIABETIC RETINOPATHYPATIENTS BASED ON SEVERITY

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ABSTRACT

Diabetic retinopathy (DR) is a leading cause of vision loss and occurs as a result of pathologic changes of the retinal vasculature. The prevalence and severity of DR increases with the duration of diabetes; however, it is inversely correlated to glyce- mic and blood pressure control. **AIM & OBJECTIVES:** Study was conducted to determine the health related quality of life in DR patients based on severity. To describe the impact of visual acuity and DR on the health-related quality of life (HRQOL) among patients with DR. **STUDY DESIGN:** Tertiary care hospital based cross sectional study was conducted. **METHODS AND MATERIAl:** Study was done in 76 patients in total, patients suffering from DR with severe complications in the department of general medicine' ophthalmology is highly enrolled in this study by using SF12 questionnaire and VFQ

25 questionnaire. **RESULTS:** The study shows higher risk in males than females and the P values shows in physical component summary PCS (>0.05) and in mental component summary MCS (<0.01). **CONCLUSIONS**: Based on results it was concluded that more number of people in the age group of 60-69 years is affected with DR. This study indicates that type 2 diabetic patients with macular oedema experience a decreased VR-QOL compared with type 1 diabetic patients with DR, glaucoma or cataracts. In this study, it indicates that prolif- erative DR patients shows more prevalence based on severity than non proliferative DR patients. The physical component and mental component summaries showed statisti- cally significant difference determined by student t-test. This study suggests, that co morbidities will also reduces the quality of life of DR patients.

KEYWORDS: Diabetic retinopathy, quality of life, diabetic patients

T112: EFFECT OF ANGIOTENSIN CONVERTING ENZYME INHIBITORS ON SERUM AMYLASE AND LIPASE IN PATIENTS WITH HYPERTENSION

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ABSTRACT

Introduction: Angiotensin-converting enzyme (ACE) inhibitors are a class of potential drugs used as first line agents for treatment of hypertension and heart failure in physi- ologically young patients despite of its side effects. Apart from the other common side effects, they are known to induce bradykinin release which alter vascular permeability leading to pancreatic edema resulting in intra-pancreatic entrapment of enzymes, toxins and acute pancreatitis. **OBJECTIVE:** To determine the effect of long term ACE inhibitors use on serum amylase and lipase levels. **METHODS:** A total of 122 patients were divided in two groups as case and control group, where case group includes patients using ACE inhibitors for more than 8 months and control group includes patients who are on other antihypertensive. Pancreatic enzyme levels were measured by ELISA method, and the elevation of pancreatic enzymes were determined in both the groups and compared by Unpaired T-test. **RESULTS:** Study showed significant difference in amylase levels between case and control groups (P ≤0.002) and Lipase level among case and control groups (P ≤0.003). Further, confounding factors were adjusted on ACE inhibitor usage. **CONCLUSION:** The use of ACE inhibitors showed significant association with elevated serum amylase and lipase levels in hypertensive patients. Our study suggests the moni- toring of serum amylase and lipase levels in patients who are on ACE inhibitors and its administration must be stopped as soon as an increase of serum amylase and lipase is evident for causing acute pancreatitis.

Key Word: Hypertension, ACE inhibitors, Serum Amylase and Lipase

T113: PHARMACEUTICAL CARE FOR PERSISTENT ASTHMA PATIENTS: ASSESSMENT OF KNOWLEDGE, ATTITUDE, PRACTICE AND QUALITY OF LIFE

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ABSTRACT

BACKGROUND: Current treatment guidelines for asthma - Global initiative for asthma (GINA) emphasize the importance of patient education to asthmatics. Assessment of knowledge, attitude, practice (KAP) and health-related quality of life (HRQoL) is crucial for patient improvements and well-being as well as preventing them from complications**. AIM:** The present study is designed to evaluate the pharmaceutical care for persistent asthma patients. **METHODOLOGY:** The Institutional Ethics Committee (IEC) approval was obtained prior to the commencement of the study. Patients were distributed with GINA rec- ommended the patient education material. KAP and HRQoL will be assessed using validated questionnaire. **RESULT:** Patient education resulted in better improvements in knowledge, attitude and practice of patients when compared to baseline values. At the end visit, except symptom score, other scores had significant improvements (p<0.05) i.e. activity scores, impact scores and total scores were compared to baseline. Pearson correlation efficient test was performed to find out the correlation between % FEV1 and KAP scores of the study arms. No significant correlation (p>0.05) was observed for these efficacy variables. **CONCLUSION:** The present study concludes that distribution of GINA recommended patient education material to patient and patient education had significantly increased (p<0.05) knowledge, attitude and practice of their disease and disease management. However, HRQoL has not improved significantly.

KEYWORDS: Asthma, health-related quality of life, patient education.

T114: EFFECT OF OMEGA-3 FATTY ACIDS IN CARDIOVASCULAR PROTECTION

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ABSTRACT

BACKGROUND: Supplementation of omega-3 fatty acids benefit the health of the patients with established cardiovascular disease or an increased risk of cardiovascular disease but many researchers claim that it is not so. **METHODS:** We are performing a randomised interventional study, in 164 patients who were having a risk of cardiovascular disease or with current and previous cardiovascular disease. The patients were randomly divided into two groups, the first group was given atorvastatin 10mg and the second group was given omega-3 fatty acids 1g (460mg of EPA and 380mg of DHA) with the diet control. All the patients were followed up at baseline at 3 months. **RESULTS:** The study has been performed for a few months and is still in progress. **CONCLUSION:** This study will suggest that the omega-3 fatty acids have no effect on mortality or cardiovascular health. It does not alter the risk cardiovascular events like myocardial infarction, coronary artery disease and ischemic heart disease in patients with risk of developing cardiovascular disease. Omega-3 fatty acids (EPA and DHA) may slightly reduce the triglyceride level and increase the HDL level but there is no evidence that it reduces the heart disease or death.

KEYWORDS: omega-3 fatty acids, cardiovascular disease.

T115: WERNICKE'S ENCEPHALOPATHY- "AN ATTEMPT TO EXTEND THE LIMITS" OF PATIENT PROFILE - A CASE REPORT

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ABSTRACT

Wernicke's encephalopathy (WE), an acute neuropsychiatric condition, is caused by thiamine deficiency. Traditionally, it has been associated with patients with a background of alcoholism. However, in the past few decades, with increasing trends in the incidence of We among patients without a history of alcohol consumption, a press-ing need was felt to examine the existing guidelines for the management of WE and its resulting conditions. The need for a revision was felt as the guidelines for the manage-ment of WE were developed around the premise that this cause of harm is observed mainly among alcoholics. In light of the opportunity presented to us by one of our patients who did not 'fit the bill' of a traditional case of WE, we decided to compare and contrast the management of WE among patients with and without a background of alcoholism.

KEYWORDS: Wernicke's encephalopathy, Alcoholism

T117: A CASE STUDY ON ERYTHRODERMIC PSORIASIS

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ABSTRACT

Psoriasis is a chronic inflammatory, auto immune, non-contagious, dry and ugly skin disorder which can affect the entire system of the body. Among all types of the psoriasis erythrodermic psoriasis is the most severe and life-threatening type of the psoriasis. We reported the case of the Erythrodermic psoriasis with its management. A 22 years male patient had complained a tightness of skin, erythema, scaling, itching and fever. The personal history of the patient was a chronic alcohol abuse. Patient followed a treatment with methotrexate and Acitretin from a local dermatologist physician for 20days. During the course of treatment patient developed the erythema to the whole body, then the patient admitted in the SVIMS hospital of dermatology department. On laboratory investigations the patient had a mild anemia and increased alkaline phosphatase. Then the patient was diagnosed with the Erythrodermic psoriasis and the patient was managed with the drugs, methotrexate, dexamethasone and other support-ive therapy based on the clinical symptoms. After one week, patient responded better to the therapy and was discharged with the drugs methotrexate and dexamethasone, pre-scribed for one month for better management, to avoid the recurrence of the disease.

KEYWORDS: Erythrodermic psoriasis, Erythema**.**

T118: EFFECT OF VITAMIN C ADJUVANT THERAPY ON LIPID PROFILE IN DIABETES PATIENTS WITH CO- MORBID CARDIOVASCULAR DISEASE

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ABSTRACT

Objectives: The study was aimed to evaluate the effect of Vitamin C adjuvant therapy significantly on lipid profile and HbA1c in diabetes patients with co-morbid cardiovas- cular disease. **METHODS:** A total of 64 diabetic patients were enrolled by using a randomization pro- cedure and assigned to control group and an intervention group. The interventional prospective study registered in Clinical Trial Registry India (CTRI/2017/10/010035). Patients in the intervention group received Vitamin C 500mg BID supplementation along with antidiabetic and antihyperlipdemic therapy as per the standard treatment protocol for a period of three months, whereas patients in the control group received only antidiabetic and antihyperlipidemic therapy for a period of three months. **RESULTS:** The mean age of the patients was 50.04±14.58 and 48% of the patients were male. The mean BMI, duration of diabetes, SBP and DBP of the subjects were 27.94±4.71, 9.93±4.83, 137.28±20.06c and 81.78±10.23 respectively. The incidence of elevated CRP was found to be 68%. No statistically significant difference for any variable of comparison of Tot. Cholesterol, TGL, HDL, LDL, VLDL, FBS, PPBS, HbA1c and CRP was detected at baseline. There was a reduction in levels of clinical variables found after 3 months of daily use of vitamin C 500mg bid in the intervention group. The statistically significant differences obtained in the intervention group in T. Chol (p=0.004**) TGL (p=0.032*), LDL (p<0.001), HDL (p=0.041*), FBS (p=0.038*), PPBS (p=0.047), HbA1c (p=0.026*) and CRP (p<0.001). The statistically significant differences between groups were observed in TGL (p=0.029*), LDL (p=0.019*), VLDL (p=0.041*) and FBS (p<0.001**). This means that the reduction in levels of clinical variables after 3 months of daily use of 1 g of vitamin C (500mg bid) were true and resulted from the effect of the supplement- **CONCLUSION:** Based on the results of this study, it can be concluded that Vitamin C as an adjuvant therapy produces beneficial effect in type 2 diabetes patients. Vitamin C 1g/ day showed improved lipid profile which helps in cardiovascular risk mitigation.

KEYWORDS: VitaminC, Adjuvant therapy, ntihyperlipidemic therapy

T120: HEADACHE: A BURDEN IN FEMALE LIFE AND ITS SELF CARE

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ABSTRACT

BACKGROUND: Headache is the most common disorder affecting human beings through-out the globe. Pathophysiology of headache is explained by three hypothesis namely vascular hypothesis, platelet hypothesis and central nervous system hypothesis.It affects people of all groups, sexes, races and social classes around the globe and occur due to various trigger factors like stress, emotions, environmental factors, genetic factors, diet, sleep disturbances hormonal factors (menstruation,oral contraceptives).Management of headache can be of both pharmacologic and non pharmacologic i.e. self care. The present article is about self care in teenage girls and women. **OBJECTIVES:** To know the frequency and self care of headache in teenage girls and to determine the trigger factors of headache in teenage girls. **METHODS:** In this cross-sectional Observational study, a validated self-administered, questionnaire was used to collect data among girls. **RESULTS:** Of the 250 teenage girls, headache is more frequent in many of them that are due to stress and other reasons and number of girls' response towards a menstrual headache is low. A headache is generally managed with self-medication and even self- care**. CONCLUSION:** The practice of self-care in managing headache is found in females using relaxation and other non-pharmacological management than pharmacological man- agement.

KEYWORDS: Headache, stress.

T122: UNCONTROLLED AND RESISTANT HYPERTENSION IN PATIENTS WITH DIABETES: AN EPIDEMIOLOGICAL SURVEY

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ABSTRACT

Diabetes and hypertension are commonly associated diseases, particular in patients difficult to control hypertension. In ALLHAT (Antihypertensive and Lipid Lowering Trial to Prevent Heart Attack Trial), diabetes predicted lack of blood pressure control during the course of the study. Clinical trials have indicated that to achieve lower blood pressure; goal recommended for patients with diabetes, an average range of 2.8 to 4.2 anti-hypertensive medications will be needed. The prevalence of uncontrolled and resistant hypertension is not known precisely and more so in Indian diabetic patients. It is also important to understand the prevalence of nephropathy among diabetic patients. This study evaluated the prevalence of uncontrolled/ resistant hypertension and dia-betic nephropathy in an eastern Indian population. Any subject more than 18 years of age, diagnosed to have diabetes and willing to give consent were included in this study. Patients not willing to participate, pregnant women and children were excluded from this study. Data was collected from five diabetic clinics including prevalence of resistant hypertension, uncontrolled hypertension, diabetic nephropathy (overt nephropathy and micro-albuminuria), and the duration of disease, lipid profile, prevalence of car-diovascular disease, and the treatment pattern of the resistant hypertension. All the demographics, history and pathological parameters were recorded in a predesigned format during interview. Biochemical parameters were evaluated by the help of an auto-analyser. This research revealed 51% of total cases of diabetes having more than 5 years of duration and 5% from having diabetes more than 20 years. This means there is a greater need for public awareness and professional education to strengthen health related services. About 63% of the diabetic populations are graduates and 6% of them are found to be illiterate, where as nearly 2.4% are found to be unemployed. However, data also revealed that about 55% of the total diabetic population are suffering from hypertension. Around 10% of the total population evidenced of nephropathy associ-ated diabetes and hypertension. Most of these patients were above the age of 40 years, which means lack of adherence to the cause might have contributed to emergence of nephropathy among the patients. Almost 50% of total population had a habit of either smoking or drinking alcohol. So from this study it may be concluded that diet, exercise, genetic heritance, bad social habits and non-adherence to drugs may attribute to the pathogenesis of diabetes and associated co-morbidities. By developing awareness with consideration to the above parameters can improve quality of healthcare.

KEYWORDS: Resistant hypertension, Nephropathy, Micro-albuminuria, lipid profile

T124: A STUDY ON COMPLICATIONS OF POLY PHARMACY IN DIABETIC GERIATRIC PATIENTS

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ABSTRACT

A 49 years old lady presented with lump in right breast FNAC suggestive of ductal carcinoma and FNAC of right axillary tail suggestive of invasive carcinoma. Digital mammography showed lobulated hypoechoic mass with speculated margins in right breast with adjacent architectural distortion suggestive of malignant lesions –BIRADS category 5 and right axillary lymphadenopathy metastatic. Patient under-went right breast conservative surgery and axillary lymph node dissection. Post that, patient was PT2N3M0, ER/PR-0% and Her2neu2+have received 8cycles of adjuvant chemotherapy with Adriamycin and Cyclophosphamide followed by radiation therapy. 5 months post chemotherapy with continuous follow up patient presented to OPD with c/o blackouts 4-5episodes within 1month duration. PET CT revealed hyper metabolic nodule in upper and inner quadrant of left breast, indeterminate nodule in upper lobe of right lung, hyper metabolic enhancing lesion in left parietal-occipital region (3cm) (brain metastasis) with extensive perilesional edema and indeterminate nodule in upper lobe of right lung. The patient was started with gemcitabine and carboplatin – 3weekly regimen, after receiving 5th cycle the same patient was admitted for severe vomiting (6-7episodes), headache and thrombocytopenia and hyponatremia which were treatedMRI brain shows minimal increase in the size of lesion in left parietal lobe and increase in perilesional edema. MRI spine shows early cervical and dorsolumbar spondylosis. After 10days patient came with c/o tingling sensation of hands and feet and blurring of vision. Perimetry shows right near total visual impairment and left superior quadrantonopia. In spite of these patient was with chemotherapy 7th cycle of gemcitabine and carboplatin the patient was subjected to QOL questionnaire and the responses were assessed. Due to the Impact of disease patient experienced physical symptoms, psychological and economic burden that is adversely affecting the quality of life (QOL) of the patient. The psychosocial distress faced by the patient upon diagnosis can affect the treat-ment as these symptoms can be overwhelming (sad, anxious, shocked, and scared). Psychological treatments will help patients come to terms with their emotions. Patient was given counselling for acute stress disorder and panic attacks.

KEYWORDS: ductal carcinoma, gemcitabine, metastasis.

T126: WALLENBERG SYNDROME – A CASE REPORT

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ABSTRACT

INTRODUCTION: Wallenberg syndrome also known as lateral medullary syndrome is a neurological condition in which an infarction, or stroke occurs in lateral medulla of brain stem resulting in blockage of posterior inferior cerebellar artery, superior middle and inferior medullary arteries. The underlying cause is usually infarction secondary to vertebral artery occlusion which encompasses several symptoms due to neurologi-cal disorder of the nuclei and nerve tracts of brain stem affecting bodily functions. The most common symptoms include difficulty in swallowing, breathing, speaking and perceiving senses, dysphagia, diplopia, nystagmus, headache, facial pain, hiccups, ataxia, vertigo, trouble with balance, numbness in one side of body. **CASE PRESENTATION:** A 56 years old male patient presented with complaints of slurring of speech and weakness of right side of the body since 20 days, not able to hold things, not able to stand, sit or walk, sways to left side while walking. He is known case of CVA 10 years back and was admitted for similar attacks and was treated. **INVESTIGATIONS:** The patient underwent MRI of brain and MRA circle of wills which showed multi-infarct state with bilateral thalamic infarct with lateral medullary syndrome. **TREATMENT:** The goal of therapy is to minimise symptoms and impairments, maxi-mise independence, prevent complications and reduce morbidity and mortality rate. The patient was managed with intermittent oxygen inhalation and Ryle's tube feeding. Anticoagulants and Antiplatelet agents such as Aspirin 150mg OD and Clopidogrel 75mg OD, Neuroprotectives like Citicoline 500mg BD were prescribed.Analgesics such as Paracetamol and Tramadol combination and Diclofenac is used for symptomatic relief of pain. The treatment was supplemented with physiotherapy to achieve optimal health. The patient responded well with the treatment schedule. **DISCUSSION AND CONCLUSION:** Lateral medullary syndrome is a rare disor-der of the posterior cerebrovascular circulation and has implication on one's activity of self-caring. This case illustrates that with a proper symptomatic treatment, clinical monitoring and effective post-stroke care, the prognosis for patient recovery will be positive. Most patients with this syndrome have minimal deficits at six months and over 85% develop functional independence with ambulation within a year. One should recognise these symptoms quickly and managed appropriately.

KEYWORDS: Lateral medullary syndrome, infarction, neurological, Wallenberg syndrome.

T127: ROLE OF CLINICAL PHARMACIST IN BREAST CANCER CARE: AN EXPERIENCE

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ABSTRACT

INTRODUCTION: The role of a clinical pharmacist in an oncology setting is quite a crucial one as it involves thorough Cancer patient care by using the knowledge on medication use. **CASE STUDY**: A patient XYZ aged 49 years who has been a case of Carcinoma Right Breast, visited the hospital for 6th cycle. She was on the TCH regimen which is Trastuzumab, Carboplatin and Docetaxel regimen. She is a known case of Hypertension and is on regular treatment with Amlong 2.5mg. Patient was put on 6th cycle of che-motherapy. The patient was given Pre Medications prior to the TCH regimen and was monitored, Post to 6th cycle the patient complained of loose stools for about 8 episodes, dehydration and weakness. As for lab investigations, the patient was also slipping into Hyponatremia (Na levels: 121 mEq/L). The corrective measures given to the patient were, Injection Magnex forte 2gm, an antibiotic that was given which is a combina-tion of two medicines: Cefoperazone and Sulbactam, given in this case to rule out any consequences of infection. Metrogyl Injection 500mg for preventing infections in the bowels. Tablet Lomotil were also given as oral drugs for the occurrences of loose stools. **RESULT:** Intervention by Clinical Pharmacist

- Assessment of patient before chemotherapy- Verifying the checklist for chemotherapy that includes patient details, Patient Anthropometry, Lab investigations, Any Minor Issues
- Checking pharmacy Indents for correctness
- Coordinating with pharmacy regarding dispensing of different drugs strengths, Ensuring cold chain and correct dispensation
- Double checking medicines brought
- Monitoring the drug dilutions for Accuracy (Diluent percentage and volume)
- Monitoring drug administration
- Monitoring for acute side effects (Infusion Reaction)

KEYWORDS: Carcinoma Right Breast, TCH regimen, Hypertension

T128: CASE PRESENTATION POTT'S SPINE

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ABSTRACT

INTRODUCTION: Spinal tuberculosis (TB) or Pott's spine is the most common extra- pulmonary manifestation of TB. Percival Pott was the first person to present the classic description of spinal tuberculosis (TB) in 1779; hence, spinal TB was called 'Pott's Disease'. It spreads through hematogenous route. Clinically, it presents with consti-tutional symptoms back pain, tenderness, paraplegia or paraparesis, and kyphotic or scoliotic deformities. Pott's spine accounts for 2% of all cases of TB, 15% of extra pul-monary, and 50% of skeletal TB. The morbidity and mortality rate due to spinal TB is higher than other infections in developing countries with dense population. **CASE PRESENTATION:** A 65 year old woman came with the symptoms of lower back pain since 3 months at a Govt. hospital in Bangalore. She had complaints of severe lower back ache which aggravated on walking, bending forward and sideward. **INVESTIGATIONS:** On admission, hematological tests showed increased ESR and decreased blood count.Magnetic Resonance Imaging of spine illustrated spon- dylodiscitis at T10, T11 and T12 levels, with multiple paravertebral and epidural abscesses. Polymerase chain reaction (PCR) of the patient's gastric fluid was positive for Mycobacterium tuberculosis (MT).Results of the culture showed colonies of MT and confirmed the diagnosis afterwards. **TREATMENT**: The goal of therapy is to improve symptoms, to reduce complications and reduce morbidity and mortality. Based on MRI and PCR findings, standard treat-ment for TB was initiated.Treatment was initiated with analgesics, muscle relaxants, multi-vitamins and ATT (Anti-Tubercular Treatment). Anti-TB treatment was initi-ated and was continued upto nine months. Aceclofenac, Pregabalin, methycobalamine, Oral iron formulations, and multivitamins were given for symptomatic relief. **DISCUSSION AND CONCLUSION:** Tuberculosis of the spine (pott's spine) is the commonest and most dangerous form of skeletal TB. Delay in establishing diagnosis and management can cause spinal cord compression and spinal deformity resulting in serious neurological deficit and bad prognosis. Differential diagnosis of multiple spi- nal lesions must include tuberculous spondylitis, metastatic neoplasm and pyogenic spondylitis. Nowadays presentations of tubercular spondyltis are variable and atypical, hence whole body bones can or MRI spine will be helpful in the diagnosis. Since early diagnosis avoids unnecessary delay in the treatment thereby reducing morbidity and possible complications.

KEYWORDS: Tuberculosis, Pott's spine, Mycobacterium tuberculosis.

T130: CASE REPORT ON GUILLAIN-BARRÉ SYNDROME

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ABSTRACT

INTRODUCTION: Guillain-Barré Syndrome is a disorder characterised by progressive (GBS) symmetrical paralysis and loss of reflexes, usually beginning in the legs. The paralysis characteristically involves more than one limb (most commonly the legs), is progressive, and usually proceeds from the end of an extremity towards the torso. Areflexia (loss of reflexes) or hyporeflexia (diminution of reflexes) may occur in the arms and legs. The overall annual incidence of GBS varies between 1/91,000 and 1/51,000**.** GBS occurs after a respiratory or gastrointestinal infection and is apparently caused by misdirected immune response that result in direct destruction of myelin sheath surrounding the peripheral nerves or the axon of the nerve itself. **CASE PRESENTATION:** This is the case of a 37-year-old male who came with complaints of fever and weakness of both upper and lower limbs since one week which was insidious in onset, progressive in nature. Patient also has deviation of right angle of mouth & dif-ficulty swallowing since 1 week. Physical examination revealed the presence of pallor. Patient also had sinus tachycardia and hypotonia**. INVESTIGATION:** CNS examination showed B/L VIIth, IXth, Xth nerve palsy and hypo- phonia. Patient has motor difficulty and absence of deep tendon reflexes. Total count was increased and CSF analysis revealed albuminocytologic dissociation. **TREATMENT OUTCOMES AND FOLLOW-UP:** There are two ways to treat GBS. Plasmapheresis and receiving intravenous immune-globulin, along with good nursing, medical care and phys- iotherapy. The patient was made to undergo physiotherapy and plasmapheresis regularly along with methyl prednisolone (1g IV), ceftriaxone/sulbactam (1.5 gm) and azithromycin.

DISCUSSION: Guillain-Barré Syndrome is an acute demyelinating disorder of the peripheral nervous system that results from an aberrant immune response directed at peripheral nerves. Average annual incidence is 1.7 per 100,000. A typical GBS patient presents with rapidly ascending symmetrical weakness, which may progress to respi- ratory failure in 30% of patients. The disease can be diagnosed clinically by tests like EMG/NCS and lumbar puncture**. CONCLUSION:** Guillain-Barré Syndrome can result in permanent damage to the cardiac conduction system. Patients with multiple episodes of bradycardia and a systole in Guillain-Barré Syndrome should be evaluated and considered as potential candidates for permanent pacemaker implantation.

KEYWORDS: Guillain-Barré Syndrome, Plasmapheresis, symmetrical paralysis.

T131: CASE SERIES ON PHARMACOLOGIC MANAGEMENT OF SEVERE PAIN WITH OPIOIDS IN CANCER PATIENTS

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ABSTRACT

INTRODUCTION: Patients diagnosed with cancer have diverse symptoms, impair- ments which includes physical and psychological functioning, and other difficulties that can affect their quality of life. Pain from cancer is considered as one of major healthcare problem. The prevalence of chronic pain is about 30–50% among cancer patients undergoing active treatment for a solid tumour and 70–90% among those with advanced disease. **OBJECTIVE:** The study was conducted to assess and monitor the pharmacological management of pain and report ADRs in cancer patients on opioids. **METHODOLOGY:** A Prospective Observational Pilot study was conducted in in- patients in a Cancer hospital as a part of Internship programme in Oncology setting. We could collect information from 5 patients who were admitted in Pain and Palliative care unit and those started on opioids were included. The demographic details, clini- cal details, diagnosis and medication details were collected in a case report form. The selection of opioid therapy was individualised, depending on severity of pain and tem- poral features (onset, pattern and course); location (primary sites and pattern of pain radiation); Severity of pain was measured using the verbal rating scale ,rating from 0- 10.The pain rating of 1-4 was corresponding to mild pain; of 5-6 as moderate pain ; and of 7-10 as severe pain. The daily assessment of pain was done using the same scale and a post opioid therapy pain score was taken 2 days after starting opioids and they were also monitored for side effects. **RESULT**: Five patients who were enrolled had diagnosis of metastatic carcinoma prostrate metastasis, malignant epithelial neoplasm consistent with metastatic, cancer pancreas, metastatic carcinoma colon and metastatic carcinoma oesophagus. Mean age of patients was found to be 54 years. Mean Pain score before starting opioids was found to be 7.4. Out of 5 patients, 4 patients were receiving morphine tablet (10,20 & 30mg) in variable duration and 1 patients was put on fentanyl patch (50mcg). Mean pain score after opioids administration for two days was found to be 5.2. The fentanyl was not associated with any side effect while one patient on morphine complained of constipa- tion and another patient on morphine complained of difficulty in breathing.

KEYWORDS: Metastatic carcinoma, Opioid therapy.

T132: IMMUNOTHERAPY (NIVOLUMAB) THERAPY IN PATIENTS WITH CARCINOMA TONGUE AND MAXILLA

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ABSTRACT

A male patient aged 49 years was diagnosed to have carcinoma tongue in 2016 in a different hospital. Partial glossectomy and modified radial neck dissection was done along with radiation therapy. Patient came to Sri Shankara Cancer Hospital with complaints of Ulcer over hard palate in 2018. Biopsy showed well differentiated Squamous cell carcinoma and PET CT confirmed with second primary carcinoma of hard palate and he was planned for surgery. Patient underwent left radical maxillec-tomy, anterolateral thigh flap reconstruction and tracheostomy, patient was planned for adjuvant chemotherapy with Cisplatin and 5-Flourouracil therapy regimen for three days followed by cycle 2 with Paclitaxel Cisplatin -5 Flourouracil regimen for three days. Post to cycle 2 patient developed 8-9 episodes of loose stools, generalised weakness and hyponatremia. These ADRs were managed symptomatically. Patient was planned for immunotherapy with Nivolumab 2 weekly regimen in view of second primary cancer. Nivolumab 200mg was infused along with pre medications. Patient tolerated well. Post to 1st dose of Nivolumab patient developed fever and generalised weakness after 2 days, which was treated and managed. Immunotherapy, also called asbiologic therapy, is a type of cancer treatment that boosts the body's natural defences to fight cancer. It uses substances made by the body

or in a laboratory to improve or restore immune systemfunction. Nivolumab used for the treatment used in the patients with metastatic melanoma, metastatic small cell carcinoma, advanced renal cell carcinoma, hodgkins lymphoma, metastasis squamous cell carcinoma and metastatic small cell lung cancer. Nivolumab is a human immunogloubin (Ig-G4) monoclonal antibody that binds to PD 1 receptor and blocks its interaction with PD-L1and PD-L2, releasing PD 1 pathway mediated inhibiton of the immune response including anti-tumour immune response. It acts as a targeted therapy. Common side effects are fatigue, lympocytopenia, hypoka- lemia, decreased appetite, cough and shortness of breath.

KEYWORDS: Partial glossectomy, Nivolumab, asbiologic therapy, metastasis.

T133: AWARNESS OF BREAST CANCER AND ITS EARLY DETECTION: A CASE STUDY

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ABSTRACT

A female patient aged 52 years attended a Cancer awareness camp. She learnt self breast examination in the camp. 8 months she noticed a painless lump and approached the doctor. She was diagnosed with carcinoma of breast. Breast cancer occurs as normal cells in tissue start to grow and divide in an out of control manner. 90% of cancers are curable if detected in stage I. This abstract focuses on empowering women by teaching them how to find cancers in early stage by making them aware of:

1. Firstly, the signs and symptoms of breast cancer like lump in the breast, skin dimpling, change in skin colour or texture, clear or bloody fluid that leaks out of the nipple

2. Secondly, teaching them to do breast self examination.

How to do-begin by lying on your back, place your right hand behind your head with the middle fingers of your left hand gently at firmly press down using small motions to examine the entire right breast, next sit or stand feel your armpit, gentle squeeze the nipple checking for discharge, repeat the same pro-cess for the other, look at your breasts directly and in the mirror look for changes in skin texture such as dimpling, indentations or skin look like a orange peel, check to see if nipple turns inward. Who to do (age above 20 years). When to do (menstruating women-4 days after the end of periods, menopausal and pregnant women - same date each month). Why to do (for early detection of cancer). It attempts to ut power back in hands of women and creates a call to action-put an end to last stage detection. There are several myths governing the disease which hinders early detection. Hence, it is very important to educate the women with right knowledge.

1. Cancer is a death sentence.
2. I am too young to get breast cancer.
3. Men can't get breast cancer
4. Only women with a family history of breast cancer are at risk.
5. I have never had children, so I can't get breast cancer.

There are several Barriers that also hinders such as:

1. Belief in alternative therapy (homeopathy, ayurveda, witchcraft).
2. Low awareness and perceived seriousness of signs and symptoms of disease (like I didn't feel any discomfort, pain, I think I won't get cancer).
3. Social inhibition (stigma associated with cancer).
4. Non-Availability of treatment facilities nearby. (No availability of specialist).
5. Financial constrains (we don't want to waste our money).
6. Less family support.

CONCLUSION: Early detection in turn can bring down mortality and morbidity.

KEYWORDS: Self breast examination, carcinoma of breast.

T134: A PROSPECTIVE STUDY ON ASSESSMENT OF EFFECT OF TERIPARATIDE ON POST MENOPAUSAL WOMEN WITH OSTEOPOROSIS USING BONE BIO- MARKERS AND BMD EVALUATION

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ABSTRACT

OBJECTIVE: The study was conducted to know the effect of teriparatide on post-meno- pausal women with osteoporosis using bone bio-marker and BMD evaluation. **METHODS:** In a prospective study, 80 women aged 45 and above were treated with 20mcg of teriparatide for a period of 6 months. Baseline characteristics were measured at the beginning of the study. Parameters like serum calcium, urine calcium, vitamin D and bone specific alkaline phosphatase were repeated at third and sixth month of the treat-ment. Changes in measured parameters were analyzed statistically using Spearman's correlation, Student's t-test and logistic regression. **RESULTS:** There was significant improvement observed in bone mineral density (< 0.05) and bone-specific alkaline phosphatase(<0.05) along with increase in serum Calcium, urine calcium and vitamin D. Treating osteoporotic postmenopausal women with 20mcg teriparatide for a period of 6months resulted in significant improvement in bone mineral density and bone-specific alkaline phosphatase (bio-marker). **CONCLUSION:** The study proves that it is a potentially useful therapy in the treatment of osteoporosis. The relationship between changes in bone mineral density and fracture risk reduction could not be measured since the study was of 6 months duration.

KEYWORDS: osteoporosis, teriparatide, bone mineral density, bone alkaline phosphatase**.**

T135: ADVERSE DRUG INTERACTION BETWEEN ASPIRIN AND FUROSEMIDE

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ABSTRACT

A 60 years old female patient came with complaints of chest pain since 6 pm on the day of admission, which is burning type of pain and also H/O breathlessness. She is a K/C/O HTN & DM since 5 years on medications i.e., T. Atenolol-5mg-1-0-0, T. Amlodipine-5mg-1-0-0 and T. Metformin-500mg-1-0-1, patient appetite was reduced and sleep disturbed. On examination BP was 120/100 mm Hg, PR: 80bpm, Spo2: 94% with room air, RS: B/L coarsecrepts +, pallor + remaining S/E are NAD. Laboratory reports show Microcytic Hypochromic with Neutrophilia and thrombocytosis, USG: B/L Grade I Renal parenchyma disease. Patient ongoing treatment was T.Aspirin-325mg stat and 150mg 0-1- 0, T. Clopidogrel 300mg stat and 75mg 0-1-0, Tab.Atorvastatin 80mg stat and 40mg 0-0-1, Inj. Furosemide 40mg IV 1-1-0, Inj. Nitroglycerin 2amp in 1 pint NS @ 12drops/min and stopped on second day, Inj. Pantoprazole 40mg IV 1-0-1, Inj. Heparin 5000 IU IV 1-1-1, Inj. Insulin-R 8-8-6 S/C 1- 0-1 started from second day, T. Enalapril 2.5mg PO 1-0-1 given on 2nd and 3rd day, T. Amlodipine 5mg PO 1-0-1 given on 2nd day and stopped, Inj. Insulin 1pint in 25% dextrose, Inj. Calcium Gluconate and Neb asthalin was given only on the 3rd day. Here come 6 major inter-actions between Amlodipine & Clopidogrel, Aspirin & Furosemide (causes possible nephrotoxicity), Clopidogrel, c- Aspirin & Heparin (increase the risk of bleeding) and also Heparin with Nitroglycerin. **CONCLUSION:** Patient was diagnosed as Grade I renal parenchyma disease in the mid- dle of the treatment which is caused by the interaction between Aspirin & Furosemide.

KEYWORDS: Adverse Drug Interaction, Aspirin, Hypertension, Diabetes Mellitus.

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TRACK 2: DRUG SAFETY, MEDICAL - MEDICATION ERRORS

T203: ASSESSMENT, MONITORING AND REPORTING OF ADVERSE DRUG REACTIONS DUE TO POLYPHARMACY

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ABSTRACT

INTRODUCTION: Poly-pharmacy significantly increases the likelihood of adverse reactions to drugs, the risk of hospitalization and medication errors related to drugs. It depends on the number of drugs, the disease, and patient-related factors. Poly- pharmacy is a major risk factor for severe adverse drug reactions (ADR'S) and is associated with increased risk of mortality. **AIM OF THE STUDY**: The main aim of this study is the assessment and monitoring of polypharmacy leading to adverse drug reactions. **RESULTS:** A Prospective observational study was carried out in Rajiv Gandhi Institute of medical sciences (RIMS), a 750 bedded tertiary care teaching hospital, Kadapa, for the period of 7 months in all departments of the hospital. A total of 448 cases of poly-pharmacy were identified, among that males were 246 and females were 202. Out of 448 cases, 252 patients were major polypharmacy and 196 were minor polypharmacy. Among 114 ADRs, 22.80% from MICU, 31.57% from MMW, 27.19% from FMW, 10.52% from PSY and 7.89 from DVL, The identified ADRs were reported to the phy-sician and the causality assessment was done for 114 ADRs by using Naranjo's scale. According to Naranjo's scale 24 (60.28%), ADRs were definitely, 52 (57.42%) were prob-able, 38 (81.37%) were possible. **CONCLUSION:** Building awareness to healthcare professionals for spontaneous reporting of adverse drug reaction and following the evidence-based medicine (EBM) would help in preventing polypharmacy and medication-related problems like ADR. The role of pharmacists is important to continually educate but also to have access to complete patient records. So they could look at all of the medications that may be given to the patient for better patient care.

KEYWORDS: Poly pharmacy, adverse drug reactions

T204: A STUDY ON IDENTIFYING AND MANAGING MEDICATION ERROR IN PEDIATRICS DEPARTMENT USING A MEDICATION ERROR CHECKLIST IN A TERITIARY CARE HOSPITAL

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ABSTRACT

BACKGROUND: Paediatric patients are the most fragile population particularly prone to medication errors in a hospital setting. Paediatric in-patients may have three times more medication errors than adult in-patients and these errors are frequently harmful. The goal of medication therapy is to increase the quality of life and minimizing risk to the patient.**AIM:** The main target of the study was to evaluate, categorize and to minimize the medication errors in paediatric patients, to provide awareness among nursing and pharmacy staff to reduce errors in intending, dispensing and administration process, to inform the physician on most commonly occurring errors, and to assess the measure of errors managed after the intervention. **METHODOLOGY**: The study was conducted in in-patients and out-patients of the paediatric department divided into three phases. We assessed, analyzed and categorised the medication errors which happened in a period of three months (phase 1). Phase 2 was carried out by pro- viding leaflets to the various departments of the hospital settings where the errors have been occurred and providing patient counselling to the out-patients while followed by Phase 3 in a period of three months to assess the adherence towards the intervention. **RESULTS:** The total number of patients involved in the study was 180. Among them in phase 1 there were 62 out of 100 and whereas in phase 2 there were 30 errors out of 80 patients (p value< 0.05). We have categorized the errors mainly into 4 catego-ries according to NCC MERP categorization of medication errors as prescribing, drug administration, dispensing, and patient compliance errors. Our study was able to reduce the prescribing errors followed by dispensing errors and the errors in outpatient had a statistically significant decline as our P value is 0.01. The more number of medica-tion errors were detected from the physicians in the drug prescription followed by the nursing staff, patients and other healthcare professionals**. CONCLUSION:** At the end of the study, the dispensing error was found to be nil in the post-interventional phase and the medication error in outpatients had significantly reduced after proper counselling and corrective measures adopted by the clinical pharmacists.

KEYWORDS: Medication error, Paediatrics, Medication error checklist

T205: EFFECTIVENESS OF REMINDER CARD SYSTEM VERSUS MOBILE APPLICATION TO IMPROVE MEDICATION ADHERENCE OF ASTHMA PATIENTS IN A TERTIARY CARE HOSPITAL

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ABSTRACT

BACKGROUND: To successfully treat a medical condition with medications, an equally important element is to use these medications according to instructions of the prescriber. There are strong evidences which show that many patients with chronic illness have difficulty adhering to their recommended medication regimen. Non- adherence encompasses the wide range of behaviours, which lead to underuse or overuse of prescription medications. **AIM:** To assess and compare the effectiveness of Reminder card system versus Mobile appli-cation to improve medication adherence of asthma patients in a tertiary care hospital. **METHODOLOGY:** A prospective interventional study was carried out for a period of six months in 100 asthma patients of age greater than or equal to 18 in Pulmonology department of a tertiary care hospital at Malappuram district in Kerala. **RESULTS:** In card group, comparison of baseline score of medication adherence with follow up has shown a mean difference of 3.44, P value= 0.001, which shows a highly significant association between medication adherence and reminder card. In applica-tion group, comparison of baseline score of medication adherence with follow up has shown a mean difference of 4.02, P value= 0.001, shows a highly significant association between medication adherence and Mobile Application. Comparison of effectiveness of Reminder Card and Mobile Application in improving the medication adherence of asthma patients showed a mean difference of 0.72 and p value= 0.088 (> 0.05) at baseline, reveals that there is no significant difference in adherence status before the intervention**.** After intervention comparison of card and application group has shown a mean difference of 0.86, and P value=0.001 (P value< 0.05), reveals that there is a significant difference in adherence status after the intervention**. CONCLUSION:** This study concludes that the provision of proper interventional tools can improve asthma medication adherence and among the two interventions, the mobile application was found to have more effectiveness than medication reminder card.

KEYWORDS: Asthma adherence, Medication reminder card, Mobile application

T206: ADVERSE DRUG REACTIONS: ASSESSMENT OF PUBLIC AWARENESS AND ATTITUDE

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ABSTRACT

Safety and efficacy are the two major concerns about a drug. The adverse effect of a drug may be uncommon, and many patients may be affected due to a poten-tial risk before the relationship with the drug is established. Adverse Drug Reactions (ADRs) are an imperative public health crisis striking a substantial economic bur-den on the society and health care system. ADRs affect irrespective of the age group of patients with varying magnitude causing morbidity and mortality. According to Uppsala Monitoring Centre (WHO), Sweden; only 6-10% of all ADRs are reported that to ADRs reporting is of prime importance in the success of any Pharmacovigilance (PV) program. Direct patient reporting of ADRs into PV systems as patients provide a different insight into drug safety compared to healthcare professionals (HCPs). PV program of India (PVPI) is in an infancy period. The new trend of future PV is toward the patient, it seems to be more appropriate as patient is the group of people who are directly affected from the ADRs of a particular drug and not the HCPs. By increasing patient familiarity and providing clear reporting systems could better achieve patients reporting of ADRs. Reporting of ADRs helps the safe use of medicines to protect public health. The ease of completing the ADR form & education level is predictive of patient confidence to report ADRs. These factors should be considered in designing public promotional activities to encourage patient contributions to PV. The objective of this study was to explore the knowledge of the general population towards ADR & their reporting system. A cross-sectional questionnaire-based online survey was conducted among the general public. Among 206 respondents, 82.9% were unaware of the ADR reporting process. 63.8% reported that their doctor didn't inform about the possible side effects. 19.6% were unable to identify side effects even though 47% stopped the medicines after side effects. More than 69% of respondents reported that they don't always feel free to talk about side effects. Respondents reflected inadequate

knowledge on ADR & reporting. This needs to be corrected as the trend of future PV is toward the patient. Pharmacists can play a major role in ADRs monitoring and create a trusted environment by counselling patients on ADRs.

KEYWORDS: ADRs, Pharmacovigilance, ADRs awareness, ADRs reporting

T207: IMPACT OF AMITRIPTYLINE ON FUNCTIONAL NAUSEA AND VOMITING

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ABSTRACT

BACKGROUND: Functional gastrointestinal disorder [FGID] is one of the most common digestive diseases worldwide and leads to significant morbidity and burden on healthcare resources. The treatment for functional nausea and vomiting remains empirical for all patients. Tricyclic Antidepressants have mixed response on a wide variety of neurotransmitters and receptors throughout the gut-brain connection. AIM: To determine the efficacy of Tricyclic antidepressant drug Amitriptyline in treat- ing patients with functional Nausea and Vomiting. **METHODOLOGY:** The study was a prospective observational study comprising of 47 patients with functional Nausea and vomiting, who visited inpatient & outpatient department of Gastroenterology. The data were extracted using a structured recording form and the patient diagnosed with functional nausea and vomiting was prescribed with a low dose of antidepressant Amitriptyline 10mg for a specific duration of days. Each patient was reviewed and followed up to ≥1 month after the initiation of Amitriptyline therapy. If the patients claimed to decrease in symptom to any degree then the medication was considered. **RESULTS:** Functional Nausea and vomiting involved young female predominantly (Male 23, Female 27, age 15-24 yrs). Postprandial vomiting soon after a meal without self-induced maneuver was the most common pattern of functional vomiting. Each patient was treated with Tricyclic antidepressants Amitriptyline for the GI symptoms and the subjects were followed for 1-2 months. Moderately satisfied with response occurred in 30 patients (69.7%), slightly satisfied with response in 8 (18.6%) and not at all satisfied with response in 2 (4.6%). Among 43 subjects, 5 patients had drowsiness as the predominantly observed effect and others were milder. **CONCLUSION:** Functional nausea and vomiting can be easily diagnosed based on a typical history in the absence of a structural or biochemical explanation. Selecting an appropriate drug often depends on type and severity of symptoms, patient's previous experience with the drug, cost, side effects profile and presence of psychiatric co-morbid conditions. The evidence for efficacy and the low cost of TCAs make them attractive, but their side effects need to be monitored and treated. TCA agents have been successful in the treatment of various functional gastrointestinal disorders and the high percentage of patients responding in TCAs in this trial would be supportive of this study.

KEYWORDS: Functional nausea and vomiting, Amitriptyline, Nucleus tractus solitaries

T208: THE ROLE OF CLINICAL PHARMACIST IN PHARMACOVIGILANCE AND DRUG SAFETY IN TERTIARY CARE TEACHING HOSPITAL

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ABSTRACT

INTRODUCTION: The WHO defines pharmacovigilance as the "the science and activities concerned with detection, assessment, understanding and prevention of adverse reactions to medicines. It was first introduced in 1937. As a means of pooling existing data on Adverse Drug Reactions (ADR`s).WHO'S programme for international drug monitoring was started in 1968. The network has since expanded significantly as more countries worldwide developed national pharmacovigilance centres for the recording of ADR'S. It mainly includes identifying new infor- mation about hazards associated with medicines and preventing harm to patients. **AIM OF THE STUDY:** The aim of the study is to study the role of clinical pharmacist in pharma-covigilance and drug safety in tertiary care teaching hospital**.** **METHODOLOGY**: This prospective observational study was conducted for a period of 6 months involving patients of all age groups in inpatient and outpatient department units of general medi-cine, psychiatry, dermatology of Rajiv Gandhi Institute of medical sciences (RIMS), a 750 bedded tertiary care teaching hospital, Kadapa after taking informed consent from them. A total of 60 patients were recruited under inclusion criteria that is patients of all age groups with both genders, who are diagnosed with diseases and on treatment, who had been hospitalized due to an ADR by using materials like patient data collection Performa, ADR reporting form, Naranjo's scale, ADR confirmatory scale, W.H.O scale, severity scale, preventability scale. **RESULTS AND DISCUSSION**: Out of three departments included in the study 16(26%) were observed in dermatology, 7(12%) were in psychiatry, 37(62%) were in general medicine. Out of 60 adverse reactions observed during study period, 8(13.33%) were corticosteroids and antipsychot-ics, antihypertensives,

1(1.67%) were anti-inflammatory,antidiabetic,diuretic, Disease modifying antirheumatic drugs (DMARD), Hematinic,antiplatelet,antiprotozoal,antiacne,antidepressant s, immunosuppressants, 2(3.33%) were antihistamines, GABA inhibitor, antiviral; 3(5%) were antiepi-leptic, cardiac glycoside, antiulcer,bronchodilator;6(10%) antibiotic**. CONCLUSION:** Most of the observed results were compared to literature reviews. The severity of the ADR'S was mild according to Hartwig and Siegel severity assessment scale. Majority of ADR's were probably preventable according to Schumock and Thorntown scale. The number of ADR'S reported during the study period was good but still, it requires continuous education on pharmacovigilance programme of India and to increase awareness and knowledge of the healthcare professionals. Clinical pharmacists can contribute improved patients outcomes by monitoring, identifying, assessing and prevention of ADRs and can also promote rational use of drugs.

KEYWORDS: Pharmacovigilance, Adverse drug reactions, clinical pharmacist

T209: IMMUNIZATION STATUS - COVERAGE AND PRACTICES AMONG CHILDREN A CROSS SECTIONAL SURVEY

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ABSTRACT

BACKGROUND: Disease prevention is the key to public health, and one of the most basic methods for the prevention of diseases is immunization. This is the safest and most effective tools for protecting children from various potentially serious childhood diseases. It works by stimulating the immune system, the natural disease-fighting sys- tem of the body. **OBJECTIVES:** To assess the immunization status of children under the age of 10 at Perithalmanna municipality of Malappuram district in Kerala**. METHODOLOGY:** A cross-sectional survey was conducted to assess the immu- nization status of children under the age of 10 at Perithalmanna municipality of Malappuram district in Kerala for a period of three months. The primary tool used for the survey was a structured and pre-validated questionnaire in the regional language which consisted of 23 questions. A total of 174 families were randomly selected as the sample for the survey. **RESULTS AND DISCUSSION:** A total of 174 families were randomly selected as the sample for the survey. Of these, (77.6%) families had been immunized in com- parison to (22.41%) which were not immunized. The impact of the child's delivery setting on immunization status was assessed, which indicated that (95.69%) children were immunized when their delivery setting was a government hospital as compared to (73.03%) in private settings. no impact of parent's education on the immunization status of children. Reasons for abstinence from immunization were obtained through the questionnaire and the most commonly found reason was fear of side effects (20.51%), opposition from parents, relatives & friends (17.95%) and loss of immunization card. The study indicates that there is a need for increasing the practices of immunization among children in Kerala. **CONCLUSION:** The government authorities and health department have to imple- ment awareness program and methods like implementation of computerized system instead of vaccination card, vaccination help desk, mobile vaccination unit, vaccination alert booth etc. This shall help to improve the status of immunization and achieving the desired goal from immunization programme.

KEYWORDS: Immunization status, paediatrics, cross-sectional survey.

T210: A PROSPECTIVE STUDY ON CLINICALLY SIGNIFICANT DRUG-DRUG INTERACTIONS BY SYSTEMATIC REVIEW OF CASE FILES IN A SOUTH INDIAN TERTIARY CARE HOSPITAL

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ABSTRACT

BACKGROUND: Drug-drug interactions have increasingly acquiesced as an area of major concern. Drug-drug interactions constitute one of the potential mechanisms leading to often preventable adverse drug events and health damage. **AIM:** The main target of the study was to recognize potential drug-drug interactions, thus reducing their potential risk and improving pharmaceutical care by minimizing medication-related problems. **METHODOLOGY:** A prospective interventional study conducted among the inpatients of Pulmonology, Nephrology, Gastroenterology and General Medicine departments of a tertiary care referral hospital. The study was divided into three phases. In the pre-interventional phase, all the relevant information was collected from the patient's case file, medication chart and by interviewing the patient. The data was anal- ysed using Lexicomp and Drug interaction probability scale. During the interventional phase, an information letter with a list of commonly occurring drug-drug interactions with its

significance and severity was prepared and distributed to the physicians of the departments involved in the study. In the post-interventional phase, all the relevant information was collected from another set of patients to compare the results of pre and post interventional phase to evaluate the impact of clinical pharmacist intervention in reducing drug-drug interactions. **RESULTS:** The total number of patients involved in the study was 200. Out of the total 495 interactions, 368 interactions occurred in the pre-interventional phase and 127 inter-actions in the post-interventional phase (p value< 0.05). As part of clinical observations in the study, we have observed that the occurrence of major interactions were 136 and 21 in pre and post- interventional phase. The occurrence of moderate interactions was 217 and 98 respectively. The occurrence of minor interactions was found to be 15 and 8 respectively. Interactions were further classified according to the Lexicomp risk rate and Drug interaction probability scale. Majority of interactions were of pharmacokinetic type. **CONCLUSION:** At the end of the study, we were able to reduce all the major drug- drug interactions to an extent due to the proper counselling and corrective measures adopted by the clinical pharmacists.

KEYWORDS: Drug-drug interactions, Lexicomp risk rate, Drug interaction scale

T211: ORAL THRUSH INDUCED BY INHALER CORTICOSTEROIDS

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ABSTRACT

Candidiasis is a fungal infection caused by yeasts from the genus Candida. It is commonly called oral candidiasis or thrush when it affects the mouth. It is one of the common side effects associated with the long-term use of steroid inhal-ers. Nebulizing therapy with corticosteroids is a widely accepted treatment approach for patients with acute exacerbations of Chronic Obstructive Pulmonary Disease. The other side effects of steroid inhalers include hoarseness of voice, dysphonia which are usually considered as safe and ignorable. We report this case of a 74-year-old male patient who was on Metered dosage inhaler and nebulizer therapy with corticosteroid and presented with oral candidiasis.

KEYWORDS: corticosteroids, candidiasis, inhalers

T212 TO DETERMINE THE COMPLIANCE OF PRESCRIBING PATTERN OF ANTIBIOTICS IN A TERTIARY CARE REFERAL HOSPITAL BASED ON WHO EML 2017

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ABSTRACT

BACKGROUND: Antibiotics are one of the most commonly prescribed drugs in mod- ern medicine and play a major role in prophylaxis and treatment of infectious diseases. Inappropriate or indiscriminate use of antibiotics is responsible for the emergence of antimicrobial resistance. By analysing the prescription pattern and by comparing the compliance with updated WHO EML LIST 2017 we can assess the prescribing practices in healthcare settings. **AIM:** The major aim of the study is to determine the compliance of prescribing pattern of antibiotics in a tertiary care referral hospital based on WHO EML 2017. As well as obtain information about commonly prescribed antibiotics, analyzed whether antibiot- ics are prescribed after obtaining culture and sensitivity reports, Percentage of common combination drugs used and common antibiotics used for prophylaxis. **METHODOLOGY:** This study was conducted in 9 departments of tertiary care referral hospital. Patients who received antibiotics were selected in the study. Data were col-lected from the medical records and by interviewing the patient and necessary details were entered in a predesigned data collection form. All relevant details were entered into an excel spreadsheet and further statistical analysis was performed. RESULTS: The total number of patients involved in this study was 499 in number. Among them, 310 were males and 189 females. The total number of subjects were distributed into 9 departments with 108 patients in Orthopaedics, 100 in General Medicine,106 in General Surgery and remaining patients from Pulmonology, Paediatrics, Urology,Gast roenterology,2Ophthalmology and ENT department. Majority of patients were under the age group of above 60 years. From a total, only 106 patients were given antibiotics after taking culture and sensitivity report. Cefoperazone + Sulbactum were found to be the most common prophylactic as well as combination drug prescribed. The indication for which majority of antibiotic prescribed was for postoperative treatment. The most common WHO EML category prescribed drug was from WATCH group. **CONCLUSION:** The study provided a well-defined evaluation of antibiotic pre- scription pattern and its compliance with WHO 2017 EML. It was found that there are chances of errors in prescribing antibiotics in hospital scenario. Certain recom- mendations in current policies and practise should be made to enhance the rational prescribing of antibiotics.

KEYWORDS: WHO EML 2017, Antimicrobial resistance.

T215: A CASE REPORT ON PREDNISOLONE INDUCED PEDAL EDEMA

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ABSTRACT

INTRODUCTION: Prednisolone is a highly potent synthetic glucocorticosteroid which has minimal mineralocorticoid activity. Prednisolone is used as an anti-inflam- matory or immunosuppressive agent, which is indicated in the treatment of various conditions. Glucocorticoids are adrenocortical steroids and cause profound and varied metabolic effects. In addition, they modify the body's immune responses to diverse stimuli. Majorly it causes Cushing Syndrome, peptic ulceration, edema, hypokalemia, muscle weakness, behavioural changes.**CASE**: A 55-year-old female patient was consulted in dermatology department with chief complaints of swelling and redness of blisters on mouth and forehead, difficulty while swallowing since 2 months, past medical history of the patient includes; she was already taking treatment for this condition which includes Tab. Chlorphenaramine malate 4mg, Tab. Prednisolone 25mg, Tab. Vitamin C 500mg, Ointment. Clobetasol 0.05% w/v, Glycerine lotion 5ml. Again patient was consulting in the dermatology department with complaints of swelling and itching at both lower limbs. On general examination, patient was conscious and coherent. On physical examination, PR-82bpm, BP-130/80 mm/Hg. On systemic examination, CVS-S1S2+, RR-20 CPM, RS- clear, pedal edema at both lower limbs with 4mm depth. On laboratory examination shows Hb: 11gm/dl, WBC: 9,500 cells/cumm, ESR: 28mm/hr. Based on the above information here we have suspected it as possible ADR (pedal edema) with prednisolone **DISCUSSION:** Edema may be defined as a clinically detectable increase in intersti- tial fluid volume. Edema develops when excess sodium is retained either as a primary defect in renal sodium excretion. In our case, patient had a history of usage of Tab. Prednisolone and developed severe edema at both lower limbs. During treatment course as a clinical pharmacist we have identified adverse drug reactions as follows, the patient was under the medication with Tab. Prednisolone based upon the literature reviews and based on local examination and other investigations we have concluded that this condition is due to the drug Prednisolone and performed causality assessment, severity, preventability, predictability. After the identification, we have immediately withdrawn the drug prednisolone and provided appropriate treatment.

CONCLUSION: Better vigilance is necessary for the implementation of safe and effec-tive treatment for each individual patient. In order to prevent serious adverse drug interactions need to consider thorough drug history and patient risk factors, knowledge about actions of drugs, close monitoring during the treatment course, individualization of therapy, recognition of the problem, and careful management of all patients who experienced this type of effect is essential.

KEYWORDS: prednisolone, pedal edema.

T216: PHENYTOIN SODIUM INDUCED CHRONIC LIVER DISEASE-A RARE CASE REPORT

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ABSTRACT

INTRODUCTION: Phenytoin has a broad spectrum anti-seizure activity, effective in the management of status epilepticus, Complex partial and generalized tonic-clonic seizures. Phenytoin has a number of effects on hepatic function; it mainly causes ele- vation of hepatic transaminases in plasma and often occurs asymptomatically in the course of the first several months of therapy**. CASE:** A 39 years female patient was admitted in the female medical ward with chief com-plaints of right quadrant upper abdominal pain which is insidious in onset and gradually progressive, abdominal distension since 2 weeks, yellowish discolourisation of eyes 1 month back associated with fever, decreased urine output and constipation. Patient past medical history includes patient was a known epileptic since 12 yrs and is on medication with Tab. Phenytoin-100mg.Personal history of patient includes mixed diet, disturbed sleep and Bowel & Bowel habits includes constipation. Patient had family history of epilepsy. On gen-eral examination, the patient was conscious& coherent & on physical examination her vitals were found to be HR: 80 bpm, RR: 24 Cpm, BP: 110/70 mm of Hg. On systemic examina-tion P/A: Bilateral edema. Patient laboratory parameters shows as follows Ultrasound scan abdomen: Liver- hepatomegaly (14.7cm) and severe ascites. Liver function test: SGOT- 119 IU/L, Alkaline phosphatase - 143 IU/L. Based on the subjective and objective Her labora-tory investigations shows increased SGOT levels(119 IU/L) and increased ALP levels(123 IU/L) & USG abdomen report shows gross ascites with hepatomegaly**. DISCUSSION:** Epilepsy is a collective

chronic neurological condition characterized by continuing seizure activity. After hospital admission as a clinical pharmacist we have identified adverse drug reactions as follows, the patient was on the medication with phenytoin, based upon the literature reviews and based on laboratory investigations we have concluded that this condition is due to the drug phenytoin and performed causality assessment, severity, preventability, predictability. After the identification we have immediately withdrawn the drug phenytoin and provided appropriate treatment. So, monitoring of liver function tests is necessary during treatment with phenytoin. **CONCLUSION**: Better vigilance is necessary for implementation of safe and effective treatment for each individual patient. In-order to prevent serious adverse drug reac-tions of this drug, dosage adjustment according to the bodyweight and frequency, close monitoring during treatment course, creating awareness, recognition of the problem and careful management of all patients who receive this medication are essential.

KEYWORDS: phenytoin, epilepsy, chronic liver disease.

T218: A CASE REPORT OF DIGOXIN INDUCED VENTRICULAR TACHYCARDIA

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ABSTRACT

Digoxin is extensively used in the treatment of Congestive Heart Failure (CHF). It improves blood circulation to peripheral tissues by increasing con-tractility of myocardial cells by binding to Na+-K+ ATPase pump. Arrhythmias are the major Adverse Drug Reaction (ADR) of Digoxin which may lead to hospitalization, morbidity and even mortality. A 60 years' male patient was admitted with breathless-ness, pedal edema and was diagnosed CHF. He was prescribed with Digoxin 5-day therapy along with other medications, on 5th day we observed Electro Cardio Gram (ECG) changes indicating ventricular tachycardia as a suspected ADR of Digoxin and was confirmed by causality assessment, immediately suspected drug was stopped, patient was monitored for progression and on 9th day ECG showed no tachycardia changes. We strongly recommend monitoring the patients receiving digoxin (especially those aged > 60years of age) for safe and effective outcome of therapy.

KEYWORDS: Digoxin, Tachycardia, Inducedventricular

T219: FORMULATION AND EVALUATIONOF RAPID DISINTEGRATING TABLETS OF DIPHENHYDRAMINE HCL USING POLYMER CARRIER SYSTEM

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ABSTRACT

INTRODUCTION: During the pregnancy, untreated urinary tract infections or respi- ratory tract infections are treated by different antibiotics which are associated with significant morbidity, including low birth weight and spontaneous abortion. **METHOD**: Our study was conducted on women who gave the birth between 15th December 2017 to 1st September 2018. **RESULTS:** Accounting for 75% of prescription medication in pregnant women are beta-lactam antibacterial/penicillin's group and the specific antibiotic amoxicillin were most commonly prescribed. Other antibiotics such as metronidazole, fluconazole, and vancomycin were also prescribed. **CONCLUSION**: Approximately three in five women were prescribed antibiotics dur- ing the pregnancy in the Andhra Pradesh which is comparable with rates from other states.

KEYWORDS: Pregnancy, Antibiotics, Infections.

T220: ERTAPENEM USE ASSOCIATED WITH CNS EFFECTS AND OTHER ADVERSE REACTIONS IN DIABETIC FOOT ULCER PATIENTS

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ABSTRACT

PURPOSE: The main purpose of this study is to establish the definite, probable and possible adverse effects caused by the use of ertapenem. Even though ertapenem has fairly large effect on complicated community acquired infections and other intra- abdominal and skin structured infections, it will also suspected to cause significant adverse reactions.

METHODS: The study is carried out cross-sectionally among 63 patients of age group 30-85 years, with diabetic foot ulcer and cellulitis. They were furnished with naranjo probability scale after receiving ertapenem for more than three days. **RESULTS**: The use of ertapenem 1g, i.v once a day for more than 3days shows statisti- cally high significance in occurrence of adverse effects and allergic reactions in diabetic foot ulcer patients, P=0.05%. **CONCLUSION:** Considering all the factors involved in the study, I concluded that, even though ertapenem furnish a great effect on complicated infections, it has various adverse effects like hallucinations, delusions, seizures, confusion, altered mental status and some allergic reactions. On other hand withdrawal of ertapenem will subside the acquired adverse effects. Therefore, care must be taken while administering ertapenem and awareness must be created among the patients to avoid unwanted examinations or hospitalizations regarding altered mental status.

KEYWORDS: ertapenem, adverse reactions, diabetic foot ulcers.

T221: MONITORING THE SIDE EFFECTS OF PSYCHOTROPIC DRUGS PRESCRIBED IN TERTIARY CARE HOSPITAL

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ABSTRACT

OBJECTIVES: To monitor the side effects of psychotropic drugs prescribed in a ter- tiary care hospital. **METHODOLOGY**: A descriptive-observational study was carried out in the psychia- try department of MVJ medical college and research hospital for a period of six months from October 2017 to March 2018. A total of 107 in-patients were enrolled into the study after fulfilling the study criteria and obtaining informed consent. Causality was assessed using WHO UMC scale and UKU scoring was done to assess the side effects. The baseline side effects score was recorded and the subsequent data were collected at the end of each week, for three weeks consecutively. The obtained data were analyzed statistically and descriptively. **RESULTS**: A total of 107 patients were enrolled into the study of which majority of the patients were females (54%). Most of the patients belong to the age group of 28-37years (47.6%). 93% of our sample populationwere married. Schizophrenia was found to be the most common type of psychotic disorders with prevalence 26.7%.On analysing the prescription, most of the patients were treated with two psychotropic agents (58%), of which antidepressants + benzodiazepines combination was more frequently used (33%), followed by antidepressant mono therapy (13%). Our study also revealed, there was a total of 33 drug- drug interactions found out of which 22 were major. The side effects found were grouped into four classes - psychic, neurologic, autonomic and others, as per UKU scale. Majority of the patients experienced side effects under psy-chic class (82%). The side effects were found to be statistically significant with P value <0.0001 (CI=95%) using logistic bi-variant fit analysis **CONCLUSION:** Our study showed that dry mouth, sedation, headache, weight gain and constipation are the most common yet serious side effects of anti psychotics. Among these, weight gain is one of the predominant side effects in our study and second gen- eration anti psychotics are the offending agents.The side effects associated with anti psychotics are confounded by various factors like drug-drug interactions and poly pharmacy.

Keywords: Psychotropic agents, Antidepressants, Mood stabilizers.

T223: PRESCRIPTION ERRORS IN DOSAGE FORMS AND WAYS TO IMPROVE THE AUXILIARY LABELLING FOR PATIENT CARE IN MANCHESTER OF SOUTH INDIA

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ABSTRACT

CONTEXT: A dosage form errors is a failure in the treatment process that leads to harmful effect to the patient. However, it is important to detect them, since system failures that result in minor errors can later lead to serious errors. **OBJECTIVES**: Avoiding the errors in dosage forms that is important in proper pre- scription, which guides/directs the use of a medicine which is relevant to the patient's condition. Within the limits of community pharmacists, the uncertainty is often lead to confusion which ultimately directs towards improper decisions. The purpose of this work is to identify and quantify the prescribing errors involved in dosage forms and suggest ways to improve/modify/change the auxiliary labelling for patient care. **EXPERIMENTAL DESIGN:** We all make errors in dosage forms from time to time. There could be many sources of dosage form errors that can be avoided. However, we must start by being conscious, that errors are possible, necessary steps to be taken to avoid/minimize the risks or outcome. This study was

performed to evaluate prescrib- ing errors related to dosage form in various hospitals in Coimbatore zone, Tamilnadu.

MAIN OUT COMES PARAMETERS: Potential errors during prescribing the dosage form, importance and improvement of auxiliary labelling for patient care. **RESULTS**: A total of 1000 clinically significant prescription involving dosage form error were identified for over the period of six months and outcomes were recorded. This result shows that63% of prescription was not having any dosage form error, but 37% of data showed prescription errors. This survey result shows that 95%of pharma- cist reported insufficientdata in labelling. In this study, we also took the suggestion from 200 community pharmacists to improve the auxiliary labelling. **CONCLUSION:** This study will be useful, in identifying the possible errors and ways to avoid them. This will also enlighten the prescriber and health care professionals. These suggestions and outcomes, will also be useful to the pharmaceutical companies and health care community, to follow the guidelines strictly for the improvement of overall patient care.

KEYWORDS: Prescription, Community Pharmacist, Auxiliary labelling and Patient care.

T226: LOW DOSE THALIDOMIDE INDUCED AGRANULOCYTOSIS IN A LEPROSY PATIENT: CASE REPORT

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ABSTRACT

BACKGROUND: Thalidomide is used as an immunomodulatory agent with a possible mechanism of TNF suppression in Erythema Nodosum Leprosum (ENL). Somnolence, constipation, peripheral neuropathy, skin rash, and deep vein thrombosis have been reported as frequently observed side effects. Hematological toxicity is an infrequent side effect (<5%). Agranulocytosis is reported for higher dose thalidomide therapy (200-400mg) given for multiple myeloma. **CASE DESCRIPTION**: A 67-year-old male patient was diagnosed with Hansen dis-ease and started on MDR-MB regimen. After 20 days, patient developed fever with chills and nodular lesions all over the body with lab reports showing leukocytosis. ENL was diagnosed and started on capsule Thalidomide 50 mg twice daily. Patient presented with fever after 2 weeks of treatment. Lab investigation revealed leukopenia with severe grade IV neutropenia (18 cells/cumm). Thalidomide and MDR-MB regimen was stopped. Patient blood counts improved slowly over a week after the administration of Inj. Filgrastim 300µg for 3 days. ROM regimen was started for leprosy**. CONCLUSION:** This case finding suggests that Thalidomide can cause agranulocytosis even in lower doses for ENL because of which regular hemogram follow up may be needed.

KEYWORDS: thalidomide, agranulocytosis, Erythema Nodosum Leprosum

T227: BENDAMUSTINE INDUCED ERYTHEMA MULTIFORMAE– A CASE REPORT

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ABSTRACT

BACKGROUND: Erythema multiformae (EM) is an uncommon, acute eruption char- acterized by fixed, targetoid skin lesions with or without mild mucosal lesions. It's a type IV hypersensitivity reaction to bacteria, virus, drugs and chemicals. Common drugs causing EM are antimicrobials, barbiturates, analgesics, antifungals and antineo- plastic agents. Bendamustine, a DNA alkylating agent, used in Chronic Lymphocytic Leukemia (CLL), Non-Hodgkin lymphoma (NHL). Myelosuppression, GIT, hepatic and renal toxicity are frequently encountered adverse effects with Bendamustine. EM is a rare, yet serious adverse effect seen with Bendamustine**. CASE DESCRIPTION:** A 51 year old female presented to medical oncology depart- ment with complaints of breathlessness and cough with expectoration for 20 days. She was diagnosed to have low grade stage I Non-Hodgkin's lymphoma. Patient was started on injection Bendamustine 170mg. Following the injection, patient complained of itchy skin lesions over upper limbs and neck. On examination, palpable erythematous, targe- toid skin lesions over the dorsal surface of defined areas. Diagnosis of drug induced EM was made and treated with antihistaminics and steroids. Patient recovered in 2 weeks without sequelae**. CONCLUSION:** This case illustrates Bendamustine, an efficacious and widely used alkylating agent, can induce serious adverse effect like erythema multiformae.

KEYWORDS: Bendamustine, erythema multiformae, hypersensitivity.

T228: ANTICONVULSANT HYPERSENSITIVITY SYNDROME INDUCED BY PHENYTOIN – AN ATYPICAL PRESENTATION

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ABSTRACT

INTRODUCTION: Anticonvulsant Hypersensitivity Syndrome (AHS) is an uncommon, potential idiosyncratic drug reaction. It is commonly seen with aromatic antiepileptic drugs like phenytoin, carbamazepine, and phenobarbital; and character- ized by severe exanthematous rash with minimal or no mucosal involvement, fever, facial swelling and other signs of hypersensitivity like lymphadenopathy, eosinophilia following 2-4weeks of drug therapy. Since fever or systemic involvement were absent in this case, it is considered atypical. **CASE DESCRIPTION:** A 59year old male patient presented with seizure to the department of neurology and was prescribed with oral phenytoin 100mg twice daily and levetiracetam 1g twice daily. After 15 days, patient developed peeling of skin all over the body, associated with facialedema and itching. Physical examination showed scaling and exfoliation of skin with diffuse erythema all over the body.Only phenytoin was withdrawn and patient was managed as a case of drug hypersensitivity syndrome. Patient recovered without any sequelae in 5weeks. **CONCLUSION:** This is a rare example for atypical presentation of Anticonvulsant Hypersensitivity Syndrome by phenytoin**.**

KEYWORDS: phenytoin, Anticonvulsant Hypersensitivity Syndrome

T229: ORAL METOPROLOL INDUCED PSORIASIS: A CASE REPORT

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ABSTRACT

BACKGROUND: Psoriasis is a chronic immune mediated inflammatory disorder of the skin.Certain drugs caninduce new onset psoriasis or exacerbates pre-existing pso- riasis. Drug induced psoriasis has been reported for lithium, terbinafine, NSAIDs and antimalarial drugs**. CASE DESCRIPTION:** A 68 year old male presented to the dermatology outpatient department of our hospital with complaints of scaly skin lesions on multiple sites on the body since 3 months. He was a known case of hypertension and was on oral telmis- artan since 2 years and oral metoprolol since the last 5 months. Physical examination revealed multiple well defined erythematous scaly plaques on multiple sites of the body. The patient was managed as a case of plaque psoriasis secondary to beta blockers. The drug metoprolol was withdrawn and he was treated symptomatically. The patient showed remarkable improvement and no new lesions were seen in the follow up period of 2 months after withdrawal of oral metoprolol. **CONCLUSION:** This case demonstrates the induction of psoriatic lesions by beta blockers and the importance of recognizing potential drug related psoriasis for its opti- mal management.

KEYWORDS: metaprolol, psoriasis, beta-blockers**.**

T230: EXPERIMENTATION ON API AND DOSAGE OF BUPROPION HYDROCHLORIDE TO EXPLORE THE IMPURITY CONTAINED THROUGH HYPHENATED ANALYTICAL TOOLS AND AMELIORATING TO REDACT THEIR GENOTOXICITY EFFECT THROUGH AMES KIT

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ABSTRACT

'Drug Safety' is a term in the recent trends of medication therapy which comprise diverse process of identification of drugs activity and safe use towards the human health, selectively of drug activity is done for better development of life. This drug safety concept has earned a lot of attention during the past decade due to the fact it plays a major role in patients' health. Recent laws stress this concept should be included in the process of new medications' approval and continued conduct of post-marketing drug evaluations. Side effects are not due to the active ingredients itself, rather they were caused by the presence of some excipients being used. Bupropion Hydrochloride is a unicyclic, aminoketone, second generation antidepressant drug molecule. Chemical name of Bupropion Hydrochloride is 2- (tert-butylamino)-1-(3-chlorophenyl) propan-1-one; hydrochloride. The mechanism of its therapeutic actions does appear as weak inhibitor of the neuronal uptake of norepinephrine, serotonin, and dopamine, and does not inhibit monoamine oxidase [2]. The hydrochloride is available as an aid to smoking cessation treatment.The pH value of BUH is 6.7. The drug is freely

soluble in the Water. It presented with enantiomer of in the present scenario the enantiomeric impurities assessment place a major role on the Pharmaceutical products. The magnified literature review explored that, the Bupropion HCl (BUH) enantiomeric as well the related sub-stances based impurity profiling area had not been explode in detail to confirm its bio safety. Moreover the genotoxicity study for the enantiomer and enantiomeric impurity, related substances safety also not been revealed. So, decided to extract out all the enan-tiomer, degradant based impurities through high performance liquid chromatographic techniques and then for identification and characterization of these products through several spectral analysis like LCMSMS, NMR etc. Lastly, to assure the drug safety of Bupropion Hydrochloride have to perform genotoxicity testing of the metabolites iso-lates for betterment of patients' health.

KEYWORDS: Bupropion Hydrochloride, drug safety, excipents

T231: ASSESSMENT OF KNOWLEDGE, ATTITUDE AND PRACTICE ON ADR REPORTING AMONG NURSE PRACTITIONER AT A TERTIARY CARE HOSPITAL-AN INTERVENTIONAL STUDY

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ABSTRACT

INTRODUCTION: It is evaluated that only 6-10% of all ADRs are reported globally to which the contribution of India amounts below 1%. A nurse is fore-most health care professional directly involved in patient care and contributing in reporting Adverse Drug Reactions (ADR`s) as they also deal with administration of drugs. The nurses can detect newsigns and symptoms and also educate the patients and bystander about the same**. OBJECTIVE:** To investigate and assess the knowledge, attitude and practice of the nurses towards ADR reporting. Additionally, to intervene for increase in quality and number of ADR reporting process. **MATERIALS AND METHODS:** This interventional study involved 357practicing nurses from various departments during January 2018 to July 2018. The voluntary reports of the reactions submitted by nurses were documented as baseline data for first 3 months. For next month, the questionnaires were validated and administered to the nurses as a pretest. Followed by pretest, the nurses were trained and post test responses were recorded to assess improvement in knowledge and attitude towards pharmacovig- ilance. On questionnaire based assessment, the nurses answering more than 50% of the questions were considered to have improvement in respective domain (KAP). For the last 3 months, again the voluntary reports by nurses were collected and were compared with baseline for analyzing the effects of our intervention. The data was subsequently subjected for the statistical analysis. **RESULTS:** Out of 400 nurses, 357 (89.25%) of them cooperated and participated in the study. Their demographic details were stratified and analyzed systematically. Total num-ber of ADR reported voluntarily by nurses before interventions were 22 for a period of three months. After the intervention, the number of voluntary ADR reports reached to47 in the last three months. There was a substantial increase (113 %) in number and quality of ADR reports. Comparing pre-test and post-test, it was revealed that 154 (43%) of nurses (114 versus 268), 129 (36%) of nurses (100 versus 229) and 175 (49%) of nurses (136 versus 311) showed improvement in knowledge, attitude and practice, respectively. Lack of time (67%) was the major discouraging factor to report ADRs. **CONCLUSION:** The extent of ADRs reporting is directly proportional to the knowl- edge, attitude and practice of nursing staff. The training programme, symposia, workshops and CMEs should be regularly conducted to reinforce the importance of pharmacovigilance.

KEYWORDS: Adverse drug reactions, nurses, pharmacovigilance**.**

T232: SHORT ACTING STEROID INDUCED HYPERGLYCEMIA

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ABSTRACT

INDRODUCTION: Corticosteroid therapies are widely used as potent anti-inflam- matory and immunosuppressive agents to treat a wide range of diseases. However, they also have a number of side effects, including new onset hyperglycemia in patients without a history of diabetes mellitus (DM) or severely uncontrolled hyperglycemia in patients with known DM. **AIM:** To analyze the severity of hyperglycemia caused by Injection Hydrocortisone.

METHOD: We undertook a 3 days study with 9 patients from general wards who were prescribed with Injection Hydrocortisone. Fasting Blood Sugar (FBS) and General Random Blood Sugar (GRBS) values of all the 9 patients were analyzed**. RESULTS:** Out of 9 patients selected, 5

patients showed an increase in their blood glu-cose levels during the therapy. 3 patients had a history of DM with their FBS values varying between 200-300 mg/dl and GRBS values varying between 300-500 mg/dl. Remaining 2 patients with new onset hyperglycemia showed FBS values between 140- 180 mg/dl. Age, body mass index, genetic predisposition and dose of steroids may be a risk factor for the development of steroid induced hyperglycemia. Thus, treatment for steroid induced hyperglycemia should take into account the pattern of hyperglycemia as well as the dose and duration of steroids used**. CONCLUSION:** Steroid induced hyperglycemia had significant clinical implications in patients with DM and without DM. Monitoring of FBS and GRBS values is mandatory as part of the pretreatment investigation during the evaluation as well as in the course of management in all patients on steroid therapy.

KEYWORDS: Corticosteroids, Hyperglycemia, Hydrocortisone

T233: ANTIBIOTIC ASSOCIATED DIARRHOEA (AAD)

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ABSTRACT

INTRODUCTION: Diarrhoea is a very frequent adverse effect of antibiotics. Diarrhoea can be defined by any of the following criteria: mushy or watery stool, frequency of stool more than three per day or stool weight of greater than 200g. Antibiotic-associated diarrhoea (AAD) has been suggested to be clinically significant when there are three mushy or watery stools per day. Diarrhoea usually can develop from a few hours up to 2 months after the intake of antibiotics. The incidence of AAD can differ with the antibiotics and varies between 5% and 25%. Erythromycin is usually poorly absorbed and often results in an irritative diarrhoea. Ceftriaxone can significantly alter the flora in individuals and causes diarrhoea in up to 50% of children; it can cause diarrhoea in adults, but less frequently. **AIM:** To study the incidence of Antibiotic-associated diarrhoea (AAD). **METHOD:** Children aged 1 month to 5 years treated with antibiotics and its combina- tion for a proven or suspected infection such as Pneumonia, Lower Respiratory Tract Infection (LRTI), and Upper Respiratory Tract Infections (URTI) were enrolled from pae- diatric ward for a period of 3 days. **RESULTS:** 10 patients of the age group 1- 5 years were selected and who were on anti-biotic treatment of the dose range of 350mg to 1gm.Out of the 10 patients observed, 6 of the patients had the occurrence of Antibiotic-associated diarrhoea (AAD). They had 4-5 episodes of diarrhoea after the intake of prescribed antibiotic. The incidence of AAD was higher in children less than 2 years than in those more than 2 years. The incidence of AAD was particularly high after administration of certain antibiotics (Ceftriaxone compared with other antibiotics). **CONCLUSION:** AAD continues to become frequent due to increase in broad spec-trum antibiotics and increasing frequency of healthcare-associated outbreaks. Some of the major factors that increase the risk of AAD are: host characteristics (age, co- morbidity), exposure to fomites (prolonged hospital stays, shared hospital rooms), medications (antibiotics, antacids). Proper monitoring along with supplement of pro- biotics and the rational use of antibiotics can reduce the incidence of AAD

KEYWORDS: Antibiotic-associated diarrhoea (AAD), Antibiotics, Ceftriaxone

T234: A STUDY ON COMPLICATIONS OF POLYPHARMACY IN DIABETIC GERIATRIC PATIENTS

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ABSTRACT

OBJECTIVES: The aim of this study was to assess the medication adherence, drug- drug interactions, adverse drug reactions, and incidence of falls among diabetic geriatric in-patients who had been admitted in department of general medicine, MVJ medical college and research hospital Hoskote, Bangalore, India. **SUBJECTS AND METHODS:** 100 diabetic geriatric patients who were on polypharmacy (more than 4 drugs) were evaluated prospectively, in an observational study over a period of 6 months. All patients were followed up for incidence of ADR. Causality and severity of the ADRs were assessed by Naranjo scale and Modified Hartwig & Siegal scale respectively. Medication adherence of the patients was evaluated by using Morisky medication adherence scale. The potential drug-drug interactions were checked by Lexicomp online database and the episodes of falls were monitored through telephonic follow up with respect to one month. The patients' details were recorded and results were analyzed by descriptive statistics. **RESULTS:** The mean number of drug per prescription was found to be 8.6. Out of 100 participants enrolled into the study 81 patients (81%) had at least one **co-**morbid condi-tion. 41% of the patients showed medium adherence while 32% and 17% showed low and high

medication adherence respectively. We have observed 108 potential drug-drug interactions. Among them 6 interactions were major, 59 interactions were moderate and 42 were minor as well. The significant drugs involved in the drug interactions were found to be enalapril, diclofenac, metformin, glimepiride, aspirin, ondansetron and norfloxacin. Six adverse drug reactions were found. One ADR was moderate and five ADRs were mild. The ADRs were metformin induced hypoglycemia (50%), glimepiride induced dyspepsia (33.33%), and metformin induced diarrhea (16.66%). There were 6 falls observed among the participants during our study period. CONCLUSION: Polypharmacy among diabetic geriatric population is a significant issue. Combined care and effort from healthcare professionals required to resolve decreased medication adherence, adverse drug interactions, more number of potential drug-drug interactions and cognitive impairment.

KEYWORDS: Polypharmacy, diabetes, medication adherence, drug-drug interaction

T235 A STUDY ON THE UTILIZATION OF ANALGESICS IN POSTOPERATIVE PATIENTS

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ABSTRACT

OBJECTIVE: To assess the most commonly prescribed analgesics and their therapeutic effect and safety frequently prescribed as alone or in combination to treat the major postoperative patients from the departments of orthopedics, obstetrics and gynecology and intensive care units. **METHODOLOGY:** A hospital based prospective study was conducted in MVJ medical col-lege and research hospital for a period of six months after getting consent from the patients. The prescribing patterns (route of administration, frequency, dosage, pain intensity, duration of treatment) of analgesics were analyzed with reference to WHO prescribing guidelines. Most frequently prescribed analgesics were selected from the three departments. The pain relieving effect of analgesics was assessed using the Wong Baker's Faces scale including sleep duration using a PSQ-3 Questionnaire. **RESULTS:** Totally 158 patients were enrolled. Female patient population (57.5%) was more than male population. The mean age of all the patients was (18-80 years). On anal-ysis of prescribing pattern, diclofenac (intramuscular) and diclofenac + paracetamol (orally) were prescribed most frequently as alone as well as in combination respectively, for treating the postoperative patients. Among the analgesics that were frequently prescribed, diclofenac as alone and diclof- enac with its combinations were selected to study their pain relieving effect including safety in postoperative patients from the above three departments.122 patients received diclofenac (intramuscular) while the combination of diclofenac+paracetamol (58) and diclofenac+ serratiopeptidase(44) were received orally. Diclofenac reduced pain score by 82% while combination of diclofenac reduced the pain by 85% from its baseline value in postoperative patients, while correlating the sleep score with pain it was found that there was a drastic increase in the sleep score of the patients as the pain had sub- sided. **CONCLUSION:** Diclofenac as alone and diclofenac with its combinations were prescribed frequently among other analgesics to treat postoperative patients from the departments of obstetrics and gynecology, orthopedics and intensive care unit. In addition, above medications were very effective in relieving postoperative pain.

KEYWORDS: Analgesics, Post-operative pain, Prescribing Pattern, Utilization, score

T236: PARENT RELATED FACTORS INFLUENCING THE IMPROPER USE OF ANTIBIOTICS IN CHILDREN

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ABSTRACT

OBJECTIVE: To determine the parent related factors which are influencing the improper use of antibiotics in children. **BACKGROUND:** Antibiotics are the most commonly used drugs for treating infections. Parents' knowledge and practices to use medicines have important effects on the management of childhood illness. Improper use of the antibiotics could be because of some strongly influ-enced parent related factors. **METHOD:** A prospective study was conducted in 200 subjects from the randomly chosen

communities in Bangalore. Door to door visit was done by the investigators. Demographic datas were collected using CRF [Case Report Form] and Questionnaires were used to assess parental knowledge and practice of antibiotic use in children. Questionnaires were validated and either of the parents was asked to answer the questionnaire. Answers collected using the questionnaire was correlated with some of the parent related demographic factors. **RESULTS:** Our study revealed that majority of the responders were mother and most of them are of middle age and have myth about the antibiotic use in children. Education level of the parents has a direct impact on knowledge about antibiotic use. Increase in number of children in a family have a correlation in improper practice of antibiotic use. Income status is related with the practise of the antibiotic use. Occupation also plays an important role in the practice of antibiotic use in children. Residing area also influences in antibiotic use by parents. Parents' non-adherence towards antibiotics for their children is also governed by various adverse drug reactions like allergic conditions, nausea, vomiting, fever etc. Improper guidance by retail pharmacist in choosing alternative antibiotic based on availability of the prescribed one also controls parents' practice of antibiotics. **CONCLUSION:** Proper education should be given to the parents regarding the use of antibiotics in children and they should be informed about the side effects due to improper use which in turn may improve the practice. With a shared diligent effort from various health care professionals in correcting the factors related to improper use of antibiotics, the Knowledge and Practice towards antibiotic use in children is possible, if not now, in the very near future.

KEYWORDS: Knowledge, Practice, Case Report Form, Questionnaire**.**

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TRACK 3: PUBLIC HEALTH, ALLIED HEALTH RESEARCH

T302: ROLE OF PHARMACIST LED HOME MEDICATION REVIEW IN COMMUNITY SETTING AND THE PREPARATION OF MEDICATION LIST

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ABSTRACT

BACKGROUND: Home Medicines Review (HMR) is a consumer-focused, structured and collaborative health care service provided in the community setting, to optimize quality use of medicines and consumer understanding. It is a service designed to assist consumer's living at home to maximize the benefit of their medication regimen and prevent medication related problems. **Aim:** This study was conducted to identify, prevent and resolve actual or potential medication-related problems, optimize pharmacotherapy and assist in achieving better health outcomes for patients at home. **METHODOLOGY:** It was a cross-sectional interventional study conducted for a period of 6 months in 85 patients at different regions of Malappuram district in Kerala. **RESULTS:** Data from a total of 85 patients were collected among which 48 were males (56%) followed by females (n=37, 44%) ($\lambda 2$=1.424, d.f=1, p>0.05). Among the various drugs prescribed, the patient had a lack of knowledge in many factors like the name of the drug they are using (34%), the reason for taking the medication (27%). Drug interaction was the main discrepancy found in majority of the prescriptions. Significant positive correlation existed between total number of drugs and total number of dis-crepancies (r=0.4176 t=4.187, d.f =83 p <0.01). Since the coefficient of correlation was positive and significant, it indicated that the number of discrepancy increased with the increase in number of drugs. Around 32% of the population, experienced ADR on taking the medication indicating that considerable amounts of population in the society are left suffering from ADR, without being treated ($\lambda 2$=11.306, df= 1, p<0.001). Errors in 'Multiple Drug Storage' have higher significance than all the rest ($\lambda 2$= 55.497, d.f= 4, p<0.001). The mean score before intervention was significantly higher than that after intervention. The main intervention done was medication management (62%), followed by therapeutic intervention (19%). Conclusion: The study clearly showed that the subjects were unaware of the Home Medication Review (HMR) service and yet majority was accepting the program. It is demonstrated through the study that qualified pharmacists can play a major role in improving the appropriateness of prescribing, preventing medication related adverse events. Hence pharmacist in collaboration with General Practitioner can optimize patient medications.

KEYWORDS: Home Medication Review, Medication list, Pharmacist role.

T303: AN OBSERVATIONAL STUDY TO ASSESS THE PREVALENCE OF OBESITY AND THE CLINICAL PROFILE OF ASTHMATIC AMONG OBESE PATIENTS

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ABSTRACT

BACKGROUND: Obesity is an increasing health problem worldwide. The effect of obe-sity on asthma diagnosis, control and exacerbation severity is increasingly recognized. The contemporaneous rise in asthma and obesity rates has triggered the researchers to investigate relation between asthma and obesity. Asthma prevalence is increasing worldwide affecting all ages and gender in India. **OBJECTIVES:** The main objective of the study was to assess the prevalence of obe- sity among asthmatic patients and their clinical profile to the treatment by managing asthma among obese patients**. METHODOLOGY:** A prospective study conducted among the outpatients of pulm- onology department of tertiary care referral hospital. The study was divided into three phases. In phase I, all the relevant informations like pulmonary function tests were col-lected from patients and were evaluated, categorized and recorded in a documentation form. In Phase II, the patients were categorized as underweight, overweight and obese according to International classification of BMI. All the patients were provided with proper counseling and leaflet was distributed.In phase III the pulmonary function tests were repeated in the same patients and the values were compared**. RESULTS AND DISCUSSIONS:** The total number of patients involved in the study was 100.Out of these 37% was found to be obese (class I &class II). Nearly two-fifth of the non- obese patients suffering from asthma showed improvement, one-third of the obese patients showed no improvement. Among selected patients, female patients were significantly higher in number. While comparing pre and post treatment, it has been found that the normal lung function of

the study population has been significantly improved after patient counseling. These findings should encourage policy makers to develop and evaluate the public health intervention that promote weight reduction. **CONCLUSION:** In conclusion our prospective study provides the first evidence dem- onstrating an association between obesity and asthma in adult male and female patientElevated BMI, particularly obesity is associated with subsequent poor asthma control. These findings further support the importance of facilitating weight loss in overweight and obese adults with asthma. The incidence of both asthma and obesity conditions has been increasing and they share common risk factors.

KEYWORDS: Obesity, Asthma, Counseling

T304: IMPACT OF CLINICAL PHARMACIST INITIATED PATIENT COUNSELLING IN PATIENTS WITH METABOLIC SYNDROME IN A TERTIARY CARE HOSPITAL

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ABSTRACT

BACKGROUND: The National Cholesterol Education Program Adult Treatment Panel III report (NCEP ATP III) identified the metabolic syndrome (MetS) as a risk factor for cardiovascular disease (CVD).The contribution of the study was to make up the effects of patient counselling on Quality Of Life (QOL), to improve prevention and treatment strategies for MetS**. OBJECTIVES:** Systematically review whether a pharmaceutical care intervention can result in better understanding about MetS. **METHODOLOGY:** An observational interventional study was carried out prospec-tively for 6 months by assessing all MetS. Study had both pre and post interventional phase. Patient information leaflets were provided to patients, after 3 months follow up were conducted. **RESULTS AND DISCUSSION:** The sample size was 90. Among them 61 were males and 29 were females and majority falls between the age group of 40-50. 41.1% were overweight, 35.6% falls into obese category. Most of the patients were nonalcoholic (81.1%) and nonsmokers (67.8%). Most of them were following mixed diet (47%) and vegetarians were least (14.4%). All the laboratory parameters in phase I were compared with the results of phase II and found that there is a control in the condition. WHOQoL-BREF questionnaire was used to analyze the QoL of the patients which showed there is a significant hike in QoL of patients after the counselling phase. **CONCLUSION:** The study provided a complete evaluation, categorization and system-atic analysis of MetS. All the patients were at high risk and had abnormal laboratory values. Abnormal obesity was found to influence Fasting Blood Sugar (FBS) and Blood Pressure (BP). BMI was found to be a useful index for prediction of risk factors of MetS. The dietary habits were reported to be poor in 3/4th of the participants. Therefore maintenance of healthy weight through proper diet, exercise is importance for prevent-ing MetS. The key strength of this study was patient counseling which improves the patient understanding about the illness, medication, diet, exercise, lifestyle modifica-tion. The result of this study clearly highlights the necessity to continue surveillance of various criteria of MetS. The guided risk management strategy was effective in improv-ing the knowledge and attitude of patients regarding the prevention of MetS.

KEYWORDS: Metabolic syndrome (MetS), Quality of life (QOL), Patient counseling

T305: A PROSPECTIVE STUDY ON DIAGNOSIS AND MANAGEMENT OF LIVER ABSCESS

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ABSTRACT

BACKGROUND: Though Liver abscess was described as early as 460-377 B.C. by Hippocrates, it still remains a challenging situation. India has 2nd highest incidence of liver abscess in the world. The rising incidence in alcoholics, diabetics & immune compromised individual has become a matter of grave concern as complication rates are high especially in this sub-group leading to the increased morbidity and mortality. Liver abscesses is, even to-day, considered as a 'desperate disease' and it is no won- der that many 'desperate' measures have been tried to cure this condition. As more advanced facilities for investigation are now available, a more concrete picture of liver abscesses is slowly evolving. Much work, however, remains to be done. The story has not ended: it has only just begun. **AIM**: The aim of this study is to evaluate various clinical presentations and treatment modalities of liver abscess. **MATERIALS AND METHODS:** Patient data will be collected from all patients attending Govt. Royapettah Hospital General

Surgery OPD, Casualty and Inpatient department, irrespective of their age/gender/background/socio economic status. Detailed history of patients will be entered in proforma. Complete haemogram, liver function test (LFT), prothrombin time, stool for ova, cyst, and serology for amoebic antigen will be sent immediately on presentation. Preliminary Ultrasound (USG) of Abdomen and Pelvis will be done on the same day of presentation. These patients will be evaluated and followed up according to protocol. **RESULTS:** This study is based on the reports of 60 patients treated for liver abscess, most common age group affected by Liver abscess was between 41-50 years. The most common symptom were fever, followed by pain abdomen. The right lobe was more commonly affected. Multiple small abscesses and solitary abscess with volume less than 50 ml were managed successfully on conservative antimicrobial therapy alone CONCLUSION: Since the Pearson correlation coefficient value is 0.304, there is a posi-tive correlation between both Hospital stay duration and Complication. Also, if less than 50 ml, can be managed conservatively.

KEYWORDS: Liver abscess, Liver function tests, morbidity, antimicrobial therapy

T306: A STUDY ON INCIDENCE AND CLINICAL PROFILE OF TUBERCULOSIS PERITONITIS AMONG THE CIRRHOSIS OF LIVER WITH ASCITES PATIENTS

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ABSTRACT

Tuberculosis is a disease caused by bacteria called mycobacterium tubercu- losis. The bacteria usually attack the lungs, but they can also damage the other parts of the body. According to WHO, Tuberculosis is second to AIDS as the greatest killer worldwide due to a single infectious agent. **AIM OF THE STUDY:** To study the prevalence of tuberculosis peritonitis (TBP) among the patients diagnosed with cirrhosis of liver**. MATERIAL & METHODS:** This prospective observational study was conducted for a period of 24 months in RIMS, kadapa. A total of 90 patients were included based on the inclusion criteria i.e. Patients with Cirrhotic ascites having, clinical features suggestive of chronic liver disease. Age more than 18 years of both sexes are taken into the study with the above features. Informed written consent is obtained from the patients, who are willing to participate in the study in the language known to them. All the investigations are done free of cost to the patients in the institution. The cost of the ADA test is met by the investigator. Method of ADA Estimation the ADA assay was performed using the sensitive calorimetric method of Galanti and Guisti principle. Kit: TULIP diagnostics – Micro press for the determination of ADA in Biological fluids. **RESULTS AND DISCUSSION**: A total of 90 patients were constituted in the present study, among which majority patients were in the age group of 45± 10 years (77%). Ranging from 32 to 68 years, with a mean age of 47.8 ±7.70 years. The present study demonstrates the incidence of tuberculosis peritonitis among cirrhotic ascites. There are many studies in which the clini-cal features, laboratory diagnosis and treatment options for tuberculosis peritonitis have been described, but there are few case studies in which tuberculosis peritonitis among cirrhosis of liver patients. There exists a large difference in the incidence of TBP among Cirrhotic ascites in literature, taking into account its concomitant risk factors with rates ranging from a low of 13% to a high of 44. **CONCLUSION:** Incidence of TBP among Cirrhotic ascites patients is 18.8% in the present study. Abdominal pain, tenderness and fever in Cirrhotic ascites are common clinical mani- festations in TBP. Serum Bilirubin is not reliable indicator in diagnosing TBP. Abnormal Chest X- ray i.e., suggestive of Pulmonary Tuberculosis (PTB) has more specificity (98.63%) than sensitivity (47.06%) in diagnosing TBP. Early treatment can be initiated without waiting for the reports of ascitic fluid for Acid Fast Bacilli (AFB) staining and culture.

KEYWORDS: Tuberculosis Peritonitis, Acid Fast Staining, Mycobacterium Tuberculi.

T307: 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

BACKGROUD: The symptoms of Gastroesophageal reflux disease (GERD), such as heart- burn and acid regurgitation,

are serious problems that cause discomfort and impair quality of life (QOL). Although Proton pump inhibitors (PPIs) are first line therapy for GERD, in many cases proper response is not seen. In these cases it is essential to screen for the associa- tion of psychiatric co morbidities in the progression of GERD. **AIM:** The main target of the study was to investigate the relationship between GERD related symptoms and psychological symptoms, as well as clinically diagnosed generalized anxiety disorder and panic disorder and effectiveness of Sertraline and Benzodiazepines in control- ling these conditions. **METHODOLOGY:** A prospective interventional study conducted among the outpatients of Gastroenterology department of tertiary care referral hospital. Failure of response to PPIs was assessed and refractory GERD was confirmed. ICD 10 diagnostic criteria were used to diagnose anxiety and panic disorder in refractory GERD. The therapy with Benzodiazepines and Sertraline was initiated in patients with refractory GERD having panic and anxiety symptoms. Proper dose tapering and maintenance therapy was initiated and 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. **RESULTS:** The prevalence of panic and anxiety disorder in patients with refractory GERD in our sample was found to be 68% and 32% respectively. Panic disorder was the most common psychological disorder found to be co-morbid in these patients. Alcohol dependence was significantly observed in males; while in females anxiety disorder was more commonly seen. BMI significantly influenced the GERD HRQL SCORE (p=0.00001) and the disease severity. Patients with abnormal BSA has large GERD HRQL score when compared to patients with normal BSA (p=0.00001). There was a significant decrease in the score of GERD HRQL after the administration of interventional drugs (p=0.001). **CONCLUSION:** At the end of the study, we were able to conclude that the novel therapy of sertraline and benzodiazepines will be a milestone in the treatment of psychiatric co- morbidities in correlation with GERD thereby reducing the total severity score of GERD.

KEYWORDS: Refractory GERD, Generalised Anxiety disorder, Panic disorder.

T309: A STUDY ON BENEFICIAL EFFECTS OF METOPROLOL IN CONGESTIVE HEART FAILURE

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ABSTRACT

Metoprolol has beneficial effects in congestive heart failure (CHF), it binds with beta adrenergic receptors of brain, heart, and kidney there by it will reduce sympathetic neurotransmitters release, decreases heart rate, force of contraction and cardiac output, decreases renin hormone release from the kidneys. By these three actions it will reduces pre load and after load on heart. It directly opens the specific L- type of membrane calcium channels in the heart and also glycogenolysis, which leads to increase in pumping capacity of left ventricle, thereby heart will meet various meta- bolic demands of the body**. AIM:** To provide Safe and effective management of patients with congestive heart fail- ure by adding metoprolol (selectiveβ1 blocker). **MATERIALS AND METHODS:** 6 minutes walking test, chest X-Rays, ECG, 2 D- Echo and other required investigations are conducted for validation of beneficial effects of metoprolol in improving ejection fraction at base line and also at follow up by using various study materials in four months duration. Over 2.4 million patients who are hospitalized have CHF as a primary or secondary diagnosis, and nearly 300,000 deaths per annum are directly attributable to CHF. Statistical Analysis- Data was articulated in percentage. Design - A concurrent interventional cohort study**. RESULTS:** A total of 70 patients were recruited; among which, 50 patients were test and 20 patients were standard. Exercise capacity and ejection fraction of test group patients and standard group patients were estimated. Improvement in ejection fraction, exercise capacity of the test group was compared to standard group at first (0.92%), (0.72 min) and final follow up (3.74%), (3.24 min) respectively. Statistically significant difference was observed in ejection fraction (< 0.05) and exercise capacity (< 0.05) in test group, but not in standard group (E.F.- 0.067**,** E.C.- 0.079). Also found improvement in chest X-ray, ECG at base line on final follow up **CONCLUSION:** Metoprolol use in congestive heart failure- increases left ventricle ejection fraction, exercise capacity, anti-remodeling effect by decreasing myocardial apoptosis and also reduces cardiac disability frequencies, prevents long term compli- cations, reduces morbidity and mortality. For providing better patient care to CHF patients, addition of metoprolol is essential.

KEYWORDS: Congestive Heart Failure, Ejection Fraction, Exercise Capacity, Electrocardiogram, Chest X Ray, 2D-Echo, ß-blockers, Metoprolol

T310: SIGNIFICANT ENDOWMENT OF CLINICAL PHARMACIST IN HEMOLYTIC UREMIC SYNDROME (HUS) INDUCED BY ARSENIC: A CASE REPORT

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ABSTRACT

Arsenic is a heavy metal which is a natural component of the earth's crust. It exists in compounds that may be organic or inorganic. It is highly toxic in its inorganic form. Poisoning can occur by ingestion, inhalation or dermal absorption. Elemental arsenic is the least toxic. Trivalent arsenic is well absorbed through the skin and is 60 times more toxic than penta-valent arsenic, which is well absorbed by the gut. Arsenic has been used in many medicines and was widely used to treat syphilis until the mid-20th century. It is currently used to treat acute promyelocytic leukemia and other myelo-proliferation disorders. Arsenic exposure is usually occupational or environmental but can also result from deliberate poisoning. Symptoms usually start within 30 minutes to 2 hours. Acute arsenic ingestion is typically followed by a severe gastroenteritis, garlic odour and hyper-salivation. The organs of the body that are usu-ally affected by Arsenic poisoning are the lungs, skin, kidneys, and liver. The final result of Arsenic poisoning is coma to death. Purpura or small areas of bleeding in the skin may be seen because of low platelet counts (Thrombocytopenia).

Keywords: Trivalent Arsenic, Dermal absorption, Promyelocytic leukemia, purpura, Thrombocytopenia.

T311: PICTOGRAMS FOR PREVENTIVE MEASURES OF INFECTIOUS DISEASES – REDUCES THE RISK OF ANTIBIOTIC RESISTANCE

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ABSTRACT

In present days, spread of infections and Antibiotic resistance development are major risk factors for morbidity and mortality of people. Antibiotic resistance is increasing gradually and it demands the invention of new potent Antibiotics. The major reason for the development of Antibiotic resistance is due to indiscriminate use of Antibiotics and spread of bacterial resistance strains from infected persons to normal persons. One of the major ways to reduce antibiotic resistance is to prevent the occur-rence of infections and providing the rational use of antibiotics. Based on this concept, we focused on the Preventive measures of infections in the form of pictograms that are easily understandable by maximum percentage of people residing in communities irre-spective of Literacy and Employment. This illustrates the proverb 'PREVENTION IS BETTER THAN CURE'. We have collected various pictograms released by WHO and other standard sources. Our intention to select this concept is, to bring awareness about different ways by which spread of infection can be prevented among rural and urban people who have direct impact in reducing the risk of Antibiotic resistance.

KEYWORDS: Antibiotic Resistance, Preventive measures, Pictograms, Rationality of Antibiotics.

T313: ECONOMIC BURDEN OF UNUSED MEDICINES AND ITS CAUSES IN HOUSEHOLDS OF PERINTHALMANNA REGION

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ABSTRACT

BACKGROUND: The medical expenditure among the public in Malabar region have been skyrocketing. The increased tendency to let the medicines unused ultimately leads to medicine wastage and huge economic loss. The sheer quantity of unused medicines can pose serious challenge to an average household in proper handling and disposal techniques, along with other consequences of unused medicines. **AIM:** To evaluate economic burden of unused medicines and its causes in house-holds of Perinthalmanna region. **METHODOLOGY:** A community based cross sectional descriptive study was carried out among 350 households of VIIIth ward & nearby wards. The self prepared question- naire was incorporated. Questionnaire comprised of questions on medication taking behavior, medication handling techniques including storage and disposal. The data col- lection form recorded the details of leftover medicines. Paper bags & leaflets were used for the conduct of study **RESULTS:** The study revealed that 53.1% of households had unused medicines, with an average of 24 medicines per

household. The total economic burden of the popula- tion was computed to be Rs. 72,195.38, which sums up to Rs.260 per household. Only a mere 12% of the chronically ill patients were found to be highly adherent to the treatment regimen. The study showed that 51.1% of households did not complete the course of antibiotics. 38 % of the households tend to share their medications. The major method of disposal was dumping (70.6%). Solid dosage formulations were the most abundant dosage forms found unused (92%). Out of the total number of unused drugs we documented (8145 numbers), 69 % were non expired medicines. Storage conditions in households were satisfactory. **CONCLUSION:** The evaluation of economic burden of unused medicines, utilization of medicines describes low medication adherence, high drug storage, higher leftover medicines and inappropriate use of medicines which suggests the need to educate the patients about proper and rational use of medicines. The findings raise concerns about economic burden due to leftover medicines within the community. The fact that there are no proper disposal techniques for medicines points out the need of public aware-ness on safe handling, storage and disposal of drugs in the households.

KEYWORDS: Medication adherence, economic burden, utilization of medicines, dis- posal of drugs.

T315: IMPACT OF RADIATION INDUCED ORAL MUCOSITIS ON ORAL HEALTH RELATED QUALITY OF PATIENTS TREATE WITH HEAD AND NECK CANCER RADIATION: A PROSPECTIVE OBSERVATIONAL STUDY

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ABSTRACT

Head and neck cancer treatment generally consists of a combination of radiotherapy, surgery, and concomitant chemotherapy. This multimodal and aggressive cancer therapy causes a plethora of short-term and long-term oral and oropharyngeal side effects. Mucositis is a debilitating and dose limiting toxicity of cancer therapy among head and neck cancer patients with an incidence of 36-100%. Oral mucositis, pain, dysphagia, and altered taste perception may lead to impaired oral functions and can lead to poor quality of life. **OBJECTIVE:** The study was aimed to assess the onset and severity of oral mucositis and its impact on oral health related quality of life of head and neck cancer patient's undergo-ing radiation therapy. **METHOD:** This prospective observational study was conducted on 30 head and neck cancer patients who were scheduled to undergo radiation therapy. Data was collected by using a baseline proforma, WHO Oral Toxicity scale and oral health impact profile (OHIP-14). The patients were examined weekly for the development of oral mucositis and were asked to rate their oral health related quality of life using oral health impact profile (OHIP-14) at the beginning and end of the treatment. **RESULT:** The study findings revealed that all the subjects developed oral mucositis at the end of third week which was progressed to grade 3 or 4 mucositis by the end of therapy. The total OHIP-14 score was decreased from 56.20 (±13.50) at baseline to 45.72 (±10.98) at the end of radiotherapy. Paired t test revealed a significant reduction in oral health-related quality of life (p=0.02) after radiotherapy. The functional limita- tion and physical disability were the domains more affected among the patients .Oral mucositis scores were negatively correlated with oral health related quality of life scores (spearman correlation r=0.72,p=0.01). **CONCLUSION:** Severe and painful oral mucositis is a dose limiting adverse effect of radiation therapy and its detrimental effect on oral functions leads to the impairment of oral health related quality of life of head and neck cancer patients.Hence adequate preventive measures of mucositis is to be identified to enhance the quality of life of head and neck cancer patients receiving radiation therapy.

KEYWORDS: impact, radiation induced oral mucositis, oral health related quality of life

T316: A CROSS SECTIONAL STUDY TO DETERMINE THE ASSOCIATION AND PREVALENCE OF IRONDEFICIENCY ANEMIA IN FEBRILE SEIZURE AMONG PEDIATRIC POPULATION IN PERINTHALMANNA REGION

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ABSTRACT

BACKGROUND: Iron deficiency is a state in which there is insufficient iron to maintain normal physiologic function which leads to the dysfunction of myelination as well as tyro- sine and tryptophan hydroxylase synthesis, which are necessary for neurotransmitter from vesicles. Iron deficiency stimulates the function of neurons and

consequently increases the risk of convulsion.

OBJECTIVES:

- To find out the association and prevalence of iron deficiency anemia in febrile seizure.
- To find out the percentage of children with anemia.
- To find out percentage of children with Iron Deficiency Anemia (IDA).
- To find out any relationship between analyzed variables**. METHODS**: A prospective Cross sectional study was carried out in the Paediatric inpatient setting of KIMS Al Shifa hospital. A total of 100 children with a diagnosis of Febrile Seizure, under the age of 6 months to 6 years meeting up inclusion and exclusion criteria were included for the study. The laboratory value of the following parameters like Temperature, Hb, MCV, MCH, MCHC, RBC, RDW were collected. The collected data was analyzed using SPSS version30.0. Binomial proportion test and chi square test were carried out. **RESULT AND DISCUSSION:** The types of seizures found are nearly in equal distribution including generalized tonic-clonic seizure, clonic seizure, and Tonic seizure. There were mean values of Hb (10.96%), PCV (32.85%), MCV (67.62Fl), MCH (23.96 Pg), MCHC (37.90g/dl), RDW (15.40%). The study concluded that 51% of the total patients were found to have less Hb value implicating that they are basically anaemic and 100 % patients showed lesser value of MCV implicating that 100 of them have microcytosis creating the potential for overlooking some causes of anaemia. **CONCLUSION:** Iron Deficiency Anaemia can be associated as a moderate risk factor that predisposes to febrile seizure in children. We present IDA as a modifiable risk factor here, which could be prevented on early stage of pregnancy with sufficient iron supplements con- tinuing it to the toddlers and children under 6 years of age when necessary,otherwise a prime focus should be laid upon the diet being consumed by children under this age group**.**

KEYWORDS: Febrile seizure, Iron Deficiency Anaemia (IDA), microcytosis**.**

T317: ASSESSMENT OF METFORMIN INDUCED VITAMIN-B12 DEFICIENCY AMONGST TYPE-II DIABETIC PATIENTS VIS-À-VIS EVALUATING THE QUALITY OF LIFE

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ABSTRACT

BACKGROUND: Metformin is the cornerstone medication in the management of type 2 diabetes mellitus (T2DM), with estimates that it is routinely prescribed to 120 million patients with diabetes around the world. Several studies reported the long-term use of metformin lowers vitamin -B12 levels and its clinical manifestation can be misdi-agnosed as diabetic peripheral neuropathy. Thus, the study was undertaken to assess the vitamin-b12 deficiency in type II Diabetic patients with long-term use of metfor-min, an association between vitamin B12 and peripheral neuropathy and evaluating the quality of life in (T2DM) patients. **METHODOLOGY**: A prospective observational case-control study was conducted at the outpatient and inpatient departments of RVM Hospital. Total 34 (controls) healthy volunteers and 34 (cases) Type 2 diabetes patients using metformin for more than 6 months were recruited for the study. Data was collected using designed profile form, structured questionnaires and venous blood samples were collected in K2 EDTA vacu-tainers from the patients and centrifuged at 1500 rpm for 10 minutes, settled plasma was transferred into cryovials, estimating the parameters such as Vitamin-B12, HbA1c and CBP. The statistical analysis was done using SPSS (v25) software. **RESULTS:** The prevalence of serum vitamin B12 deficiency and borderline deficiency in T2DM patients is 20.5%, the mean HbA1C levels in our study T2DM subjects is <9.07 % which is reflecting either poor control of diabetes despite high doses of metfor- min or lack of compliance. 83% of T2DM patients with 1-10 years of metformin use resulted with Vitamin-B12 deficiency. **CONCLUSION:** Vitamin-B12 deficiency and Borderline deficiency prevalence in T2DM patients was found to be high in our study population when compared to control subjects. The reliability test was done to evaluate their quality of life which concludes that the quality of life was poor amongst the study participants. Considering the regular screening of vitamin-B12 as a cost factor, the peripheral smear can be done in T2DM patients on long-term metformin to detect macrocytic anaemia followed by biochemi- cal analysis periodically in rural areas.

KEYWORDS: Vitamin B12 deficiency, Metformin, Type 2 Diabetes mellitus, macro- cytic anaemia**.**

T318: IMPLEMENTING A VIDEO ASSISTED TEACHING PROGRAMME ON BREAST SELF EXAMINATION; EVALUATING THE KNOWLEDGE OF ADULT WOMEN

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ABSTRACT

Every country in the world is progressing towards the destiny

of "Health for all".Breast is the important organ for each woman as these are the symbol of moth-erhood and women hood.Breast is susceptible to numerous benign and malignant conditions. Breast cancer is probably the most feared cancer in women because of its frequency and psychological impact. It affects the perception of sexuality and self-image to a degree greater than any other cancer. The incidence of breast cancer is rising world-wide especially in developing countries such as India. Breast Self Examination (BSE) is an important screening measure for detecting breast cancer among women; those who correctly practiced BSE monthly can detect a lump in the early stage of its development and can be treated for a better survival rate. Hence, the investigator is interested to educate the adult women about breast self examination. **OBJECTIVE:** The aim of the study was to assess the effectiveness of video assisted teach- ing programme on knowledge regarding the BSE among adult women in selected hospital at Bangalore. **METHOD:** The research approach used for the study was descriptive research approach which was evaluative in nature. Research design included pre test and post test group. The setting of the study was at vanivillas hospital Bangalore. Purposive sampling tech- nique was used to select the subjects for study. The sample size consisted of 30 adult women. The tool used for the study was self-prepared questionnaire and video assisted teaching regarding breast self examination. The obtained data was analyzed by descrip- tive and inferential statistics. **RESULT:** The findings of the study showed that there was a significant difference between pre-test knowledge score (8.6333) and post-test knowledge score (15.2000). Paired t test was conducted in order to assess the effectiveness of video assisted teaching pro-gramme on knowledge regarding BSE and was found to be effective ($t=12.679$ $p<0.05$) at level of significance. **CONCLUSION:** BSE is a simple technique to identify the risk for breast cancer, but major barrier to carry out is the lack of knowledge and confidence among adult women. Nurses through video assisted teaching and demonstration, made them confident and knowledgeable**.**

KEYWORDS: Breast self examination, breast cancer, malignant conditions, psycho- logical impact.

COGNIZANCE OF JUNK FOOD AND HEALTHY EATING HABITS - A PEDAGOGICALLY MOTIVATED STUDY

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ABSTRACT

BACKGROUND: Good nutrition caters the individual's growth and development holis- tically. Inadequate nutrition has an impact on student's health status and academic performance. The transition from schooling to college provides them the autonomy to choose their eating habit. The college students are vulnerable to make poor dietary choices and consume plenty of junk food items that are non nutritional and can cause significant health problems. Thus to improve their knowledge regarding junk food and its harmful effects, various instructive strategies are used based on their background knowledge, experience, situation and environment which aids in motivating the schol- ars to maintain healthy eating habits. **PURPOSE**: To assess the cogency of a self instructional module (SIM) on cognizance of junk food and healthy eating habits amidst non health professional students**. METHOD:** A Pre-experimental one group pre-test and post-test design was used to col- lect the data and 50 non health professional students were selected through convenient sampling technique. The knowledge of students regarding junk food was assessed by the questionnaire after obtaining informed consent. Students were provided with a self instructional module and re-assessment was done after 7 days. **RESULT:** There is a substantial improvement in the knowledge of students after distribut- ing the self instructional module. The pretest mean score is 11.8 and the posttest mean score is 20.1 which shows a significant improvement in the knowledge of the students and the't' value ($t= 15.1$, $p<0.05$) reveals that the Self instructional module is highly effective**. CONCLUSION:** In compendious, the self instructional module could enhance the stu- dent's cognizance of junk food and healthy eating habits and it also conveys the interest of college students in self learning by alternative means. Beyond a shadow of doubt, it can be concluded that SIM is an effective pedagogical method to actuate the college students in learning and enlightening their knowledge.

KEYWORDS: Cognizance, Junk food, healthy eating habit, self instructional modules (SIM), professional students/college students

T322: PROFESSIONAL STUDENT'S

T326: Oligohydramnios Complicating Pregnancy; A study in a Tertiary Care Hospital

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ABSTRACT

Oligohydramnios is a condition in pregnancy characterized by a defi-ciency 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 dif-ference 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 oligo-hydramnios and a control group of 40 patients without oligohydramnios. Amniotic fluid assessment was done by ultrasound. The selected end points which were used to judge the pregnancy outcome in both groups of patient were rate of cesarean section for fetal distress, rate of induced labour, presence of meconium in amniotic fluid, apgar score of baby, rate of still birth and intra uterine growth retardation. The outcome of pregnancy in study group was compared with that of control group.The ultrasound examination of patients was done and an amniotic fluid index of 5cm or less was taken as the criteria for diagnosis of oligohydramnios. The indications of ultrasound examination were similar for study group and the control group. The pregnancy outcome in study group includes IUGR (Intra uterine growth retardation), maternal hypertension and decreased fetal movements. There was a significantly higher rates of induced labor, cesarean section, IUGR (Intra uterine growth retardation) babies, still births, low Apgar score and meconium-stained amniotic fluid in the study (Oligohydramnios) group as compare to control groups. The results of present study indicate that the risk of adverse pregnancy outcome is increased in patients with oligohydramnios. So, its management and fetal scanning during the pregnancy would reduce the pregnancy complications and malformations or growth restriction.

KEYWORDS: Oligohydramnios, Amniotic fluid index, Intra uterine growth retardation, still birth.

T327: EVALUATION OF KNOWLEDGE OF GARMENT DUST INDUCED BRONCHIALASTHMA AMONG TEXTILE WORKERS

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ABSTRACT

One of the important factors that influence proper management of asthma is patient education. Patients must have knowledge about the aetiology, usage of medication regarding asthma. Evaluation of disease knowledge and attitude is of great importance for the patient's health improvement, wellbeing and for preventing patients from asthma complications. Data regarding disease knowledge and drug adherence within the occupational asthma is negligible in INDIA. Hence this cross sectional study was conducted in textile industry to evaluate disease knowledge and attitude among asthmatic patients. With regards to this study the required information had been taken out of 1157 patients yielding response at the rate of 100%.Majority of the participants were between 30- 60 years of age(99%). The ratio of male and female was found to be 64.91%:35.09%. The maximum value of disease knowledge was 20 and 54% and atti-tude score was 15 and 43% respectively. Therefore present clinical study concluded that the patients lack the knowledge and medication adherence to prescribed regimen that leads to misconceptions on disease management, precisely in patients suffering from occupational asthma.

KEYWORDS: Garment workers, occupational asthma, disease knowledge and attitude

T329: IMPACT OF PATIENT COUNSELLING IN IMPROVING KNOWLEDGE, ATTITUDE, PRACTISE AND HEALTH RELATED QUALITY OF LIFE IN COPD PATIENTS

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ABSTRACT

OBJECTIVES: The objectives were to asses the Baseline KAP and HRQoL among Chronic Obstructive Pulmonary

Disease (COPD) patients, to provide/patient counselling inter-ventions to study population and to assess the impact of pharmacist assisted patient counselling to improve KAP and HRQoL in COPD patients. **METHODOLOGY**: Educational Interventional Study was conducted in the department of General Medicine in MVJ Medical College and Research Hospital and Hoskote Taluk, Bangalore. The medical records of the patients were screened and the baseline KAP and HRQoL of COPD patients were assessed for the patients who met the inclusion criteria. Patient centered pharmacist counseling was done for all patients using various coun-selling/educational aids and were reviewed after 2 months for follow-up purpose. The impact of pharmacist's counselling in improving the KAP and HRQoL was determined by comparing the baseline and follow up data. **RESULTS:** A total of 100 patients were included in the study. After providing patient coun- selling, it was observed that there was a significant improvement in certain domains of KAP and HRQoL from the baseline scores. Patients were educated and counselled that smoking is the main cause for COPD, therefore, there was a significant value of 0.0004* for awareness of smoking cessation. After counselling, there was a statistically signifi-cant improvement in the HRQoL scores which showed a p value of <0.0001*. **CONCLUSION:** Pharmacist assisted patient counselling had a significant impact in improv-ing KAP and HRQoL in COPD patients. However, a more comprehensive approach should be adopted that addresses solutions for providing better patient education on smoking cessation, counselling the patient's family members, providing special care for geriatric patients.

KEYWORDS: Chronic obstructive pulmonary disease (COPD), Patient counseling, KAP, health related quality of life (HRQoL).

T336: ASSESSMENT OF PARENTAL KNOWLEDGE, ATTITUDE, PRACTICE TWOARDS ANTIBIOTIC USE IN CHILDREN

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ABSTRACT

OBJECTIVE: To assess the impact of pharmacist assisted counseling in improving Parental Knowledge, Attitude and Practice [KAP] towards antibiotic use in children**. METHODOLOGY:** A Prospective, Educational Interventional Study was conducted in 200 subjects, from the randomly chosen communities in Bangalore. Door to door visit was done by the investigators. The basic demographics data of parents and their chil-dren were collected using standard Case Report Form (CRF) and the baseline towards antibiotic use in Children was collected from parents using validated questionnaire. In presence of both parents, only one of them was supposed to answer the question-naire. Pharmacist assisted parent centered interventional counseling was provided with the help of Patient Information Leaflets (PIL).Follow-up and post interventional KAP assessment were done after 2 months from the baseline measurement. The changes in parental KAP towards antibiotics use in children were being assessed by comparing the Pre-test and Post-Test responses using statistical analysis**. RESULTS:** The knowledge of parents towards antibiotic use in children was medium to good in the baseline KAP assessment; however in majority of the participating par- ents it was not satisfactory in attitude and practice domains. A statistically significant improvement was seen in KAP of parents towards antibiotic use in children after the pharmacist assisted interventional counseling. Thus, Investigators could bring excel- lent changes in the knowledge part; whereas the result for changes in the attitude and practice were good to medium respectively. **CONCLUSION**: The study reflects upon the idea that knowledge moulds attitude; andattitude drives proper practice. Our study showed a significant improvement in Knowledge, Attitude and Practice of parents towards antibiotic use in their children but extending the study for up to at least a year with more numbers of follow-up, can provide better changes on antibiotic use in children.

KEY WORDS: Pre- test, Post- test, Knowledge, Attitude and Practice, Patient Information Leaflet, Follow-up, Case Report Form

T335: PHENOMENOLOGICAL STUDY ON PROFESSIONAL ROLE TRANSITION OF NEW GRADUTE NURSES

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ABSTRACT

Nursing is a unique career in which those who are new to the

field face numerous chal- lenges. Newly graduated nurses often experience culture shock during transition from the academic ideal of nursing to the clinical reality of nursing practice (Valdez, 2008). **AIM:** The study aimed at addressing the professional role transition of new graduate nurses during their initial years of practice. **METHODOLOGY:** Phenomenological research approach was used for the study. The sample for the study consisted of five female graduate nurses who are graduated from accredited Bachelor of Science nursing programs and presently working as staff nurses in a tertiary care hospital. The data was collected in two phases: Phase I: Focused group interview and Phase II: Individual interview. Permission was obtained and the interviews were audio taped and transcribed. Trustworthiness of the data was assured by using Audit trail, Memoing and Peer debriefing. **RESULTS:** The collected data was categorized into three stages based on Judy Boychuk Duchscher's transition theory. During the initial 3-4 months (Doing stage) the nurses were initially excited to work but quickly realized that they were unprepared for responsibility and work load of their new role. Subjects felt scared and stressed during this phase and realized that the reality is different. During the next 9-12 months (Being Stage) their competency, skill and confidence improved. They realized being trusted by seniors and other health care personnel. From 12 months and above (Knowing phase) the subjects experienced less stress and gained confidence and improved individual capacity to cope**.** The study findings highlight the need for mentoring the novice nurses as they progress through the different phases of professional experience.

KEYWORDS: Transistion; New graduate Nurses; phenomenological study

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TRACK 4: FORMULATION DEVELOPMENT

T404: NOVEL DUAL RELEASE NANOSTRUCTURED LIPID CARRIER (NLC) LOADED TRANSDERMAL PATCH: FORMULATION, IN-VITRO AND IN-VIVO EVALUATION

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ABSTRACT

Dual release NLC loaded transdermal patch was developed to enhance the bio- availability and therapeutic effect of low bioavailable drugs like Simvastatin and Carvedilol. NLC formulations were prepared by optimized hot homogenization technique and were characterized by Particulate characteristics, Scanning Electron Microscopy (SEM) and Entrapment efficiency (% EE) by applying Box Behnken optimization design. Among 17 formulations S1-S17 of Simvastatin NLC and C1-C17 of Carvedilol NLC, S7 (Simvastatin NLC) and C16 (Carvedilol NLC) formulation were selected as the best NLC formula-tion by following data. Chosen optimized NLC S7 has its desired PS as 125.4±2.66 nm, ZP as - 33.6±2.42 mV, PI as 0.480±0.24. Selected optimized NLC C16 has its desired PS as 207.1±2.02nm, ZP as -37.2 ± 1.84mV, PI as 0.331±0.22. The dual NLC (Simvastatin NLC- S7 and Carvedilol NLC-C16) loaded transdermal patch was prepared by a solvent evaporation method and evaluated for in-vivo pharmacokinetic and pharmacodynamic (Antihyperlipidemic and Antihypertensive) studies in male albino Wistar rats. In-vivo pharmacokinetic studies in NLC loaded transdermal patch show an increase in AUC0-α in mg/ml with the decrease in Cmax and Tmax when compared to marketed oral dosage form, which confirms the enhancement of bioavailability of drugs by NLC loaded trans-dermal patch. In-vivo antihyperlipidemic and antihypertensive studies in NLC patches show a statistically significant difference in lipid profile and systolic blood pressure (SBP) while comparing between the diseased group and treatment groups, which shows the P value <0.05 (ANOVA) with 95% confidence interval. From the data, it was concluded that drug-loaded NLC Transdermal patch will be a promising drug delivery system for poorly bioavailable drugs.

KEYWORDS: Nanostructured lipid carrier; Transdermal patch; bioavailability; Box-Behnken**.**

T405: FORMULATION AND EVALUATION OF ETHOSOMES LOADED WITH ROPINIROLE HYDROCHLORIDE

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ABSTRACT

Parkinson's disease is a long-term degenerative disorder of the central nervous system that mainly affects the motor system. Ropinirole hydrochloride is a new non-ergoline dopamine agonist recently introduced to treat Parkinson's disease. It has lower oral bioavailability (50 -55%) due to its significant extensive first-pass metabo- lism and short half-life of 4-6 hr. To achieve sustained release of drug, a novel lipid vesicle system called Ethosomes has been developed. They are soft malleable vesicles composed of phospholipids, ethanol, and water which enable the drug to reach the deeper layers of skin for the systemic drug delivery. The objective of the present study was to develop Ethosomes of Ropinirole hydrochloride by the Cold method. They act by interacting with the lipid bilayer thereby increasing membrane fluidity. The formu- lated Ethosomes were evaluated for entrapment efficiency, vesicle shape, vesicle size, zeta potential analysis and in vitro drug release study. The entrapment efficiency of the Ethosomal formulation was found to be 51.3% and vesicle size less than 400nm. The in-vitro drug release was found to be 70% in 24 hrs when compared to the pure drug solution which released 99% drug in 2hrs. So, from the above studies, it can be concluded that Ethosomes will be a suitable delivery system for the treatment of Parkinson's disease.

KEYWORDS: Ropinirole Hydrochloride, Ethosome, nonergoline dopamine agonist

T406: FORMULATION AND EVALUATION OF FLOATING BILAYER TABLET OF DOMPERIDONE AND RABEPRAZOLE FOR THE TREATMENT OF ESOPHAGEAL REFLUX DISORDER

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ABSTRACT

The objective of this present study was to design the bilayer tablet of Domperidone (IR) Rabeprazole (SR) for the management of the gastro-oesophageal disorder. Bilayer tablets comprised two layers, i.e. immediate release and the con- trolled release layer. The immediate release layer comprised crospovidone as a super Disintegrant and the controlled release layer comprised HPMC K100M as the release- retarding polymers. Preformulation studies were performed prior to compression. The individual layers of the bilayer tablets were evaluated for weight variation, dimension, hardness, friability, drug content, and disintegration time and in-vitro drug release using USP dissolution apparatus type II (paddle). HPMC K100M extended the release of drug from the extended release layer for 8 hr. FTIR studies revealed that there was no interaction between the drug and polymers used in the study. The release of Domperidone and Rabeprazole was found to follow a pattern of Korsmeyer-Peppas, with Quasi-Fickian diffusion. The stability studies were carried out for the optimized batch for three months and showed acceptable results. There were no changes observed in physicochemical properties and drug release pattern of tablets. Biphasic drug release pattern was successfully achieved through the formulation of bilayer tablets in this study.

KEYWORDS: Bilayer tablet, Domperidone, HPMC, Rabeprazole, sustained release

T407: DESIGN AND EVALUATION OF OCULAR HYDROGEL CONTAINING COMBINATION OF OFLOXACIN AND DEXAMETHASONE FOR THE TREATMENT OF CONJUCTIVITIS

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ABSTRACT

Hydrogels are three dimensional, cross-linked network of polymers. Water penetrates these network causing swelling and giving the hydrogel a soft and rubbery consistency. Due to the drawback of conventional therapy for ocular deliv-ery, Hydrogel containing a combination of ofloxacin (OFL) and Dexamethasone (DX) was formulated for the treatment of conjunctivitis. In the present investigation pH, the sensitive hydrogel was prepared by using polymers like Carbopol 934 and HPMC. The simultaneous estimation of the drugs was carried out by Vierordt's simultaneous equa-tion method and validated the method. The method used for simultaneous estimation of drugs found to be robust, reproducible, and stable. The FTIR spectra showed no interaction between drug/ and polymers. The pH of the hydrogel ranged from 7.21- .7.44 and quickly gelatinizes and remains for the extended period. The viscosity of the formulations ranged from 22.5-56.3 cps. The drug content ranged from70.51-86.53 %. Sterility test on hydrogels proved to be sterile and found no ocular irritation. From the antimicrobial activity test, the zone of inhibition was found to be 27–28 mm. The in- vitro drug release study showed that there was a slow and sustained release of the drugs from the hydrogel and followed zero order release. All the formulations showed good stability at 25-40/45 ºC -60% RH. There was no significant change in the drug content. Results of the study indicated that it is possible to develop a safe and physiologically effective hydrogel which is patient compliant.

KEYWORDS: Hydrogels, Conjunctivitis, pH sensitive

T408: FORMULATION AND EVALUATION OF ALOE-VERA GEL FOR THE TREATMENT OF APHTHOUS ULCER

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ABSTRACT

An aphthous ulcer is one of the most common diseases of the oral cavity with no known effective treatment so far, which could cause severe discomfort in patients. Aloe vera is a tropical plant with anti-inflammatory and immunostimulant effects, which could be of benefit in a diversity of wound healing conditions. The present study is an attempt to develop sustained and prolonged release of Aloe-vera gel by using syn-thetic polymers like Carbopol 934 and HPMC K4M in the treatment of aphthous ulcer. The gels were evaluated for various physicochemical parameters like pH, viscosity, drug content, spreadability, in-vitro release studies. In addition,

short- term stability studies were conducted for the formulation. The pH was found to be in the range f 6.8 and 7.0, the drug content was found to be more than 90% in both the formulation, in-vitro release study the carbopol containing aloe vera has shown maximum release of 97% and 92% for HPMC K4M based gel. From the above studies, it can be concluded that formulation containing Carbopol 934 shows desired properties and exhibit better release pattern when compared t the HPMC based gel.

KEYWORDS: Aphthous ulcer, Aloe-vera gel, Carbopol 934, HPMC K4M.

T409: DESIGN AND DEVELOPMENT OF DENTAL FILM CONTAINING GRAPE SEED EXTRACT FOR THE TREATMENT OF PERIODONTAL DISEASES

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ABSTRACT

Periodontitis is an inflammatory disease caused by pathogenic flora established within the gingival sulcus, which later deepens to become a periodon-tal pocket. The potential adverse effects associated with systemic administration of drug(s); hence a safe and effective low dose local drug delivery device is highly benefi-cial. The main objective of this study is to develop and evaluate dental film containing Grape seed extracts (GSE) for the treatment of Periodontitis. GSE based dental films were prepared by the solvent casting method using gelatin as polymers and PEG 4000 as a plasticizer. IR analysis showed GSE was compatible with other excipients. Prepared films were evaluated for various properties such as weight variation, tensile strength, moisture loss, and drug content, in- vitro drug release, in-vitro antibacterial activity, and stability studies. Weight variation was minimum for (0.99mg) and maximum was found be (1.42mg), Tensile strength was (1.72-2.61 kg). Moisture loss was found to be in the range of 0.95-1, In-vitro experiments demonstrated that the prepared GSE extract film containing a higher concentration of gelatin (3%) releases for more than 12 hours and considered as the optimized formulation. In-vitro dissolution studies showed an initial burst release to achieve an immediate therapeutic level of drug in periodontal pocket followed by a progressive fall and extended release of the drug with more uniformity for a prolonged period of time. The prepared dental film showed zero order release kinetics and followed non-Fickian diffusion mechanism. Stability studies did not show any significant changes with respect to content, appearance, and in-vitro drug release.

KEYWORDS: Grape seed extract GSE, Periodontitis, Tensile strength, Zero order release.

T410: EFFECT OF SPRAY DRYING TECHNIQUE ON SOLUBILITY ENHANCEMENT OF ETORICOXIB

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ABSTRACT

Etoricoxib (ETX) is a poorly water-soluble drug (BCS Class II), widely prescribed for rheumatoid arthritis, osteoarthritis and other joint diseases. In order to increase its solubility and dissolution rate, solubility enhancement method like prepa-ration of spray dried solid dispersions with different ratios of polymers like PEG and HPMC, with Etoricoxib have been investigated. The method was carried out under the following conditions: Inlet temperature of 43-500C and outlet temperature 35-400C for solid dispersions and feed pump speed of 10ml/min, aspiration speed 45, vacuum: 100-150mm, atomization air pressure of 2kg/cm2. Drug- carrier interactions were investigated by differential scanning, calorim-etry and FT-IR spectroscopy. The studies showed that solubility and dissolution rate of Etoricoxib was distinctively increased in the prepared ETX-PEG = 1:3 (F3) and ETX-HPMC = 1:3 (F6) spray dried solid dispersion compared to that of pure Etoricoxib. The saturation solubility of F3 was 146.7 µg/ml and F6 was 140.84µg/ml. Release kinet-ics followed the first order. Drug release of ETX was 97.24% at 120min whereas F3 showed 99.13% at 45 min and F6 showed 97.82% at 45 min. From the above study, it can be concluded that the spray drying technique was the most effective technique, showing the better solubility and dissolution.

KEYWORDS: Etoricoxib, Polyethylene glycols (PEG), Hydroxypropyl methyl cellulose (HPMC), Dissolution enhancement, Spray drying technique,

T411: DEVELOPMENT AND VALIDATION OF DISSOLUTION STUDY OF SUSTAINED RELEASE DEXTROMETHORPHAN HYDROBROMIDE TABLETS

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ABSTRACT

The objective of the current study was to develop a validated dissolu- tion test for sustained release Dextromethorphan hydrobromide tablets using an HPLC method. Separation was achieved on a C18 column utilizing 0.5% triethylamine (pH 7.5) and acetonitrile in the ratio of 50:50. The detection wavelength was 280 nm. The method was validated and the response was found to be linear in the drug concentration range of 10-80 µg/mL. The method was established to have sufficient intermediate pre- cision as similar separation was achieved on another instrument handled by different operators. The method was successfully applied for dissolution study of the developed Dextromethorphan Hydrobromide tablets. The method was validated according to ICH guidelines which include accuracy, precision, linearity, and analytical range and therefore the method can be employed for the routine dissolution analysis in various pharmaceutical industries**.**

KEYWORDS: Dextromethorphan Hydrobromide, Sustained release, Dissolution, HPLC

T412: 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 consist-ing 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 of 50–200 mg/ mL (R2=0.9999 and 0.9998). Chlordiazepoxide and Amitriptyline hydrochloride was subjected to stress conditions including acidic, alkaline, oxidation, photolysis and ther-mal 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 deg-radation studies**.**

T413: FABRICATION AND EVALUATION OF CAPECITABINE LOADED PRONIOSOMES USING DIFFERENT NON-IONIC SURFACTANTS

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ABSTRACT

Purpose: Deoxycytidine derivative that is used as an antineoplastic, antimetabolite in the treatment of colon, breast, and gastric cancer, has a high therapeutic potential but with very short biological half-life is 40 minutes and low bio-availability of 40-45%. To overcome these drawbacks, controlled release Capecitabine loaded proniosome dosage form was developed; to improve the bio-availability and to reduce the dosing frequency to reduce the associated toxicity of Capecitabine. **MATERIALS AND METHODS:** The maltodextrin based Proniosomal formulations were pre-pared by a slurry method using various non-ionic surfactants (Span60, Tween 60 and Brij35) in the presence of cholesterol. The prepared Capecitabine proniosomes were char-acterized for particle size, PDI, zeta potential, drug content, entrapment efficiency (EE %). In vitro drug release studied using dialysis bag method in phosphate buffer saline pH 7.4 solutions. The optimized proniosomal formulation was subjected at 5°C ± 3°C and 25 °C ± 2°C/60% RH±5% RH for period of three months as per ICH guidelines. **RESULTS AND DISCUSSION:** The λ max of Capecitabine pure drug was found to be 240 nm and measured by UV spectrophotometer. FTIR and DSC studies revealed that there was no interaction between the drug and excipients (cholesterol and non-ionic sur-factants). SEM studies showed nearly spherical shaped vesicles. In vitro, drug release results confirmed that the Proniosomal formulations have exhibited a higher retention of Capecitabine inside the vesicles such that the in-vitro release was compared to the control drug. Highest drug % EE

99.03±0.54% and in-vitro release 86.86±0.47% was obtained using Tween 60 and cholesterol in 1:1 ratio. The kinetic drug release study data of CS601 TO CBRIJ9 formulations best fitted into Korsmeyer–Peppas model. The result shows that drug release rate for all formulations followed zero order mechanism. The selected CT60F6 formulation was subjected to three months stability studies at Accelerated six months 5°C ± 3°C and 25°C ± 2°C/60% RH±5% RH showed stability with respect to release pattern and all physical parameters. From the results, it was monitored that there is not much variation in the color and also the vesicles size and cumulative percentage of drug release at the temperature 5°C±3°C when compared with 25°C ±2°C. **CONCLUSION:** we can conclude that proniosomes provide controlled release of drug and these systems are used as drug carriers for the delivery of cytotoxic drugs with fewer side effects.

KEYWORDS: Capecitabine, Non-ionic surfactants, Slurry method, Evaluation param-

T414: DEVELOPMENT AND VALIDATION OF BIOANALYTICAL METHOD FOR THE SIMULTANEOUS ESTIMATION OF ACECLOFENAC & THIOCOLCHICOSIDE IN HUMAN PLASMA BY LC-MS/MS

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ABSTRACT

A simple, selective, rapid and precise LC-MS/MS method has been devel-oped and validated for simultaneous estimation of Aceclofenac and Thiocolchicoside in human plasma. Bio-analysis is defined as the quantitative measurement of the drug molecule in the biological matrix which includes plasma, serum, urine, saliva, etc. Bio-analytical method validation used to establish the developed quantitative analytical method is precise, accurate, rugged and robust and is suitable for the biomedical appli-cations and validate the same. The Aceclofenac and Thiocolchicoside were extracted by solid-phase extraction (SPE) method. The stationary phase used as Hibar® C18 (5µm, 50 x 4.6 mm i.d.) column and the mobile phase as Solvent A (Acetonitrile) and Solvent B (10mM Ammonium acetate buffer, pH 4.0) with the ratio 80:20 v/v. The flow rate was found to be 0.5ml/min and the detection was performed by Triple quadrupole mass spectrometry LC-MS/MS using electron spray ionization (ESI) as a positive and negative mode. The calibration curve was consistently accurate for the Aceclofenac and Thiocolchicoside over the range of 785 to 15700 and 6 to 120ng/ml using Etodolac as the internal standard. Limit of Detection (LOD) and Limit of Quantification (LOQ) of Aceclofenac is 1.5ng/ml and 4.5ng/ml and of Thiocolchicoside is 1ng/ml and 3ng/ ml respectively. The precision and mean accuracy are within the acceptance limit and the correlation coefficient (R2) of Aceclofenac and Diclofenac was 0.9956 and 0.9907 respectively. The method was developed and validated as per USFDA guide-lines. The established method can be used for the quantification of Aceclofenac and Thiocolchicoside in Human plasma for Bio-availability and Bio-equivalence studies, new drug development, Clinical pharmacokinetics, and pharmacodynamics studies, research in basic biomedical and biopharmaceutical sciences.

KEYWORDS: LC-MS/MS, Bio-analytical Method Validation, Estimation of Aceclofenac and Thiocolchicoside, Human Plasma, Correlation coefficient (R2).

T415: BIO-ANALYTICAL METHOD DEVELOPMENT AND VALIDATION FOR THE SIMULTANEOUS ESTIMATION OF DAPAGLIFLOZIN AND SAXAGLIPTIN IN HUMAN PLASMA BY LC-MS/MS

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ABSTRACT

Bio-analytical technique or Bio-analysis is a sub-discipline of analytical chemistry. The Bio-analysis is associated with the measurement of small and large mol- ecules from biological fluids like blood, serum, plasma, urine, faeces etc. Nowadays, methods of measuring drug in biological media are increasingly important due to the problem associated with Bio-availability and Bio-equivalence studies, drug abuse, clinical Pharmacokinetics, and Drug Discovery and Drug Development as they are highly dependent on accurately measured drugs in biological samples. Keeping this in the mind, Bio-analytical method has been developed and validation for the simul- taneous estimation of Dapagliflozin and Saxagliptin by LCMS/MS in human plasma. Glimepiride was used as internal standard Dapagliflozin and Saxagliptin, Internal Standard was extracted from human plasma by SPE.

Chromatographic separation of analytes and internal standard was carried out using a Zorbax C18 (50 x 4.6mm,3µm) at 0.5ml/min flow rate, mobile phase used 85:15v/v (ACN: Ammonium Formate). Detection was performed at the transition of 200-600m/z for both drugs and a molec- ular ion of above mentioned analytes were selected from scan modes. The assay of Dapagliflozin was linear over the range of 15-300 ng/ml and for Saxagliptin was 2.5-50ng/ml and the regression coefficient (r2) was found to be 0.9986 and 0.9995, LOD was 10ng/ml and 1.5ng/ml and LOQ was found to be 25ng/ml and 4ng/ml as respectively. The percentage recovery value in human plasma range from 99.30-100.56% and 98.28% -101.31% and aqueous solution were ranged from 99.60-103.60% and 98.52 - 102.91% respectively for Dapagliflozin and Saxagliptin. The developed method was accurate and precise and it was developed and validated as per USFDA guidelines. The established method can be used to perform pharmacokinetic and bio-equivalence stud- ies in human plasma.

KEYWORDS: Dapagliflozin, Saxagliptin, Bio-analysis, Glimepiride, LC-MS/MS, US-FDA.

T416: METHOD DEVELOPMENT AND VALIDATION OF CERITINIB AND IT'S PHARMACEUTICAL DOSAGE FORM BY REVERSE PHASE-HIGH PERFORMANCE LIQUID CHROMATOGRAPHY

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ABSTRACT

A simple, precise and accurate Reverse Phase High Performance Liquid chromatography method was developed for the estimation of Ceritinib and its pharma- ceutical dosage form. It forms an affordable, reliable and novel method than the previous one. This method was carried out on Phenomenex Luna (C18 (2), 250*4.6mm) 5µ col-umn with a mobile phase consisting of Methanol: Acetonitrile: Water in the ratio of 60:30:10 v/v. The retention time of Ceritinib is 2.553 minutes. The flow rate was 0.08ml/ min with UV detection at 261 nm. The linear regression analysis data for the linearity plot showed a good linear relationship with correlation coefficient value for Ceritinib was r2 =0.999 concentration range of 20-100 µg/ml. The relative standard deviation for intra-day precision has been found to lower than 2.0 %. The method is validated according to the ICH guidelines. The developed method in terms of specificity, selec-tivity, accuracy, precision, linearity, limit of detection, quantification and solution stability. Sensitivity was estimated by determination of LOD and LOQ found to be 6µg/ml&1.32µg/ml for Ceritinib. The purposed method can be successfully applied for the determination of these drug in combined dosage forms.

KEYWORDS: Reverse Phase-High Performance Liquid Chromatography, Ceritinib, Phenomenex Luna

T417 DEVELOPMENT AND VALIDATION OF RP-HPLC FOR THE ESTIMATION OF ENTECAVIR IN TABLET DOSAGE FORM

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ABSTRACT

The simple, rapid and selective method was developed for the determi- nation of Entecavir in tablet dosage form. The method is based on the Reverse phase HPLC was developed by using Trifluoroacetic acid 0.025%, Acetonitrile in the ratio 93:7 as a mobile phase and Develosil ODS MG-S C18 (250 mm x 4.6 mm i.d, 5mm) column as a stationary phase. The flow rate was 1 ml/min. The UV detector was oper- ated at 254 nm. The method was validated for specificity, linearity, precision, accuracy, and limit of quantification. The recovery studies showed that the observed percentage recovery was found to be 97.0 to 103.0 %. The retention time of Entecavir was found to be 9.75min. The developed method was accurate and precise which was evident from the analytical data and recovery studies.

KEYWORDS: Entecavir, Reverse-phase HPLC.

T418 METHOD DEVELOPMENT AND VALIDATION OF RP- HPLC METHOD FOR QUANTITATIVE DETERMINATION OF IRINOTECAN HCL IN BULK AND PHARMACEUTICAL FORMULATION

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ABSTRACT

More precise, accurate, sensitive, simple and economic HPLC method was developed and validated for the quantitative determination of Irinotecan in bulk and dosage forms. Irinotecan was analyzed by using reverse phase Inertsil ODS 250 X 4.6 mm and 5µ particle size column. 0.02 M KH2PO4 buffer and acetonitrile were used as a mobile phase in the ratio of 40:60 v/v. The pH of the buffer was adjusted to 3.2 with o- phosphoric acid. The flow rate was 1.0 ml/min and the run time was 5 min. The analysis was carried out at 222 nm with UV detector at ambient temperature. The developed HPLC method was validated and stability studies were conducted under dif-ferent conditions. Irinotecan was eluted at retention time 2.1 min and the calibration curve was linear in the range 40-120 µg/ml concentration. The correlation coefficient was found to be 0.9999. The Irinotecan test and standard stock solutions were stable over the period of 5 days. The LOD and LOQ were found to be 0.8 ng/ml and 2.0 ng/ml. % RSD of Irinotecan content was < 0.5% and the assay was found to be 98.2-100%. The proposed method is observed to be rapid and selective when compared to the methods reported in the literature. The retention time of Irinotecan was found to be very less (2.1 min). The method is also cost-effective with respect to solvent consumption.

KEYWORDS: RP-HPLC, Irinotecan, Inertsil ODS

T419: BIO-ANALYTICAL METHOD DEVELOPMENT AND ITS VALIDATION FOR THE ESTIMATION OF FAMOTIDINE IN RAT PLASMA AND ITS APPLICATION FOR PHARMACOKINETIC STUDIES BY RP-HPLC

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ABSTRACT

A simple, sensitive and rapid reverse phase High performance liquid chro- matography (RP-HPLC) method was developed and validated for the determination of Famotidine 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 vali-dation parameters and applicability of the assay. The present method can be useful for pre-clinical pharmacokinetic studies of Famotidine with desired precision and accu-racy along with high-throughput. The developed analytical method for Lercanidipine in reverse phase chromatographic method utilizing C18 column (250mm×4.6mm, 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 Famotidine 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. The method was found to be linear from 2 to 500ng/ml Famotidine (r2 ≥ 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: Famotidine, RP-HPLC, Rat Plasma

T422: FORMULATION AND IN VITRO EVALUATION OF GASTRO RETENTIVE MUCOADHESIVE FLOATING TABLETS OF BROMOHEXINE HCL

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ABSTRACT

In the present research work gastro retentive floating matrix formulation of Bromhexine HCL by using various polymers were developed. The formulation was developed by using different concentrations of polymers of Guar gum, HPMC K15M and HPMC K100M as polymeric substances. The formulation blend was subjected to various preformulation studies, flow properties and all the formulations were found to be good indicating that the powder blend has good flow properties. Among all the for- mulations the formulations with HPMC K100 M as polymer retarded the drug release up to desired time period i.e., 12 hours in the concentration of 40 mg. whereas in low concentrations the polymer was unable to produce the desired action. (F8 Formulation, 99.98 % Drug release). The optimized formulation dissolution data was subjected to release kinetics; from the release kinetics data it was evident that the formulation fol- lowed higuchi release kinetics.

KEYWORDS: Bromhexine HCL, Guar gum, HPMC, Mucoadhesive floating tablets.

T423: DESIGN, OPTIMIZATION AND EVALUATION OF VEE GUM BASED RANITIDINE FLOATING MICROSPHERES USING D-OPTIMAL DESIGN FOR OPTIMIZATION

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ABSTRACT

OBJECTIVE: Ranitidine is histamine H2 antagonist widely used in the treatment of gastric ulcer. It is a suitable drug for gastro retentive floating microspheres due to its short half life and poor absorption in lower gastro intestinal tract. In the present research work, D-optimal design was used for optimization of levels of independent variables (sodium bicarbonate, beeswax, ethyl cellulose & citric acid) on dependent variables t50 and time taken for 100% release in the formulations of ranitidine gastro retentive floating gran-ules with less experimentation. **METHODS:** Calibration curve of ranitidine hydrochloride were prepared in 0.1N HCl solution (pH-1.2). Floating microspheres were prepared by solvent evaporation tech- nique using various polymers like veegum, beeswax, ethyl cellulose and gas generating agents like sodium bicarbonate, citric acid and were evaluated for drug - excipient com- patibility, density, buoyancy test, mucoadhesion force, swelling study, drug content and in-vitro release profile. **RESULTS:** From the results it was concluded that sodium bicarbonate (10%), beeswax (20%) and ethyl cellulose (10%) and citric acid (0%) were favorable for formulation of gastro retentive floating microspheres employing vee gum as release retardant. **Conclusion:** D-optimal design was useful in predicting the optimum concentrations of X1, X2, X3, X4 on t50 and time taken for 100% release of the drug with less experimen-tation in less time. From the results it was concluded that sodium bicarbonate (10%), beeswax (20%), ethyl cellulose (10%) and citric acid (0%) were ideal in formulation of floating granules and vee gum can be used as floating polymer in the formulation of floating microspheres.

KEYWORDS: D-optimal design, Floating polymers, Gas generating agents, floating con- trolled release.

T424: DEVELOPMENT AND VALIDATION FOR SPECTROPHOTOMETRIC AND HPLC METHODSFOR THE DETERMINATION OF DOXOFYLLINE IN TABLET DOSAGE FORMS

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ABSTRACT

To develop two simple, rapid, specific and selective methods for the determination of Doxofylline in tablet dosage. The first method (I) is based on UV Spectroscopy. UV spectra of Doxofylline are recorded. The absorption maxima (λmax) were observed at 274nm. Beer's law was obeyed over the concentration range from 2 to 20 µg/ml and it shows linearity. The validation of the proposed method was further confirmed by Recovery studies at 50%, 100% and 150%. The percentage recovery val- ues from 98%w/w, 100.5%w/w, 99.70%w/w, 99.96%w/w. This serves as a good index of accuracy and reproducibility of the study. The second method is based on the Reverse phase HPLC, method was developed by using Methanol: Disodium phosphate in the ratio of 30:70 as a mobile phase and Phenomenox Luna C18 (5 micron, 250 4.6 mm) column as a stationary phase. Flow rate was 1.0 ml/min. The UVdetector was operated at 274nm. The method was validated for specificity, linearity, precision, accuracy and limit of quantification. The recovery studies showed that the observed percentage recovery of doxofylline was found to be 98.4 to 98.9 %. The retention time of Doxofylline was found to be 12.77 min. The devel-oped method was accurate and precise which was evident from the analytical data and recovery studies.

KEYWORDS: Doxofylline; UV- Spectroscopy, Reverse-phase HPLC.

T425: DEVELOPMENT OF COMPLEX DRUG – DEVICE COMBINATION: REGULATORY CONSIDERATIONS AND CLINICAL CHALLENGES

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ABSTRACT

A complex drug-device combination product is the unification of drug/ device, that merge together to form single entity.The regulatory science and clini-cal design behind conducting the clinical investigation depends on the early stages of product development that helps to assign the product either to drug or a medical device. Globally there are tremendous innovative complex drug-device combinations available that gave an opportunity to achieve diagnostic and therapeutic approach at a faster pace when compared to conventional method. Over the last couple of decades there is no proper clinical guidance, the combination product should not be confused with drug-drug, device-device and fixed dose combination. The main objective is to provide the regulatory outline on the clinical investigation for complex drug device combination in order to accept the com-plex drug – device combination product for safe and effective use by the patients. The regulatory framework of USFDA is well structured over clinical investigation of complex drug – device combination when compared to other regulatory agencies. Therefore office of combination product (OCP) of USFDA provides regulatory guid- ance and assigns the particular complex drug - device combination product to the respective centres such as CDER, CBER and CDRH based on the primary mode of action (PMOA) for the purpose of clinical evaluation. The present study highlights about the clinical investigation regulation development in India on complex drug - device combination.

KEYWORDS: Clinical investigation, OCP, CDER, CBER, PMOA

T426: FORMULATION AND EVALUATION OF SOLID ORAL DOSAGE FORM WITH PORTULACAQUADRIFIDA MUCILAGE FOR ENHANCING BIOAVAILABILITY

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ABSTRACT

NSAIDs are usually prescribed for anti inflammatory ailments which are prescribed for long periods; they accumulate in tissues produce toxic effects such as retinal damage, corneal opacity and other effects like rashes, irritable bowel syndrome, myopathy and neuropathy which can be minimized by increasing bioavailability thereby lowering the dose of the drug. Allopathic dosage form gets metabolized by first pass metabolism and the rest reaches the circulation. To increase the bioavailability of such drugs an agent is incorporated to enhance the drug bioavailability and to reduce the dose of drug is desired. Such an agent is called as Bioenhancer.A bioenhancer is an agent capable of enhancing bioavailability and efficacy of a drug with which it is co-administered, without any pharmacological activity of its own at therapeutic dose used. They tend to decrease the dose of active drug required for the optimal endpoint of the treatment strategy, bypassing the need to use injectable routes of drug admin-istration to a larger extent, might help in overcoming the resistance to antimicrobials and saving the precious raw materials for the manufacturing of medicines. Modern researchers show increased interest in the enhancement of bioavailability of most of the drugs by addition of various herbs with bio enhancing property. To achieve bio enhanc-ing property of a drug various approaches are adopted for instance by using absorption enhancers, prodrugs, micronisation, manufacturing of delayed release, sustained release capsules and spansules, permeability enhancing dosage forms like liposomes and emulsions.In Ayurveda, the concept of bioenhancer is termed as Yogvahi. It is used to enhance bioavailability, tissue distribution, increase efficacy of drugs especially drugs with poor bioavailability. Portulacaquadrifida is a small diffused, succulent, annual herb found throughout the tropical parts of India belonging Portulacaceae family. It is used as a vegetable and also used for various curative purposes. Portulacaquadrifida is an edible plant rich in mucilage. Hence, the present work was aimed to formulate a conventional dosage form incorporated with varying concentrations of drug and mucilage followed by character-ization to substantiate the efficacy of the drug with increased bioavailability by invitro studies.

KEYWORDS: Portulacaquadrifida, mucilage, bioavailability**,** bioenhancer.

T427 BIOAVAILABILITY AND DISSOLUTION ENHANCEMENT OF GLYBURIDE NANOPARTICLES

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ABSTRACT

The rate of dissolution is very slow for poorly water-soluble drugs which is a major challenge in the process of drug development. Slow dissolution rates of drugs usually show incomplete absorption that can cause therapeutic failure. Glyburide, well known as an antidiabetic drug and is under BCS-II category so it's having low solubility. The mainobjective of this study was to improve rate of dissolution

and subsequently bioavailability of Glyburide by using nanotechnology. Glyburide nano-suspension is prepared by using nanoprecipitation method and variable formulation parameters (drug, stabilizers at different concentration ratios) nanoparticles were pre-pared. The nanoparticles prepared were evaluated by drug content, differential scanning calorimetry (DSC), Fourier transform infrared spectroscopy (FTIR), scanning electron microscopy (SEM), *In-Vitro* and *In-Vivo* studies. From all formulations, F2 formulation was considered as optimised formulation which was shown maximum drug release 97.31±0.44) at 60 min.From this study it is concluded that formulation of glyburide nanosuspension may be a promising approach that improves the dissolution rate and hence oral bioavailability.

KEYWORDS: Bioavailability, dissolution, nanosuspension, glyburide, solubility

T428: DESIGN AND DEVELOPMENT OF GASTRO RETENTIVE FLOATING TABLET OF CEFIXIME TRIHYDRATE (CT) BY STATISTICAL OPTIMIZATION TECHNIQUE

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ABSTRACT

The purpose of research was to design and development of gastro reten-tive floating tablet of cefixime Trihydrate (CT) by statistical optimization technique and to investigate the effect of formulation variables on drug release characteristics. Nearly 20 formulations were prepared using Guar gum (viscoelastic agents), sodium alginate (gelling agent) and sodium CMC (Channeling agent) as independent variables so as to get the optimum formulation by central composite design of response surface methodology. The parameters such as time required for release 50% of drug (t50 %), drug release at 2h (R2h) and mean dissolution time (MDT) was considered the depen- dent variables. The F value for t50 %, R2h and mean dissolution time were found to be 26.54, 22.31 and 61.25, respectively indicating that the models are significant. Further R2 (coefficient of determination) values are 0.967, 0.818, 0.986 for the above param- eter respectively, from the multiple regression equation. The observed and predicted responses of above three parameters are in good agreement shown the maximum coef- ficient of determination (R2). Optimum formulation was found from desirability plot and overlay plot. Least precision was observed when experimental values of responses were quantitatively compared with predicted values of the optimized formulation. No chemical interaction were observed when FTIR and DSC data of pure drug and the optimized formulation (XG21) were compared. From the dissolution data, it was found that the formulation (XG21) followed Higuchi's release (R2=0.997) with a non-Fickian diffusion mechanism (n=0.62**).**

KEYWORDS: Gastro Retentive Floating Tablet, Cefixime Trihydrate, Optimization Technique

T429: FORMULATION AND EVALUATION OF ITRACONAZOLE LOADED NANOEMULGEL TO TREAT FUNGAL INFECTION

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ABSTRACT

The aim of present work was to formulate a nanoemulgel for topical delivery of poor water soluble BCS class-II drug Itraconazole which is useful in treatment of fungal infection. Being an emerging transdermal delivery tool, nanoemulgel has proved to show surprising upshots for the lipophilic drugs over other formulations. This lipophilic nature of major-ity of the newer drugs developed in this modern era resulting in poor oral bioavailability and absorption. Therefore, this novel transdermal delivery system has been proved to be advantageous over other oral and/or topical drug delivery to avoid such disturbances. These nanoemulsions are basically oil-in-water type emulsions which gelled with the use of some gelling agent. This gel phase in the formulation is non-greasy which favours user compli- ance and stabilize the formulation through reduction in surface as well as interfacial tension. Simultaneously, it can be targeted more specifically to the site of action and can avoid first pass metabolism and relieve the user from gastric/systemic inconvenience. The objective of this project was to develop a gellified nanoemulsion for control delivery of Itraconazole. In present work we prepared and optimized nanoemulsions (oil in water type) and then incorporated in 2% carbopol-934P and also made an emulgel in combination of 2% HPMC K-100 and 2% carbopol-934P. The best prepared formulation was evaluated on basis of pH, spreadability, Transparency, Viscosity, Rheological Study drug content, In-vitro release, skin irritation, Particle size, Microbial Assay, short term Stability Studies and comparison with bioequivalent marketed product. The optimized Itraconazole nanoemulgel formulation (F1and F3) was white and creamy preparation.

The particle size of optimized formulation of gellified nanoemulsions ranges between 10-200 nm. The pH values of all prepared formulation range from 5 to 6, which are considered acceptable to avoid risk of irritation upon application to the skin. The result of studied revealed that the F1 and F3 shows 95% release. The result of micro- bial assay compared with marketed product, the result shows better inhibition of optimized batch than that of marketed product. Hence it can be concluded that nanoemulsion based gel system containing Itraconazole is more effective and safe system for sustain delivery to treat fungal infections.

KEYWORDS: Itraconazole, Nanoemulsion, Nanoemulgel, Topical drug delivery

T430: FORMULATION AND EVALUATION OF VESICULAR CARRIER LOADED RIZATRIPTAN BENZOATE GELS FOR INTRANASAL DRUG DELIVERY

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ABSTRACT

Migraine is a mysterious, chronic, episodic, neurovascular disorder that affects millions of people worldwide. Triptans are the first choice of drugs for mod-erate-to-severe migraine attacks in all the management guidelines published in several countries including USA, UK, Italy, Canada, Germany and France. Rizatriptan Benzoate has an oral bioavailability of 45%. Hence an approach to deliver the drug through nasal cavity to its site of action was adopted which facilitates the drug to cross BBBthus, increasing its bioavailability as compared to oral route. The delivery of the drug through the olfactory region allows the drug to directly reach affected nerves and exert its therapeutic action. However Rizatriptan Benzoate (RZB) belongs to BCS class III and so it has limited permeability. Hence it was decided to prepare transfersomes which have extensive permeability characteristics. In the present research work an attempt has been made to design, formulate and evaluate transfersomes for nasal drug delivery loaded with RZB. It improves patient acceptability, avoids first pass metabolism, minimizes the side effects, and improves the physiological and pharmacological response by avoiding fluctuations in drug levels. Transfersomes were prepared by both the lipid film hydration method and the hand shaking method. The drug was incorporated in various formulations composed of dif-ferent ratios of soya phosphatidylcholine, span 80 and tween 80, prepared by lipid film hydration by rotary evaporation method . All the prepared formulation were evaluated for particle size, PDI, entrapment efficiency (%EE), invitro drug release and permeation profile. The vesicle size of best formulations were 78.08 nm and 119.2 nm respectively and the PDI of the best formulations werefound to be 0.738 and 0.310 respectively. The invitro release profile and the ex-vivo permeability studies will be carried out for the most satisfactory formulation.The flux, permeability co-efcient value will be reported. The enhancement of the drug permeation from drug loaded vesicles in comparison to the pure drug will be reported.

KEYWORDS: Rizatriptan Benzoate, transfersomes, nasal drug delivery

T431: "STUDIES ON DEVELOPMENT AND EVALUATION OF MATRIX-TYPE TRANSDERMAL FILMS OF GLIPIZIDE"

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ABSTRACT

OBJECTIVE: Glipizide is one of the most effective antidiabetic agent used in the manage-ment of Type II diabetes. The drug requires controlled release due to its short biological half-life (3.4 ± 0.7 h) which necessitates its administration orally in two or three doses. In the present study, attempts were made to develop and evaluate transdermal matrix films of glipizide to achieve controlled release and to improve better clinical efficacy. **METHODS:** Drug loaded transdermal films of ERL 100 and ERS 100 in different ratios were prepared with & without permeation enhancer. FTIR study was used to assess interaction between drug and polymers. All batches of films were evaluated for weight&thickness uniformity, folding endurance, water vapour transmission (WVT), drug content uniformity. The in vitro drug release studies of films through rat abdomi- nal skin was done in phosphate buffer pH 7.4 using modified Keshary-Chein diffusion cell and data was computed using dissolution software PCP DISSO V3. The in vitro release data were treated with various kinetic models such as Higuchi, first order, zero order and Korsemeyer-Peppas model. **RESULTS:** FTIR studies ensured the compatibility of polymers with the drug. Thin, flex-ible, smooth surface and transparent films were obtained. Thickness, mass, folding endurance and drug content were found to be uniform and reproducible with low SD values. WVT through all batches of films followed zero order kinetics. Comparatively, WVT was more in case of films prepared with permeation

enhancer than films pre-pared without permeation enhancer. All batches of films showed prolonged drug release over a period of 12 h. The in vitro permeation studies prepared using blends of ERL 100: ERS 100 in different ratios without permeation enhancer (F3 to F7), revealed that the drug release was decreased with increasing amount of the ERS 100. The flux and drug release rate increased in case of films prepared with permeation enhancer. The release of drug from films followed predominantly Higuchi kinetic model compared to other kinetics. Based on Korsemeyer-Peppas model the mechanism of drug release was concluded as non-Fickian diffusion controlled (anomalous diffusion). **CONCLUSION**: Transdermal matrix films of glipizide developed usingblends of ERL 100 and ERS 100 at different ratios holds potential for drug delivery to systemic circulation which gives sustained and prolonged release up to 12 h. Thematrix films also provide an additional advantage of circumventing hepatic first pass metabolism associated with the model drug glipizide and consequently achieving higher systemic bioavailability.

T434: FORMULATION AND EVALUATION OF ALGINATE BASED RAMIPRIL LOADED MUCOADHESIVE MICROBEADS: A GASTRO RETENTIVE DRUG DELIVERY APPROACH

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ABSTRACT

The aim of the proposed research work was emphasized on preparation of sustained release antihypertensive drug ramipril (RMP) loaded mucoadhesive micro-beads using natural and synthetic polymers for gastroretentive drug delivery. RMP Microbeads are prepared by ionotropic gelation technique using Calcium chloride as cross linking agent, Sodium alginate is used as gelation agent and HPMC K15, Hydroxy ethyl cellulose, Xanthan gum and chitosan were used as release modifiers. Prepared microbeads were subjectd to micromeritic properties to study angle of repose, true den-sity, Hausner's ratio, Carr's index and characterized using swelling index, entrapment efficieny, and percentage content. SEM studies revelead that microbeads are spherical and uniform in shape. FTIR, DSC, and TLC studies revealed no polymer drug interac-tion. Mucoadhesive strength of the microbeads were evaluated using ex invivo washoff test and shown good mucoadhesive property. Invitro evaluation study for drug release was performed at a pH of 2.1 for intial 2 hours and pH 7.8 for 6 Hours. Drug release kinetic study was done using Highuci, Koresmeyer's, Peppas's model, which has shown a first order release for highuchi model. Ramipril loaded with sodium alginate and HPMC K15 microbeads has shown Extended and sustained release and the method can be used successfully for formulation of sustained release characteristics.

KEYWORDS: Ramipril, Calcium alginate, Ionotropic gelation

T435 FORMULATION AND EVALUATION OF LORATADINE FAST DISSOLVING FILMS

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ABSTRACT

BACKGROUND AND OBJECTIVE: Loratadine is a second-generation H1 histamine antagonist drug used to treat allergies and symptomatic relief of allergy such as allergic rhini-tis, urticaria and skin allergies. Development of oral fast dissolving films (OFDF) by conventional solvent casting method usingnovelhydrophilic polymers. Objective of present investigation was to develop films using conventional equipments, commonly available excipients and with a small number of processing steps. **METHODS:** Loratadine OFDF were formulated by conventional solvent casting method using loratadine, HPMC E15, HPMC E5, SLS, ethanol and PEG 400. Ten different batches viz., F1 to F10 were tried during the study and the results are noted during eval-uation of each formulation for appearance, folding endurance, surface pH, thickness, elongation, weight variation, drug content, disintegration time and dissolution studies. **RESULTS:** The drug content was uniform in all the formulations with low SD values. Appearance, thickness, mass variation, elongation, folding endurance, disintegra-tion time and dissolution studies. The dissolution study suggests, the increase in drug release was dependent on type of polymer. **CONCLUSIONS:** In the present study fast dissolving drug delivery system of loratadine were successfully developed in the form of oral fast dissolving films which offers a suitable physico mechanical characteristics and practical approach in serving desired objective of faster disintegration and dissolution characteristics with increase in patient compliance by avoiding the first pass metabolism and enhance the bioavailability of the drug.

KEYWORDS: Loratadine, fast dissolving films, PEG 400, HPMC E15 and E5, in vitro dissolution.

T431: FORMULATION AND EVALUATION OF EFFERVESCENT FLOATING MICROSPHERES OF AMLODIPINE BESYLATE"

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ABSTRACT

OBJECTIVES: Amlodipine is an antihypertensive drug used for the treatment of hyperten-sion and angina pectoris. It has many adverse effects when given orally and has maximum solubility in acidic pH. Hence, effervescent floating microspheres of drug were developed to increase oral bioavailability with an aim of reducing undesirable side effects with improved patient compliance.**METHODS:** Effervescent floating microspheres of drug were prepared using Eudragit S (ES) 100 alone (F1) keeping core: coat ratio (1:9 w/w) by solvent evaporation method using sodium bicarbonate as effervescent agent. Next, floating microspheres of drug with a coat consisting of ES 100 in combination with different hydrophilic polymers namely, HPMC K100M, HEC, PVP K30, carbopol, sodium CMC, HPMC K4M were prepared at coat: coat ratio (8:1w/w) of the polymer (F2-F7). Drug and polymer compatibility study was done by FTIR. All batches of floating microspheres were evaluated for % yield, drug content, micro-encapsulation efficiency, swelling index, particle size analysis and in vitro floating ability. In vitro dissolution studies were conducted using USP type II apparatus in buffer of pH 1.2 up to 12 h and the dissolution data was computed by using dissolution software PCP DISSO V3. **RESULTS:** FTIR studies confirmed the compatibility of drug and polymers. Developed floating microspheres were fine, fairly spherical and free flowing. The % yield and drug entrapment efficiency were satisfactory and drug content was uniform. Particle size fraction of 10/16was obtained for all floating microspheres. Formulations showed excellent floating ability with the absence of floating lag time. The drug release from all floating microspheres was slow and spread over extended period of time (12 h) with excellent floating properties. A significant retardation of drug release was observed from floating microspheres of ES 100 alone (F1). The rate and extent of drug release was increased from microspheres of F2-F7 batches. The order of drug release retardation from F2-F7 batches was F7 > F6 > F5 > F4 > F3 > F2. The drug release from microspheres showed best fit to zero order model. Batches F1-F6 exhibited non-Fickian diffusion controlled release whereas, F7 batch of microspheres was considered as Super Case II transport mechanism. **CONCLUSIONS:** The designed effervescent floating microspheres of amlodipine besylate com- bining excellent buoyant ability and suitable drug release pattern are suitable to increase the gastric residence time up to 12 h. And thus enhance the bioavailability after oral administra- tion with reducing adverse side effects.

T437: NANOSPONGES IN THE TREATMENT OF NECROTIZING FASCIITIS

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ABSTRACT

Necrotizing fasciitis (NF), commonly known as flesh-eating disease, is an infection that results in the death of the body›s soft tissue. Clindamycin is the first choice of drug for the treatment of necrotizing fasciitis. It is a BCS Class III drug having low permeability which resulted in low topical bioavailability of 4-5% and proteins binding of 95% hence, nanosponges are prepared to increase the topical bioavailability as it releases the drug to specific targeted site instead of circu-lating throughout the body thereby making it more effective for treating necrotizing fasciitis. Hence it was decided to prepare nanosponges which have extensive perme-ability characteristics and sustained effect. In the present research work Nanosponges were prepared by emulsion solvent dif-fusion technique using different proportions of ethyl cellulose and polyvinyl alcohol were taken. The disperse phase containing ethyl cellulose was dissolved in 20ml of dichloromethane and slowly added to definite amount of Poly vinyl alcohol in 100 ml of aqueous continuous phase. Then the mixture was stirred at 1000 rpm for 2 hours on a magnetic stirrer. The nanosponges formed were collected by filtration and dried in oven at 40oC for 24 hours.The particle size were found to be 793.4nm and the PDI were found to be 0.270. Since the particle size were found to be too high. The modification of the emulsion solvent diffusion method was carried out by using differing the propor-tions of ethyl cellulose and polyvinyl alcohol. The reaction mixture was homogenized using Ultra Turrax followed by sonication using Probe Sonicator for 20mins. The nano-sponges formed were then lyophilized and stored in a well closed container.The particle size of all formulation

was above 300nm except formulation F3which was found to be 90.18nm and the PDI of the same was found to be 0.389 respectively. The drug loading was done for formulation F3 with 10mg of Clindamycin phosphate which showed no change in particle size. Hence the nanosponge system could be used to have better pen-etration of drug through the skin and we can speculate that clindamycin nanosponge formulation is a good candidate for topical drug delivery in the treatment of skin and soft tissue infection associated withNecrotizing fasciitis infection.

KEYWORDS: Necrotizing fasciitis, Clindamycin phosphate, Nanosponges,

T438: "FORMULATION AND EVALUATION OF NON-EFFERVESCENTFLOATING TABLETS OF NEVIRAPINE"

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ABSTRACT

OBJECTIVE: Nevirapine is an antiretroviral drug belongs to BCS class II & difficult to achieve optimal dissolution kinetics from the dosage form. Floating drug delivery system is suitable for nevirapine as the absorption and solubility of nevirapine is high at pH < 3. Hence, this work was planned to design non-effervescentfloating tablets of nevirapine using swellable polymers to enhance bioavailability and patient compliance**. METHODS:** Non-effervescent floating tablets of nevirapine were prepared using HPMC K4M alone by wet granulation method. Next, tablets were formulated using combinations of HPMC K4M: Carbopol 934P and HPMC K4M: Xanthan gum at 1:2, 1:1 and 2:1 ratios. Before compression, granules were subjected for various pre-compressional characteristics. Then tablets were evaluated for thickness, hardness, friability, weight variation test, drug con-tent uniformity, swelling studies and in vitro evaluation of floating properties of tablets. In vitro dissolution studies were performed in USP type II apparatus at 37 ± 0.5°C with 50 rpm in buffer of pH 1.2 up to 12 h. The in vitro data obtained were computed using dissolution software PCP DISSO V3. Various kinetic equations were applied to interpret the drug release rate from tablets. **RESULTS:** Pre-compressional characteristics of granule bed like bulk density, tapped density, compressibility index, Hausner's ratio and angle of repose were found satisfactory. Floating tablets were found uniform in their thickness and exhibited sufficient hardness. Friability below 1% revealed that tablets have sufficient mechanical strength. Weight variation and drug content was found within the acceptable limits as per IP standards. Swelling index was low with HPMC K4M alone tablets than with tablets formulated using combinations of matrix polymers i.e., HPMC K4M: Carbopol 934P and HPMC K4M: Xanthan gum. Tablets formulated using higher amount of carbopol 934P and xanthan gum showed higher swelling index than with lower amounts. Floating lag time of tablets was found in the range of 3-18 minutes and tablets remained buyout for more than 12 h. The in vitro drug release from tablets was slow and prolonged over a period of 12 h with excellent floating properties bymaintaining good matrix integrity. Comparatively, HPMC K4M: Xanthan gum formulations retarded drug release more than HPMC K4M: Carbopol formulations. The in vitro release drug profiles of all formulations exhibited to Higuchi's equation. **CONCLUSIONS:** Based on outcome of investigations, non-effervescent floating tablets of nev-irapine were successfully formulated using various swellable polymers like HPMC K4M, carbopol 934P and xanthan gum at different ratios by wet granulation method. Hence, the designed non-effervescent floating tablets, combining excellent buoyant ability and suitable drug release pattern are suitable to increase the gastric residence time and thus enhance the bioavailability after oral administration with reducing undesirable side effects

T439: FORMULATION AND EVALUATION OF ARIPIPRAZOLE ORODISPERSIBLE TABLETS

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ABSTRACT

BACKGROUND AND OBJECTIVE: Orally dispersible tablets (ODT) are those when put on tongue disintegrate/dissolve/disperse instantaneously releasing the drug which dissolve or disperses in the saliva. Aripiprazole has selected as model drug for the study. Objective of present investigation was to design aripiprazole orally dispersible tablets using novel superdisintgrating agent, and special directly compressible diluent. **METHODS:** Aripiprazole (ODT) were formulated by direct compression method using crosscaramellose sodium with directly compressible diluent Galen IQ. Nine different formulations viz., F-1 to F-9 were prepared and subjected for precompression and post-compression evaluation**. RESULTS:** Formulations prepared with crosscaramellose sodium at 12.5% shows better drug release when comapred to 10% and 7.5% formulations. The

similar results were observed with sodium starch glycolate at 12.5% shows better drug release when com- pared to 10% and 7.5% and crosspovidone at 12.5% shows better drug release when compared to 10% and 7.5%. **CONCLUSIONS AND INTERPRETATION:** In vitro drug release suggest that the drug release was greater to small extent with the formulations prepared with croscaramellose when compared to sodium starch glycolate formulations which are inturn greater than cross povidone formulations. The in vitro release studies proved that the tablets produced using the proposed formulations F-1 to F-9 were found to comply with pharmacopeial stan-dards for orally dispersible tablets.

KEYWORDS: Aripiprazole, orodispersible, in vitro

T440 NANOPARTICULATE BASED DRUG DELIVERY SYSTEM FOR THE EFFECTIVE TREATMENT OF PSORIASIS

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ABSTRACT

Psoriasis is a chronic inflammatory skin disorder characterized by enhanced epidermal proliferation leading to erythema, scaling and thickening of the skin, and it is a T-cell mediated auto-immune disease. It is a noncontagious, genetically influenced and immunologically based inflammatory disease of the skin and joints. Tacrolimus is a macrolide calcineurin inhibitor for topical administration in atopic der- matitis. When administered orally the drug have several drawbacks such as first pass metabolism and gastric irritation and hence an attempt is made to deliver the drug throughtopical route for the treatment of psoriasis. In the present research work solid lipid nanoparticles were prepared by hot homogeni- zation method using different proportions of the lipid glyceryl monostearate (GMS), surfactant tween 80 and 50ml of aqueous continuous phase.The lipid melt was prepared and poured into the aqueous solution of surfactant maintaining the temperature upto 60˚C. The reaction mixture was then stirred in a magnetic stirrer by maintaining the temperature at 60˚C followed by homogenization using ultra turrax homogenizer at different speeds for different time intervals. All the prepared SLNs were evaluated for particle size and PDI. The particle size of the best formulation was found to be 169nm and PDI was found to be 0.485 respectively indicating that Nanoparticulate carriers through the topical route can be a promising drug delivery for the effective treatment of psoriasis. In conclusion we can speculate that tacrolimus loaded SLNs formulation can be a good candidate for topical drug delivery in the effective treatment of psoriasis. The further studies will be carried out for entrapment efficiency (%EE) and permeability studies.

KEYWORDS: Psoriasis, Tacrolimus, Solid lipid nanoparticles.

T441 EVALUATION OF BIOENHANCING PROPERTY OF A SOLID ORAL DOSAGE FORM USING A NATURAL MUCILAGE - AN EX-VIVO APPROACHS

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ABSTRACT

Traditional aboriginal knowledge of plants is responsible for most of the medicine and food used in modern society. Herbs have been used throughout time as food and as a primary tool for maintaining health and aiding in the recovery of disease. About 80% of the world population use plant based medicines and about one third of the world countries depend on herbal medicines. In any oral allopathic dosage form the drug gets metabolized by first pass metabolism and only the other reach the circulation. To increase the bioavailability of such medicine an agent that can increase or enhance the drug bioavailability and which can reduce the dose of drug is desired. Such an agent is called bioenhancer. A bioenhancer is an agent capable of enhancing bioavailability and efficacy of a drug with which it is co-administered, without any pharmacological activity of its own at therapeutic dose used. The best way to achieve reduction in drug dosage, thereby drug toxicity and cost is by increasing the drug's bioavailability. One of the ways of increasing the bioavailability of drugs is by addition of molecules which do not have similar therapeutic activity but increase the bioavailability when incorporated in the formulation of another drug. These are called as bioenhancers and they do not show synergistic effect with the drug. Modern researchers show increased interest in the enhancement of bioavailability of most of the drugs by addition of various herbs with bioenhancing property. Trianthemadecandra is a prostate herb distributed in tropical and subtropical regions of the world. It has been known since ancient times for curative properties and it is utilized for various ailments such as burns, wounds and it is known for its antimicrobial activity. The everted gut sac technique was first described by Wilson and Wiseman in 1954 to study the transport of sugars and amino acids. The everted sac technique offers a simple and inexpensive method without any specialized equipment. It

can provide information on the mechanism of absorption and affords to investigate the differ-ences in absorption of compoundsalong the length of the gastrointestinal tract and an interspecies comparison.Thus the present work is aimed to evaluate the bioenhancing property of a solid oral dosage form using a bioenhancing agent from natural source by everted sac method.

KEYWORDS: Trianthemadecandra, bioenhancer, herb, everted sac

T442 STUDIES ON ENHANCEMENT OF SOLUBILITY AND DISSOLUTION PROPERTIES OF CELECOXIB BY SOLID DISPERSION TECHNIQUE

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ABSTRACT

BACKGROUND AND OBJECTIVE: The objective of the present study was to enhance the solubility of celecoxib by solid dispersion technique. Celecoxib is an anti-inflamatory agent having poor aqueous solubility after oral administration. Solid dispersion is one of the most commonly used techniques to improve the aqueous solubility of poorly water soluble drugs. **METHODS:** Solid dispersion systems of celecoxib with novel hydrophilic polymers viz. HPC and maltodextrin were prepared by physical mixture, solvent evaporation and kneading methods at 1:1 and 1:3 drug: carrier ratios. The solid dispersion systems were studied for its drug content, saturation solubility, FTIR and in vitro dissolution. **RESULTS:** The drug content was uniform, solubility of the drug increased linearly as a function of the carrier concentration and method. The FTIR studies suggest mild to no interaction at molecular level. The dissolution study suggests, the increase in drug release was dependent on type of method of preparation. The DE60 and DP60 of solid dispersion systems were greater when compared to pure drug. The dissolution follows first order model and obeyed Hixson- Crowell's cube root law. **CONCLUSIONS AND INTERPRETATION:** The celecoxib solid dispersion systems can be con- veniently prepared using HPC, maltodextrin by adapting conventional methods viz., solvent evaporation and kneading methods. One-way ANOVA was used to test the statistical significance of difference between pure and prepared samples. The DP60 and DE60 values were significantly higher ($P<0.05$) in solid dispersion systems prepared by kneading method when compared to pure celecoxib, physical mixture and solvent evaporation methods.

T443: PREPARATION AND EVALUATION OF CAPECITABINE NIOSOMES

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ABSTRACT

BACKGROUND AND OBJECTIVE: Niosomes are non-ionic surfactant vesicles in aqueous media resulting in closed bilayer structures that can be used as carriers of amphi-philic and lipophilic drugs. Capecitabine is a chemotherapeutic agent used in the treatment of metastatic breast and colorectal cancers. Niosomal drug delivery systems of capecitabine were planned with non-ionic surfactants for oral administration**. METHOD:** Capecitabine niosomes were prepared by thin film hydration technique using tweens, spans and cholesterol at different molar ratios. All the niosomal systems were evaluated for entrapment efficiency, drug content, size, shape andin vitro drug release studies and interactions by FTIR studies. **RESULTS**: In span 80 and span 20 formulations, as the concentration of cholesterol increased the entrapment efficiency decreased whereas, in tween 80 and tween 20 formulations as the concentration of cholesterol increases the entrapment efficiency increases. The drug content was uniform in all the niosomal suspensions with low SD values. The prepared niosomes were of uniform size and spherical in shape. The FTIR studies suggest that no interaction between the drug and added excipients. **CONCLUSIONS AND INTERPRETATIONS:** In tween 20 and tween 80 niosomal formulations the best fit model was found to be matrix and T-3 and T-5 formulations best fit model was Peppas. In span 20 and 80 niosomal formulations the best fit model was found to be Peppas. The exponential 'n' values were found to be less than 0.5 in span formula-tions and greater than 0.5 in tween formulations suggesting that the drug was released by Fickian in span formulations and non Fickian (anomalous) in tween formulations**.**

T444: FORMULATION AND EVALUATION OF MUCOADHESIVE MICROSPHERES OF LAMIVUDINE USING NATURAL POLYMERS

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ABSTRACT

BACKGROUND AND OBJECTIVE: Lamivudine has a half life of 5-7 hrs and is taken twice daily in large number of patients which leads to patient's compliance. Thus the devel-opment of mucoadhesive microspheres for controlled release would be advantageous. The objective of this study was to formulate and evaluate lamivudine mucoadhesives microspheres using sodium alginate with chitosan and mucilages isolated from bhendi. **METHODS:** The orifice ionic gelatin method was adapted for preparation of mucoadhe- sive microspheres of lamivudine. The 4 formulations viz., HA- 1 to HA-4 were prepared using sodium alginate as coating polymer and chitosan, mucilage isolated by bhen-dias mucoadhesive natural polymers. The prepared microspheres were evaluated for particle size, particle shape, surface morphology, FTIR study, encapsulation efficiency, swelling ratio, invitro wash off test and in vitrodrug release. The release rates were stud- ied by using dissolution software PCP Disso V3. **RESULTS:** Mucoadhesive microspheres were found to be spherical, discrete, free flowing. The encapsulation efficiency found to be good in all formulations. All the micro- spheres showed good mucoadhesive property and swelling index. The drug release was better at 1:3 core coat ratio than the 1:2 and 1:1 ratio irrespective of mucoadhesive polymers. Invitro release suggests the best fit model was found to be Korsemeyer pep-pas with n value less than 0.5 indicating drug release mechanism is fickian diffusion and diffusion controlled. **CONCLUSION:** All the formulations show optimum drug release at the end of desired period. HA- 1, HA-2, HA-3 and HA-4 was found to be optimum which showed maxi- mum drug release over period of 24hrs., with maximum microencapsulation efficiency and good mucoadhesive property.

KEYWORDS: Mucoadhesive microspheres, chitosan, bhendi, orifice ionic gelation

T445: FORMULATION AND CHARACTERIZATION OF CHITOSAN BASED NIFEDIPINE NANOPARTICLES

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ABSTRACT

Oral drug delivery system has been known for decades as the most widely utilized route for drug administration among all the routes.More than 50% of drug delivery systems available in the market are oral drug delivery system. Now- a - days most of the pharmaceutical scientists are involved in developing the ideal drug delivery systems.However, this approach is befilled with several difficulties such as solubil-ity, bioavailability etc. Many of the new chemical entities (approximately 40% or more) being developed through drug discovery programmers are poorly water soluble and poor bioavailability. The formulation of poorly water soluble drugs has been always a challenging problem faced by pharmaceutical scientists. The low saturated solubility and dissolution velocity leads to poor bioavailability. The problem is more severe for drugs belonging to BCS class II. Nifedipine is a selective hypertensive calcium channel protein inhibitor which targets L-type voltage-sensitive calcium channels. Nifedipine is a vasodilator that is selective for ionotropic over chronotropic cardiac effects. The therapeutic use of nifedipine is limited by the rapidity of the onset of its action and its short biological half-life. In order to produce a form devoid of these disadvantages we made nanoparticles of nifedipine by using ionotropic gelation method using chitosan and sodium TPP. Total eleven formulation s were prepared by using different drug: polymer ratios. Among them 0.5% chitosan containing F5 formulation shows maximum drug release than the other trails. So F5 formulation was considered as the opti-mized formulation. The drug content of the formulated Nanoparticles was found in the range of 72.31 to 87.22 % the entrapment efficacy of the formulated Nanoparticles was found to be in the range of75.48%-91.22%respectively. FT-IR studies revealed that drug and excipients used have no interactions.

KEYWORDS: Nifedipine, Chitosan, sodium TPP, FT-IR agent used

T446: FORMULATION AND INVITRO CHARACTERIZATION OF PALIPERIDONE NANOSUSPENSIONS

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ABSTRACT

Oral drug delivery system has been known for decades as the most widely utilized route for drug administration among all the routes. More than 50% of drug delivery systems available in the market are oral drug delivery system. Now-a - days most of the pharmaceutical scientists are involved in developing the ideal drug delivery systems. However, this approach is befilled with several physico-chemical difficulties such as solubility. Many of the new chemical entities (approximately 40% or more) being developed through drug discovery programmers are poorly water soluble. The formulation of poorly water soluble drugs has been always a challenging problem faced by pharmaceutical scientists. The low saturated solubility and dis- solution velocity leads to poor bioavailability. The problem is more severe for drugs belonging to BCS class II. Paliperidone is a SR (5-HT2) receptor antagonist and D2DR inhibitor was BCS class II drug with low water solubility and the abso-lute oral bioavailability of Paliperidone following Paliperidone administration is 28%. So, it is essential to improve the solubility to enhance its bioavailabil-ity. Nanosuspension technique is a modern and a more innovative approach used widely to increase the solubility of the drug moieties. Nanosuspension of Paliperidone by solvent evaporation method using various polymers such as SLS, Pluronic F127, PVP-K90, PVA, and methanol. IR spectroscopic studies indicated that there are no drug-excipient interactions. All the prepared formulations Entrapment efficiency was found to be in the range of 82.16%-96.20%respectively. From the in vitro dissolution studies by comparing to other all the formulations F9 is the best formulation which showed 99.86% of drug released respectively within 60 min and follows Zero order release kinetics.

KEYWORDS: Paliperidone, pluronic F127, PVP-K90, PVA, Scanning Electron Microscopy (SEM), UV Spectroscopy.

T447: DEVELOPMENT OF BUCCO-ADHESIVE TABLET CONTAINING HERBAL EXTRACT FOR HALITOSIS

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ABSTRACT

The present investigation aimed for the development of buccoadhesive tablet and was compressed by direct compression. HPMC E15, carbopol 940 and xanthan gum are the three mucoadhesive polymers selected on the basics of preliminary trial formulations. Ethyl cellulose is used as backing membrane. Box Behnken design was employed for the present study by using design expert software (version 10). Prepared tablets were evaluated for all the in process tests and bioadhesive strength, ex vivo resi-dence time and ex vivo release study. From this study, carbopol 940 show better result than the other polymer for sustaining the release with adequate bio adhesiveness and swelling property. The ex vivo release study of the optimized batch F1 and F7 shows 89.7% and 94.6% respectively. The release kinetics of F1 shows non-fickian type of release and the second optimized batch F7 involves fickian type.

KEYWORDS: Buccoadhesive tablet; Box Behnken design; Herbal extract; Halitosis.

T448: SIMVASTATIN SUSTAINED RELEASE TABLETS

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ABSTRACT

Simvastatin is a hypolipidemic drug used to control elevated cholesterol, or hypercholesterolemia. Simvastatin is a member of the statin class of pharmaceuti-cals, is a synthetic derivative of a fermentation product of Aspergillus terreus. The aim of present study was to prepare Simvastatin sustained release tablet by wet granulation method using different polymers. Tablet is an important area of research in the field of drug delivery, because then the ability to deliver

the wide range of drug for sus-tained period of time and therefore the dose and frequency of administration would be reduced hence increasing patient compliance. The formulated uncoated tablet of Simvastatin is evaluated successfully within the evaluation parameters which suggest that the tablet have better therapeutic level in systematic circulation. Among the formu-lations, formulation VI containing Methocel K15M (100mg) & Methocel K100M (80 mg) & Xanthan gum (20mg) showed better release profile than other formulations. The FTIR studies showed that there are no interactions between the excipients and the drug. The better formulation had shown a stable release profile after being kept for acceler-ated stability condition for a period of three months

T449: FORMULATION AND EVALUATION OF NIOSOMAL IN-SITU GEL OF MIRTAZAPINE FOR INTRA-NASAL DELIVERY"

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ABSTRACT

Mirtazapine is the only tetracyclic antidepressant that has been approved by the FDA to treat depression and anxiety. Mirtazapine is a potent antagonist at post-synaptic 5- HT2 and 5-HT3 (serotonergic) and central noradrenergic receptors and acts by increasing central noradrenergic and serotonergic (5-HT1) neurotransmission. Absolute bioavailability of mirtazapine is only 50% due to high first pass metabolism. Objective: The nasal mucosa has several advantages like, large surface area, porous endothelial membrane, high blood flow, avoidance of first-pass metabolism and ready accessibility that lead to faster and higher drug absorption. Keeping these facts in mind, the objective of the present study was to develop Mirtazapine loaded niosomal in-situ nasal gel. **METHODS:** Mirtazapine niosomal in situ nasal gel is formulated and evaluated with the objective to deliver drug to the brain via intranasal route. Niosomes were prepared by thin film evaporation method.Niosomes were characterized for particle size, zeta potential, entrapment efficiency and in vitro drug release.Mirtazapine loaded niosomes were further incorporated into Carbopol 934P and HPMC K4M liquid gelling system for the formation of in situ gel. The resultant solution was assessed for various param- eters, Clarity, Appearance, uniformity, consistency, and viscosity at nasal pH and gelling capacity at nasal pH. **RESULTS:** The vesicle size of all niosomal suspension batches ranges between 80-162.5 nm and PDI between 0.198-0.242. The formulation was found to have an optimum viscosity that will allow easy instillation in to nasal cavity as liquid drops, which would undergo a rapid sol-to-gel transition. Niosomal in-situ gel containing optimum concentration of Carbopol and HPMC was selected as developed formulation, with satisfactory attri-butes of gelling capacity and easy instillation in to nasal cavity. **CONCLUSION:** Thus, the application of niosomes proves the potential for intranasal deliv-ery of Mirtazapine over the conventional gel formulations.

KEYWORDS: Mirtazapine, Niosomes, In-situ gel, Intra-nasal delivery.

T450: FABRICATION AND CHARACTERIZATION OF CHITIN HYDROGEL NANO SILVER COMPOSITE SCAFFOLD FOR WOUND DRESSING APPLICATIONS

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ABSTRACT

Wounds are physical injuries that result in an opening or break of skin that cause disturbance in the normal skin. So, a wound has to be given attention and appro- priate clinical care has to be taken. A wound dressing material is the one which is applied to the wound to promote healing and to protect the wound from further harm.A scaf-fold is a wound dressing material with three dimensional extracellular architecture which can be fabricated in the shape of the tissue that we want to restore, with the help of either polymer hydrogel, self-assembly, nonwoven matrix, Nano-fibrous electro spun matrices, 3D weaving, or any other textile technology-based techniques, depend- ing upon their structural and functional requirements.One of the best approaches for treating the wound infection is the use of wound dressing with antibacterial agents having a broad-spectrum of activity and high kill rate. Chitin is one of the most abun- dant organic materials in nature and can be obtained from the shells of crab, shrimp and squid pens. Chitin is found to possess high activity as a wound healing accelera- tor. The wound healing ability and anti-bacterial activity of chitin can be enhanced by the addition of silver nanoparticles.Thus, the current work is aimed to fabricate and characterize chitin hydrogel Nano silver composite scaffold for wound dressing appli- cations. The present work involves synthesis of chitin from crab shell, preparation of chitin hydrogel, preparation of nano silver solution and fabrication

of chitin hydrogel nano silver composite scaffolds. Five formulations were developed and the optimized formulation is characterized for SEM, TEM, XRD, Zeta potential, *in-vitro* drug release and in-vitro anti-bacterial activity. The developed formulation would be a potential bio- material for wound dressing applications.

KEYWORDS: Chitin, scaffold, nanosilver, hydrogel, wound dressing.

T451: FEASIBILITY OF PALIPERIDONE FOR TRANSDERMAL THERAPEUTIC SYSTEMS: EX- VIVO PERMEATION KINETIC STUDIES OF DRUG THROUGH RAT ABDOMINAL SKIN

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ABSTRACT

The present study, feasibility of paliperidone for transdermal therapeutic sys-tems was investigated. Paliperidone is a second generation atypical antipsychotic drug used in the treatment of schizophrenia and restless leg syndrome, which is incompletely absorbed from GIT with oral bioavailability of 28%. In addition, it has low dose 1.5- 9 mg per day with high oral side effects. Performulation studies were conducted to authentify the drug and to determine its purity by melting point, solubility, partition co- efficient, ATR-FTIR, DSC and HPLC. The results indicated that the received pure drug was authentified as paliperidone and its purity at par with official pharmacopoeia. Ex-vivo permeation kinetic study for paliperidone alone and with 5% concentration of permeation enhancer's hyaluronidase, dimethylsulfoxide, groundnut oil and tween 80 was conducted using modified Franz-diffusion cell through rat abdominal skin as a barrier. The receptor phase containing of 20% PEG in normal saline and maintained at 37oC. The steady state flux (Jss), permeability coefficient (Kp) and enhancement ratio (ER) of pure drug and with enhancers was calculated. Hyaluronidase has high perme-ation enhancing activity with the highest permeation steady state flux of 12.038±0.370 µg/cm2/h and cumulative amount of drug permeated at 12 h was 207.9µg/cm2. The enhancement rate of hyaluronidase was 3.69 folds higher than the control (no enhancer) indicating it is an effective permeation enhancer than other permeation enhancers. The enhancement effect of various enhancers on paliperidone permeation through rat skin was in the rank order as follows: Hyaluronidase>Dimethylsulfoxide>Groundnut oil >Tween 80. The results seem promising for formulating the paliperidone transdermal patches with a hyaluronidase as a permeation enhancer.

T452: DEVELOPMENT AND VALIDATION OF BIOANALYTICAL METHOD FOR THE SIMULTANEOUS ESTIMATION OF HYDROCHLOROTHIAZIDE AND VALSARTAN IN HUMAN PLASMA BY LC-MS/MS

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ABSTRACT

A simple, rapid, sensitive and specific method has been proposed for the development and validation of bio-analytical method for the simultaneous estima-tion of hydrochlorothiazide and valsartan using losartan as an internal standard in human plasma by LC-MS/MS. The separation was achieved using ZORBAX SB C18 (5µmx50x3.6mm i.d), mobile phase containing ACN: ammonium Formate (70:30v/v) pH adjusted to 4.25. The flow rate was 0.5ml/min and the injection volume 10µl. The retention time of hydrochlorothiazide and valsartan was found to be 1.22 and 1.08min, respectively. The developed method was found to be linear over the concentration range of 420-8400 (r2 value 0.9932) and 6-122ng/ml (r2 value 0-9954) using losartan as internal standard. LOD and LOQ of valsartan 1 and 3ng/ml and that of hydrochlo-rothiazide was 0.5 and 2 ng/ml respectively. Column oven temperature is ambient and detector is mass detector. Hydrochlorothiazide and valsartan were extracted by Liquid-Liquid extraction method. According to USFDA guidelines the method was established and validated. This method can applied for the Pharmacokinetic, Bioequivalence and Bioavailability studies contains valsartan and hydrochlorothiazide**.**

KEYWORDS: Simultaneous Estimation, Valsartan, Hydrochlorothiazide, Human Plasma, LC-MS/MS**.**

T454 DEVELOPMENT AND VALIDATION OF CRITICAL QUALITY ATTRIBUTES OF A NOVEL FROMULATION OF AN ANTIHYPERLIPIDEMIC DRUG BY QUALITY BY DESIGN APPROACH

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ABSTRACT

The aim of this study was to formulate a novel BCS class II 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 com-mercially available product. The material attributes and CQAs were identified by risk assessment as per International Conference of Harmonization (ICHQ9) quality guide-lines. 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 were performed for the amounts of CCS and MCC in the range of 11 mg- 21 mg and 80 mg-160 mg respectively. Based on the results of screening batches a Response Surface Methodology (RSM) was used for opti-mization. A full factorial central composite design (CCD) with 10 experimental runs was performed by taking MCC and CCS in the range of 80 mg-120 mg and 11 mg-20 mg respectively. Out of these runs batch RI was found to show a drug release of 92.47% in 30mins with MCC of 120 mg and CCS of 16 mg. 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, cen-tral composite design, Atorvastatin.

T455: COMPARATIVE STUDY OF SYNTHETIC AND NATURAL SUPERDISINTEGRANTS ON THE FORMULATION DEVELOPMENT OF FAST DISSOLVING TABLETS CONTAINING MACROLIDE ANTIBIOTIC BY DIRECT COMPRESSION TECHNIQUE

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ABSTRACT

The aim of the present research work is to “Compare the impact of synthetic and natural superdisintegrants on the formulation development of Fast Dissolving Tablets Containing macrolide antibiotic by direct compression technique”. In the pres-ent study an attempt was made to prepare Fast Dissolving Tablets of Azithromycin by Direct Compression technique using synthetic superdisintegrants such as Sodium Starch Glycolate (1:2:3) , Croscarmellose sodium (1:2:3) and natural superdisintegrant such as Plantago ovate mucilage. Totally nine formulations were prepared (S I – S III), (C I – C III), (P I – P III). During the preparation, the powder blends of all the nine formulations were evaluated for various pre compression parameters such as angle of repose, bulk density, tapped density and carr’s index. The findings of all the pre com-pression parameters were within the prescribed limits. The prepared tablets of all the nine formulations were evaluated for various post compression parameters such as weight variation, hardness, thickness, friability, wetting time, disintegration time and drug content. The findings of all the post compression parameters were within the pre-scribed limits. From all the nine formulations, Fast Dissolving Tablets prepared with natural super disintegrant shows higher percent drug release than synthetic super dis-integrants. Among the three formulations of natural superdisintegrant, the formulation P-III shows higher percent of drug release than the P-I & P-II, due to the increased concentration of natural super disintegrant which leads to decreasing the disintegration time and increasing the dissolution time of the drug. Based on the lower disintegration time and higher percent of drug release, the formulation P-III was subjected to acceler-ated stability study as per ICH guidelines at 40ºC ±2ºC/75% RH ±5% for three months. The tablets were tested at different time interval (30, 60 and 90 days) for percentage of drug release and it was observed that no remarkable changes were found in the percent-age of drug release from P-III after the stability study. Hence the formulation P- III is considered as more stable and the best novel formulation.

KEYWORDS: Fast Dissolving Tablets, Azithromycin, Plantago ovata mucilage, direct compression, sodium starch glycolate and croscaramellose sodium

T456: DEVELOPMENT AND VALIDATION OF RP-HPLC METHOD FOR THE DETERMINATION OF BISOPROLOL FUMARTE

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ABSTRACT

A RP-HPLC Method was developed and validated for the determination of Bisoprolol Fumarate, using Prontosil, chromo bond C18 column(250 x 4.6 mm,5 µm particle size) with mobile phase consisting of Buffer and Acetonitrile in the ratio of 750:250 with a flow rate of 1 ml/min, UV detection 226 nm). Linearity was observed over the concentration range 25 µg/ml to 100 µg/ml, with a correlation coefficient of 0.999. The test method is specific for the estimation Bisoprolol Fumarate in Bisoprolol Fumarate Tablets. There is no interference or co-elution in quantifying the Bisoprolol Fumarate in Bisoprolol Fumarate Tablets. The test method is meeting the Repeatability and Intermediate Precision acceptance criteria. The mean recovery of Bisoprolol Fumarate at each level should not be less than 97.0% and not more than 103.0%. The system suitability parameters were evaluated on both the columns and found within the limits.

KEYWORDS: Bisoprolol Fumarate, RP-HPLC, Method development and Validation**.**

T457: DESIGN, PREPARATION AND CHARACTERIZATION OF ORAL DISINTEGRATING FILM OF CANDESARTAN CILEXETIL.

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ABSTRACT

In the present study, to develop oral dissolving films of candesartan cilex- etil with an objective to achieve rapid dissolution/absorption and further improving the bioavailability of the drug. Also, to resolve the swallowing problems in pediatric, geri-atric patients by rapid dissolution in saliva and improve the patient compliance. Oral disintegrating films of candesartan cilexetil were formulated using low viscosity grade of hydroxypropyl methylcellulose (HPMC E15) as a film forming polymer and glyc-erol as a plasticizer by solvent casting method. If higher concentration of HPMC E15 was resulted in sticky film formation.The in vitro disintegration time of the optimized batch ODF-2 was found to be 23 seconds. The films exhibited satisfactory thickness, mechanical properties like tensile strength, % elongation and elastic modulus. In vitro dissolution studies. The optimized batch was found to be (Formulation ODF-2) exhib-ited faster disintegration time showing 99.98% drug release within 15 min.

KEYWORDS: Dissolution studies, viscosity grade, bioavailability, patient compliance, polymer**.**

T458 DEVELOPMENT AND VALIDATION OF U.V SPECTROPHOTOMETRIC METHOD FOR THE ESTIMATION OF ROPIVACAINE HYDROCHLORIDE IN BULK AND PARENTRAL DOSAGE FORM

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ABSTRACT

A rapid, specific and economic U.V.spectrometric method has been devel- oped using solvent composed of methanol and water to determine the content of Ropivacain hydrochloride in parenteral dosage form. Ropivacain hydrochloride is a local anaesthetic drug belongs to the amino amide group and chemically known as 1- propylpiperidiene-2-carboxamide. Estimation of Ropivacain hydrochloride is carried out at 263nm. The method was validated statistically and studied for linearity, precision, accuracy, LOD, LOQ, range, ruggedness, and robustness. The obtained results proved the method can be employed for the routine analysis of Ropivacain hydrochlo- ride in parenteral dosage form.

KEYWORDS: Ropivacain hydrochloride, UV spectrophotometry, development, valida- tion, local anaesthetic, routine analysis

T460: DEVELOPMENT OF NEW FORMULATION TO INCREASE THE VALSARTAN CONVENTIONAL TABLETS DRUG PERCENTAGE COMPARING WITH MARKET FORMULATION USING QUERCETIN – A NOVEL PROTECTIVE FLAVANOIDS

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ABSTRACT

OBJECTIVE: Conventional tablets possess higher disintegration time so patients obtain pharmacological effect after 30 to 40 minutes of dosage form administration that may result in variable bioavailability. The objective of present research work is to develop a new formulation by adding quercetin (flavanoid). The optimised tablet formulation was compared with conventional market tablet for drug release profiles. This formula-tion showed nearly faster drug release compared to that of the market conventional tablet. The half life of valsartan was found to be 6hours. **METHODS:** Tablets containing 40mg of valsartan were prepared by direct compression method employing xanthan gum and HPMC K4M asahydrophilic polymersin the con- centration range. Compressed tablets were evaluated for various parameters like weight variation, drug content, hardness, friability, SEM, in vitro drug release and swelling behaviour. **RESULTS:** SEM studies revealed the crystalline nature of quercetin. The results of hard-ness, friability, weight variation, thickness of formulated valsartan conventional tablets were within IP limits. In-vitro dissolution studies also revealed that 98.70% of valsartan was released in 10th hour in the formulation employing xanthan gum (in the concen-tration of 12%) and HPMC K4M (in the concentration of 4%) by adding quercetin whereas the formulations of market formulation released 90% in the 10th hour. **CONCLUSION:** It can be concluded that hydrophilic polymers (with the combination of Xanthan gum and HPMC K4M) with the addition of QUERCETIN showed better conventional activity when compared to the market conventional tablet of valsartan and quercetin can be used in the formulation of conventional tablets of poorly soluble drugs.

KEYWORDS: Valsartan, Quercetin – A Novel Protective Flavanoid, Hydrophilic poly- mers, Direct Compression method.

T461 CONTROLLED COLON TARGETED DRUG DELIVERY OF INDOMETHACIN BY USING NATURAL GUMS

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ABSTRACT

This study aimed to investigate the efficacy of both Okra Gum (OG) and Coccinia Grandis Gum (CGG) controlling the release rate of the poorly water soluble drug, Indomethacin (IDM) from colon target drug delivery systems. Binary mixtures of the drug and okra gum and coccinia grandis in the ratios of 1:1 and 1:2 and tertiary mixture in the ratio of 1:1:1 IDM: OG: CGG were prepared using melt granulation technique. The prepared binary and tertiary systems were prepared into micro pellets. The dissolution profiles in pH 6.8 buffer solutions revealed that increasing the gum content in the micro pellets resulted in a decrease in the IDM release rate. The micro pellets were then coated with two different type of coat (inner and outer). The inner coat consisted of natural gums like okra and coccinia grandis solutions of different con- centrations (0.2, 0.4, 0.6, 0.8% w/v) to prevent the drug release in pH 7.4. Micro pellets were then coated with an enteric coat by dipping in 5% Eudragit (ER L100) ethanolic solution to inhibit the drug release in pH 1.2. The coated micro pellets were then dried using hot air. The prepared coated micro pellets were subjected to release rate study which indicated that the release of the drug was inhibited in pH 1.2 whereas; a low percentage of the drug was released in pH 7.4. In pH 6.8, the release profiles showed a sustained release of the drug over 12 h.

KEYWORDS: Indomethacin, Okra gum, Coccinia Grandis gum, Melt granulation, Micro pellets, Dissolution rate, Colon Target Drug Delivery Systems.

T462: IN-VIVO AND IN-VITRO STUDIES OF CLARITHROMYCIN SOLID DOSAGE FORMULATIONS

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ABSTRACT

Drug discovery and development is the lengthy process and procedure also a time taken one. Whenever we discover the new drug, it has to undergo many critical evaluations by using animal and human models, because of due to the short half-lives/ poor membrane permeability and/or associated toxicity in the administered doses of the drugs and also necessary to go for biostudies. Use of in vitro data to predict in vivo performance can be considered as the rational development of MR formulations. Present study, aimed for to conduct bioequivalence studies and develop the new bioan-alytical method for the estimation and also to establish the correlation between in vitro andin vivo as per the guidelines. Bioanalytical method have been developed and vali-dated by using Princeton C18 (100 x 4.6 mm i.d.,5) column, with the following mobile phase Acetonitrile: 0.5 % Formic acid, isocratic mode having the ratio A: B= 60:40 % v/v and flow rate was 0.5ml/min and injection volume is 20l using Auto injector anal-ysed at 30ºC, and the MS conditions were APCI and SIM mode with Positive polarity having ambient probe temperature and CDL & Block Temperature : 250º C & 200º C, detector voltage : 1.3kv, Nebulizer Gas flow & Drying gas : 2.5 L/min & 10 L/min, detection of analytes- Clarithromycin– 748.45 and Azithromycin (IS) – 749.70. Level C correlation was observed for the selected formulations at the in vitro dissolution con-ditions developed. These dissolution methods predicted also the best absorption rate for the selected MR formulations. The percent prediction error of more than 10 % for C max and AUC was obtained. Though they are bioequivalence in both the cases, not able to correlate. So the developed formulations can't replace absorption studies dur-ing the pre-approval process to develop a desirable formulation. Need to develop some more modified release formulation for further studies.

KEYWORDS: Drug Development- MR formulations- Clarithromycin-IVIVC studies.

T463: FORMULATION AND EVALUATION OF SODIUM ALGINATE BASEDCEFUROXIME AXETIL CONTROLLED RELEASE FLOATINGIN SITU ORAL GEL

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ABSTRACT

OBJECTIVE: The objective of the present study was to formulate and evaluate the sodium alginate based controlled release floating in-situ gelling system of cefuroxime axetil. **METHODS**: Sodium alginate based cefuroxime axetil floating in situ gelling systems were prepared by dissolving hydroxyl propyl methyl cellulose (HPMC E5LV) and sodium carboxy methyl cellulose (NaCMC) separately in 25% of water, to which cal-cium carbonate and cefuroxime axetil were added with stirring to form, a proper and a homogenous dispersion of .cefuroxime axetil. Meanwhile, 30% of water was heated to 60 ˚C on a hot plate to dissolve sodium alginate and cooled to 40 ˚C. The resulting solu-tion was added to HPMCE5LV and NaCMC separate solutions and mixed well. To 5% of water at 60 ˚C, sodium methyl paraben was added and dissolved and cooled to 40 ˚C and was added to the above mixtures and mixed well. The volume was adjusted finally to 100% with distilled water for above two polymeric solutions. Prepared formulae were evaluated for physicochemical properties, drug content, pH, in vitro gelling capacity, in vitro buoyancy, viscosity, water uptake and in vitro drug release. **RESULTS:** Formulation variables such as type and concentration of viscosity enhanc-ing polymer (sodium alginate) and NaCMC affected the formulation viscosity, gelling properties, floating behaviour, and in vitro drug release. Formulation F3 and F7 showed the floating lag time of 15 and 18 sec and more than 24 h respectively. A significant decrease in the rate and extent of the drug release was observed with the increase in polymer concentration in in-situ gelling preparation. Formulations F2, F3, F7 were shown to have extended drug release up to 20 hrs. **CONCLUSION:** The prepared in situ gelling formulations of cefuroxime axetil could float in the gastric conditions and released the drug in a controlled manner. The present formulation was non-irritant, easy to administer along with good retention properties, better patient compliant and with greater efficacy of the drug.

KEYWORDS: Cefuroxime axetil., Floating drug delivery, Controlled release, Floating time.

T464: FORMULATION & COMPARATIVE IN –VITRO EVALUATION OF MEFANIMIC ACID FAST DISSOLVING TABLETS USING FOAM GRANULATION TECHNIQUE AND NOVEL HOLE TECHNIQUE

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ABSTRACT

Approximately one-third of the patients need quick therapeutic action of drug, resulting in poor compliance with conventional drug therapy which leads to reduced overall therapy effectiveness. A new dosage format, the fast dissolving phar-maceutical form has been developed which offers the combined advantages of ease of dosing and convenience of dosing. So there is need to designed fast dissolving tablet to release the medicaments with an enhanced rate. Mefanimic acid is anti inflammatory drugcontrols pain very effectively.The aim of the present investigation was to prepare mefanimic acid fast dissolving tablets by using both foam granulation technique and novel hole technique. Foam granulation is a newer technique that promises better dis-tribution of the granulating system and better properties of the produced tablets. In Novel Hole technology when these fast dissolving tablets contact with gastro intestinal fluids, the fluid will enters the hole present in the tablet and immediate breaking of the tablet is going to takes place. This fast disintegration of tablets is also influenced by the formation of new absolute area. By using both techniquesthe prepared FDTs were subjected to various pre and post formulation studies. Its disintegration and dissolution rates were studied. In-vitro drug release of FDTs with sodium starch glycolate of novel hole technique (F6) showed almost 100% drug released at 6th minute and FDTs with sodium starch glycolate of foam granulation technique (F3) shows 72% drug release at 6th minute. Overall, Incomparision of these two techniques novel hole suitable for improving the solubility and bioavailability of mefanimic acid fast dissolving tablets.

KEYWORDS: Mefanimic acid, Super disintegrants, Hole technology, Foam Granulation.

T466: NANO TECHNOLOGY – THE INEVITABLE NEW TREND SETTER

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ABSTRACT

The branch of technology that deals with dimensions and tolerance of par-ticles less than 100 nanometres, with unique function at cellular, atomic and molecular levels is called nanotechnology. There are many upcoming developments in the field of nanotechnology. The Nanospectra Biosciences has been a new therapy using a combi-nation of Gold Nanoshells and lasers to destroy the Cancer Tumours by imparting heat. Nanoparticles used for chemotherapy drug carriers have made some of the greatest advances in cancer treatment. By procuring the nanoparticles the targeting of cancer cells are increased and there is a decrease in the damage of the healthy cells. Nano Sensors are used as an aid to detect and quantify the biological substancesin body fluid which lead path to the detection of diseases earlier and their respective treatments. Polymeric Nanoparticles have been extensively used as a Pharmaceutical carrier in the drug delivery system which results in controlled and sustained release of the drug which serves as a Boon for short half-life drugs. Nanotechnology have been also used in the development of Graphenelenses. Nano technology promises the construction of artificial cells, enzymes and genes. This leads to path of replacement therapy of many disorders which may be due to deficiency of enzymes, mutation of genes or any repair in the synthesis of protein. Super paramagnetic nanaoparticles conjugated with the human epidermal factor receptor 2 antibodies have been used in the imaging of pros-tate breast cancer. Nanocarriers have been used to overcome the solubility and stability issues of a drug. Nanotechnology is spreading its wings to address the key problems in the field of medicine. The success of Nanotechnology in medicine depends on the rationale design and use of nanoparticles .Our aim is to impart fruitful knowledge on the field of Nanotechnology and to enlighten the minds of the researchers

T467: STUDY OF PERMEATION CHARACTER OF ASPIRIN THROUGH DIFFERENT MEMBRANE

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ABSTRACT

Transmucosal or transdermal delivery of drugs is more challenging, as it needs to be delivered across the mucosa or skin. So, it is mandatory to screen the drug candidate through mucosa or skin to develop into formulation. The objective of the present study is to investigate the permeation of aspirin through various membranes (cellophane membrane, bovine and porcine mucosa) for the development of suitable formulation for oral cavity**. METHODOLOGY:** The permeation study of aspirin through various membranes such as cellophane membrane, bovine mucosa and porcine mucosa was carried out by using Franz diffusion cell for 6 hours and at a temperature of 37±0.5° C. The parameters - flux, permeability coefficient and percentage drug permeated were calculated. **RESULTS:** The permeation study of drug was carried out for a period of 6 hours and the percentage drug permeated was found to be 96.23±4.88% and 98.9±1.88% respec- tively through cellophane membrane and bovine

mucosa, whereas 99.59±5.2% of drug permeated through porcine mucosa in 2 hours. The flux of drug through cellophane membrane, bovine mucosa and porcine mucosa were calculated to be 212.52 µg/cm2/h, 224.3µg/cm2/h and 558.9 µg/cm2/h respectively. The permeability coefficient was found to be 0.053 cm2/h, 0.056 cm2/h and 0.13 cm2/h for cellophane membrane, bovine and porcine mucosa. This confirms that aspirin has good permeation through all the selected membranes. Hence the study concludes that aspirin should be loaded into suitable carrier system to optimize the penetration property and release the drug in sustained manner.

T468: FORMULATION AND DEVELOPMENT OF CHITOSAN HYDROGEL FOR: ANTI-FUNGAL ACTIVITY

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ABSTRACT

The objective of present research work was to prepare hydrogel of low molec-ular weight chitosan nanoparticles (NPs) for topical application using two different antifungal agents (Clotrimazole & Nystatin) as model drugs. Placebo and drug loaded nanoparticles were prepared by ionic gelation method. Sodium Tri poly Phosphate (STPP) was used as the cross linker which cross links the chitosan molecules and forms gel at particular pH by cationic interaction. Moreover, no chemical change in polymer and drug was noticed during formulation development. The prepared nanoparticles of Chitosan, clotrimazole and nystatin showed mean diameter of 273.7 nm, 983 nm, and 501 nm respectively. The encapsulation efficiency of the drug clotrimazole and nystatin was 74.6 % and 63.0% respectively. The chitosan nanoparticles were evaluated for the release of clotrimazole and nystatin by In-vitro release at pH 7.4. It was observed that both the formulation exhibited sustained drug release up to the 12 hrs. Nanoparticles were also characterized for surface morphology using SEM. Nanoparticles were spheri-cal in shape with smooth surface. Since chitosan itself has antimicrobial property, hence it was subjected for antifungal activity against Candida albicans along with the for-mulations containing drugs for comparative study. It has been noted that clotrimazole gel showed highest fungal growth inhibition followed by nystatin and Chitosan. The stability study was carried out as per ICH Q1A (R2) guidelines. The prepared Chitosan Nanoparticles based hydrogel of clotrimazole and nystatin are promising formulations for efficient treatment of topical fungal infections.

KEYWORDS: Hydrogel Nanoparticles; Low molecular weight chitosan; Clotrimazole; Nystatin; Fungal Infection

T469: FORMULATION AND EVALUATION OF ACECLOFENAC MUCOADHESIVE MICROSPHERES FOR ORAL CONTROLLED DRUG DELIVERY

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ABSTRACT

Drug delivery is a broad field of research on the development of novel materi-als or carrier systems for effective therapeutic delivery of drugs. The main purpose of delivering the drugs to mucosal membrane is lengthening of the residence time at site of drug delivery, followed by sustained release of the drug after the deposition. Aceclofenac is a nonsteroidal anti-inflammatory drug that has a half-life of 4 hours. The frequent administration of the drug irritates the gastric mucosa when it is given in conventional dosage forms. Hence in this study, mucoadhesive microspheres of biopolymer chitosan were formulated with an aim to enhance the efficacy of the drug. The microspheres of aceclofenac were prepared by o/w/o emulsification cross linking method. Various ratios of drug: polymer were studied, and it was found that microspheres with 1:2 ratio was the superior in terms drug content of 98± 0.1 % and entrapment efficiency of about 89 ± 0.11 % . The in vitro drug release profiles indicated a maximum drug release of 89 ±% 0.89% in 12 hours. The extent of mucoadhesion and ex- vivo permeation of the drug was studied using porcine intestinal mucosal sample. The microspheres were retained on the intestinal mucosa up to 12 hours. The in-vitro drug release and ex-vivo permeation rate profiles exhibited a good correlation. The surface of the selected micro-sphere formulation was observed to be uneven during surface electron microscopic studies. Infrared Spectroscopy and Differential scanning calorimetry studies indicated that there was no major interaction between the drug and polymer used. Therefore, the studies demonstrate that mucoadhesive microspheres could be an appropriate dosage to improve the gastric retention and efficacy of Aceclofenac.

T470: DEVELOPMENT AND VALIDATION OF A RP-HPLC METHOD FOR THEESTIMATION OF A NOVEL ANTIDIABETIC DRUG: CANAGLIFLOZIN

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ABSTRACT

Among all the analytical techniques available for analysis of drug samples, high performance liquid chromatography (HPLC) is most commonly used for quantification of drugs in formulations. It is a powerful tool in the day-to-day analysis. Development of newer HPLC method for new products and existing products and validation of the methods developed is a continuous research process. In the present work a new isocratic reverse phase HPLC method was developed for the quantitative determination of Canagliflozin in bulk as well as in formulations. Efficient chromatographic separation was achieved in Shimadzu, Prominence LC system comprising COSMICSIL 100 C18 5µm column at room temperature with mobile phase containing HPLC grade Acetonitrile and Water in the ratio 70:30, pH adjusted to 3.0 using ortho phosphoric acid. The flow rate of the mobile phase was 1.0 mL/min and detection wavelength 282 nm. The developed method was validated according to the guidelines of the International Conference on Harmonization with respect to specificity, linearity, limits of detection and quantification, accuracy, precision and robustness. The developed method was found to be specific, linear, precise and accurate which suggested that, the method is simple, rapid and does not require any preliminary treatment of the sample. The satisfying recoveries (98% to 102%) and low coefficient of variation (RSD<2%) confirmed the suitability of the proposed method for the routine analysis of Canagliflozin in pharmaceuticals.

T471: COMPARISON OF RELEASE PROFILE OF CO- AMORPHOUS FORM AND PHYSICAL MIXTURE OF AMLODIPINE AND ATORVASTATIN IN TABLET DOSAGE FORM

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ABSTRACT

OBJECTIVE: Amlodipine besylate (AML) and Atorvastatin calcium (ATR) belong to biopharmaceutical classification system (BCS) class II (i.e., low solubility and high permeability) which leads to variable bioavailability. Hence, the aim of this study was to enhance the solubility of both drugs by utilizing the co-amorphous technique. This converted form and physical mixture of both drugs were utilized in the formulation of tablets. **METHODS:** The co-amorphous system was prepared by using rotary flash evaporator. Solubility study was carried out to investigate the dissolution advantage of prepared co-amorphous form. Total twelve formulations were formulated by keeping constant drugs concentrations utilizing direct compression technique among which F1 to F6 contains co-amorphous AML-ATR (Co-A AML-ATR) and F7 to F12 contains a physical mixture of AML and ATR as active pharmaceutical ingredient (APIs). Pre-compression and post- compression studies were carried out to all twelve formulations. Stability study was performed to the optimized formulations as per ICH guidelines. **RESULTS:** Mixture obtained after evaporation was found to become amorphous. FTIR study shows no evidence of intermolecular interactions between AML and ATR. The solubility of both AML and ATR were increased in almost one-fold as compared to their respective crystalline counterparts. Pre-compression parameters of all twelve formulations blend fall under excellent to fair to flow properties. Post-compression parameters of all twelve formulations were within the specifications. But in vitro drug release of formulations F5, F6, F11, and F12 showed % drug release as per IP. Stability study of optimized formulations was observed with, no significant difference in % drug release**. CONCLUSION:** The co-amorphous system can be prepared by utilizing rotary flash evaporator and the same was confirmed by XRPD and FTIR studies. The dissolution rate of the co-amorphous system was greater than that of the crystalline counterpart.

T472: DEVELOPMENT OF NASAL IN SITU GEL OF FEXOFENADINE HYDROCHLORIDE FOR THE TREATMENT OF ALLERGIC RHINITIS CONGESTION

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ABSTRACT

The objective of the investigation was to prepare a novel in-situ gel for the nasal delivery of Fexofenadine Hydrochloride and to know its effect of polymer concentration on drug release. Nasal in-situ gel in allergic rhinitis is more effective with fast release from nasal congestion. It does not readily cross the blood-brain barrier and therefore less likely to cause drowsiness in comparison to other antihistamines and also minimizes the unwanted toxic effects of Fexofenadine Hydrochloride by kinetic control of drug release. The controlled release of drug formulation in the nasal cavity is of utmost importance for intra nasal drug delivery. An ion activated in situ gel of Fexofenadine Hydrochloride was incorporated into the blends of bio compatible and bio polymer such as Gellan Gum, Hydroxy Propyl Methyl Cellulose (HPMC) K 100 by Simple Mixing Method. Fexofenadine Hydrochloride in-situ gel increases the contact of formulation with nasal mucosa and hence improved the absorption of drug. The pH of all the formulations were found to be within the range between 6.45-6.55and the drug content was found to be 95.20% to 98.02%. The gelation strength of all the formulations of nasal in-situ increased as the amount of polymer was increased in each preparation. Formulation F3 which contains Gellan gum (0.4 %), HPMCK 100 (0.1%) exhibited better results than compared to other combination of polymers in different concentrations. It showed gelation strength of 43min, Drug content was found to be 98.02 % and showed release of drug up to 87.62 % in10 h. The nasal in situ gel of Fexofenadine Hydrochloride was stable at 40±2°C /75% RH for 3 Months. The results reveal that in situ gel was safe without mucosal irritation. The in-situ gel system is a promising approach for intranasal delivery of Fexofenadine Hydrochloride for the therapeutic effect improvement.

KEYWORDS: Allergic rhinitis congestion; Fexofenadine Hydrochloride; Gellan Gum; In situ gel; Nasal delivery;

T473: ENHANCED TRANSDERMAL DRUG DELIVERY FOR THE TREATMENT OF MIGRAINE: PREPARATION, OPTIMIZATION AND CHARACTERISATION

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ABSTRACT

The intent of the study was to design a transdermal delivery of Rizatriptan benzoate as the oral administration of Rizatriptan benzoate undergoes metabolism and resulting into inactive indole acetic acid derivate which in turn results into the decreased bioavailability of Rizatriptan. The main objective is to increase the flux of drug via skin into the system circulation by dose design and to reduce the time retention and metabolism of the drug in the skin. In order to improve the bioavailability and efficacy, transdermal patches of Rizatriptan were prepared by which the pre-systemic metabolism of Rizatriptan can be avoided. The transdermal formulation was prepared by incorporation of polymers like Pectin, locust bean gum in different proportions and permeation enhancers like Polyethylene glycol 400 and Dimethylsulfoxide in same proportion. FT-IR studies disclose that there was no interaction between the polymer and the drugs used. Drug release studies were performed at 37°C ±1°C for 10 h. The drug content of all the formulation was found to be within the range of 94.7% - 97.3%. Optimized formulation was found to be F2, consisting of Rizatriptan Benzoate (25mg), Pectin (4%), Locust bean gum (1%), Polyethylene glycol 400(1mL), Dimethyl sulfoxide (1mL), Glycerin (1mL). The Results of Optimized Formulation (F2) shows that the drug content was found to be 97.3 and showed drug release of 70.42% in 12 h. There were no significant changes in stability studies when stored at 75%RH± 5% / 40 ± 2°C for three Months. The optimized formulation F2 followed Korsemeyer-Peppas equation for drug release. The n- value of Korsemeyer–Peppas plot was found between 0.7- 1.546. The results reveal that Rizatriptan benzoate transdermal patch may prove to be potential candidate for effective and safe controlled drug delivery over an extended period of time. The transdermal system is a promising approach for delivery of Rizatriptan benzoate for the improvement of therapeutic effect.

KEYWORDS: controlled drug delivery, Locust bean gum, Pectin, Rizatriptan benzoate, transdermal patch

T474: DEVELOPMENT AND OPTIMIZATION OF MUCOADHESIVE FILMS FOR ENHANCED DRUG DELIVERY IN THE TREATMENT OF ORAL LICHEN PLANUS

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ABSTRACT

The work aimed at interrogation of a new Mucoadhesive Buccal Film containing Clobetasol Propionate which is suitable in the management of oral lichen planus with reduced side effects, controlled release and patient compliance. Clobetasol Propionate bind to the glucocorticoid which forms complexes enters into the cell nucleus and modifies genetic transcription. Clobetasol Propionate Buccal Films were prepared by the incorporation of the Clobetasol Propionate along with polymers like Hydroxy Propyl Methyl Cellulose (HPMC) K4M, polyethylene glycol 400 and glycerol by solvent casting method. The drug content of all the formulations was found to be 85.04% to 93.14%. The swelling index of all formulations of Clobetasol Propionate Mucoadhesive Buccal Film was found to be 82% to 94.07%. Formulation F14 which contains Hydroxy Propyl Methyl Cellulose K4M (1%) and polyethylene glycol 400 (1%) exhibited better results compared to other combination of polymers in different concentration. It showed swelling index of94.07%. Drug content was found to be 91% and showed release of drug up to 95.05% in 12 h. The optimized formula showed no significant changes on stability studies when stored at 40/75% RH for 3 months. The application of Mucoadhesive Buccal Film containing Clobetasol Propionate appeared to be effective, avoiding the side effects and the data obtained in the study suggested that Buccal Films can be successfully designed to give controlled drug delivery.

KEYWORDS: Clobetasol Propionate, Hydroxy Propyl Methyl Cellulose K4M, Mucoadhesive Buccal Films, Polyethylene glycol 400, Solvent casting.

T475 PREPARATION AND CHARACTERIZATION OF DRUG LOADED CHITOSAN NANOPARTICLES FOR INTRAVENOUS DELIVERY OF REVERSE TRANSCRIPTASE INHIBITORS

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ABSTRACT

Nano technology is a part of novel drug delivery system which has been booming at a greater rate in the field of science and technology in the present scenario. The major goals in designing nanoparticles as a delivery system are to control particle size, surface properties and release of drug in order to achieve the site-specific action at optimal rate, also biodegradable polymeric nanoparticles provide specific benefits, they help to increase the stability of drugs/proteins and possess useful controlled release properties. Tenofovir is a nucleoside and nucleotide reverse transcriptase inhibitors (NRTIs) is a drug of choice which inhibits the activity of HIV reverse transcriptase. Chitosan, also commonly known as Poliglusam, is a linear polysaccharide composed of randomly distributed β-(1→4)-linked D-glucosamine (deacetylated unit) and N-acetyl-D- glucosamine (acetylated unit) Tenofovir drug produce anti-viral property. It is an Anti-retro viral agent, used in the treatment of acute immune deficiency syndrome (AIDS). It is mainly derived from deacetylation of chitin contained in the shells of various sea crustaceans such as shrimps. Chitosan drug loaded nanoparticles at concentrations of 1:1, 1:2,1:3, 1:4,1:10 (drug: polymer) was prepared by ionic gelation method. Ionic gelation method involves two aqueous phases, first phase contain polymer like chitosan, a di-block co-polymer like ethylene oxide or propylene oxide (PEO-PPO) and the second phase contain poly anion tripolyphosphate. The characterization of the formulation has been performed which encompasses Invitro drug release, Entrapment efficiency, Scanning electron microscopy and Transmission electron microscopy. In the invitro drug release studies, the F4 samples (93.66%) have shown an extended release with higher percentage of release. The percentage of drug entrapped into nanoparticles was found to be higher in the F4 (5.27%) preparation compared with that of other formulations. Owing to the improved extended drug release and efficient entrapment, the TDF Chitosan nanoparticles would be an efficient type of delivery systems than other conventional delivery systems.

KEYWORDS: nucleotide reverse transcriptase inhibitors, Chitosan nanoparticles

T476: EMULSION BASED GEL TECHNIQUE FOR TOPICAL DRUG DELIVERY IN TREATMENT OF PSORIASIS.

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ABSTRACT

The purpose of the investigation was to design and develop the emulsion-based gel technique formulation of clobetasol propionate for the better treatment of psoriasis with reduced

side effect. Emulgel is a topical drug delivery system used in situation where other system of drug administration fails in treatment of cutaneous disorder like fungal infection, acne, and psoriasis. Most of hydrophobic drugs can-not incorporate directly into gel base because of solubility problem; hence emulgel helps incorporation of hydrophobic drugs into oil phase type of emulsion. Psoriasis is an autoimmune disorder of skin characterized by relapsing episode of inflammation lesions and hyper keratotic plaque. Clobetasol propionate is a topical synthetic corticosteroid with properties of anti-inflammatory, anti-pruritic and vasoconstriction action which help to treat psoriasis with reduce side effect. Preparation of emulgel can be done using aqueous material, oils, emulsifiers, gelling agent [polymer of HPC and HPMC], and penetration enhancers. Polymers used in preparation of emulgel are Hydroxypropyl methyl cellulose [HPMC], Carbopol 940 and Carbopol 934 and the polymers are having concentration of both emulsifying agent [2% and 4% w/v of mixture of Span 20 and Tween 20] and oil phase [5% and 7.5% w/v of the liquid paraffin]. The emulgel of clobetasol propionate was prepared by using phase titration method. The optimum formulation F9 consisted of [Xanthan gum 0.5%, menthe oil 2%, PEG 5%] and drug release was shown at 91.042%. Viscosity of the formulation was found to be ranging from 4612-6985 centipoise. The FTIR revealed that there was no interaction between polymers and drug, hence they are compatible. Emulsion base gel technique is a good and effective approach for treatment of psoriasis using clobetasol propionate to get sustained action into the skin with less side effects.

KEYWORDS: Emulgel, Clobetasol Propionate, Psoriasis, Phase-Titration Method, Pseudo-Ternary Phase diagram.

T477: MICROEMULSION BASED TRANSDERMAL DRUG DELIVERY FOR KETOCONAZOLE

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ABSTRACT

The objective of the study was to prepare and evaluate transdermal Microemulsion of Ketoconazole. Antifungal have been marketed as in the form of Creams, Ointments, lotions, Powders and solutions. These formulations require high amount of active drug to be used for effective therapy because of their low efficacy. So, there is always the demand of new formulation which can overcome such limitations. Microemulsions are a dispersion containing oil, surfactant, co-surfactant, aqueous phase, which is a single optically isotropic and thermodynamically stable liquid solution. The method of Preparation utilized was phase-titration method. The drug was dissolved in oil (Isopropyl Myristate) and to this mixture surfactant and co-surfactant was added by continuous stirring until clear dispersion was formed. Different concentrations of Isopropyl Myristate: Tween 80: PEG 400 was used to prepare different formulations. The combination of each Polymer to the drug and oil mixture was designed using 2 factorial designs. Eight formulations of ketoconazole and Isopropyl Myristate formulations (ME1-ME8) were prepared and are evaluated for the parameters like drug content, Viscosity, Transmittance, Particle size, Zeta Potential, In-vitro release. The drug content was found to be in the range of 94% and the drug release was found maximum of 94%. Comparing all the formulation ME7 (Isopropyl Myristate: TWEEN 80: PEG 400 in the ratio of 10:5:4) showed good release and is best fitted to Higuchi's model. The mechanism of the drug release from the formulation was found to be diffusion. Stability studies conducted for the best formulation showed remain unchanged in the drug content, drug solubility, Particle Size, Zeta Potential and invitro release. The study demonstrated that the Ketoconazole Microemulsions may be the good alternative as novel dosage form that can be revolutionized in the pharmaceutical and healthcare sector.

KEYWORDS: Transdermal, Ketoconazole, Isopropyl Myristate, Microemulsions

T478: ANTIFUNGAL TRANSUNGUAL DRUG DELIVERY FOR ONYCHOMYCOSIS: FORMULATION AND DEVELOPMENT

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ABSTRACT

The present investigation was to develop and evaluate an antifungal nail lacquer for treatment of onychomycosis for the model drug Miconazole nitrate by Transungual drug delivery system. Antifungals have been available in market in many dosage forms as external preparation. Mostly conventional dosage forms have very less permeation of drug in Transungual drug delivery system. To overcome the limitations there is a need of an effective system that can deliver the antifungals deep into the nail bed. Transungual drug delivery system is associated with the drug delivery through the hard keratinized nail plate to treat the diseases of

nail itself in conditions like onychomycosis and nail psoriasis. The nail lacquer formulations were prepared by simple mixing method and all the formulations were subjected for non-volatile content, gloss, smoothness to flow, drug diffusion studies, drug content estimation. Concentration of Miconazole nitrate was maintained with 2% w/w. The polymers used are Eudragit RL100, salicylic acid, 2-hydroxy propyl beta cyclodextrin. For optimization, concentration of polymers Eudragit RL 100, salicylic acid, 2-hydroxy propyl beta cyclodextrin were selected as 3 variables. Viscosity and drug release were selected as response. Optimized formula showed no significant changes on stability studies and found to be stable when stored at 400C/75% RH for 3 months according to ICH guidelines. Formulation and usage of these systems are considered to be safe, without any complication. The study demonstrated that the antifungal nail lacquer may be one of the novel dosage forms that can revolutionize the pharmaceutical and healthcare sector.

KEYWORDS: Eudragit RL100, Miconazole Nitrate, Onychomycosis, Transungual drug delivery, 2-H-β-CD

T479: EFFECT OF NATURAL POLYMER IN SUSTAINED RELEASE OF METFORMIN HCL FOR DIABETES MELLITUS

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ABSTRACT

The Purpose of the research was to develop an Oral sustained Metformin HCl to achieve therapeutically effective concentrations of drug in systemic circulation over an extended period of time. Metformin HCl, a first line drug has been selected because of its low risk of hypoglycemia, reduced risk of cardiovascular morbidity and mortality. In this research various formulations were developed using natural hydrophilic polymers such as Xanthan Gum (15-30%) and Guar gum (15-35 %) at varying concentrations and studied the effect of polymer concentrations on the pre-compression parameters like Angle of Repose, Bulk Density, % Compressibility, Hausner's Ratio and Post compression parameters like Hardness, Thickness, Friability, Weight Variation and Invitro Release Studies. Upon various trials the formulation F4b (Metformin, Guar gum, Starch, Micro crystalline cellulose, Magnesium stearate and aerosil) was found to be best among all the formulations and it is prepared by direct compression method for sustained release. From the results it was found that, as the polymer concentration of Guar Gum was increased the rate of drug release was extended. The Formulation F4b containing 30% of guar gum had an average thickness of 5.9 mm, average Hardness of 8.4 kg/cm2, Friability of 0.30% and could release 26.58% of Metformin in 1 hand the remaining drug release was sustained up to 12 h. Another trial was made by increasing the polymer concentration above 30%, but the drug release did not meet the standards. Based on this fact, the formulation containing 30% of guar gum was optimized and tested for its stability. By this it can be concluded that use of natural polymer at an optimum level can effectively control the drug release.

KEYWORDS: Metformin HCl, Sustained Release, Xanthan Gum, Guar Gum

T480: MODIFIED DRUG ENCAPSULATION OF NSAID DRUG DELVERY; PREPARATION, OPTIMIZATION AND EVALUATION

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ABSTRACT

The current study was focused to develop on potential drug delivery systems for lipophilic drugs belonging to the Biopharmaceutical Classification System (BCS) Class II. Current formulation of encapsulation of NSAID by using electromagnetic assisted drug encapsulation; preparation, optimization and evaluation, utilized electromagnetic dispersion method for Solid Lipid Nanoparticle and used Ibuprofen as model drug. Solubility of ibuprofen in various oils, surfactant was carried out. Different formulations were subjected for evaluation and the optimized formula was subjected for characterization. For optimization lipids were selected in the range of 10-50% and surfactant (tween 80) in the range of 0.5-2.5%. The amount of soya oil, almond oil and the concentration of tween 80 were selected as three variables and Particle size, drug entrapment efficiency and drug release were selected as response for optimization. The parameters like ANOVA, Studentized residuals, Residual by Predicted plot, Summary of fit, Prediction Profiler were used for optimization. Optimized formula showed no significant changes on stability studies and found to be stable when stored at 40ºC/75% RH for one month according to ICH guidelines. The studies demonstrated the promising use of Solid Lipid Nanoparticles for the delivery of ibuprofen by the oral route with improved solubility.

KEYWORDS: Ibuprofen, Microwave-assisted micro emulsion technique, Solid lipid nanoparticle, Particle size.

T483 FORMULATION AND EVALUATION OF ANTI LICE POLYHERBAL HAIR OIL

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ABSTRACT

Herbal cosmetics are now-a-days wide employed by the people owing to idea of fewer facet effects and with a far better safety and security profile. The present work was aimed to formulate polyherbal oil against head Lice containing 25% W/V leaf of Azadirachta indica, 10% W/V fruits of Phyllanthus emblica (without Seed) and 5% W/V leaf and flowers of Clitoria ternatea in Coconut oil. The formulated herbal oil was evaluated and various parameters such as viscosity, saponification value, pH etc. and found to be of has optimum standards of physicochemical properties. The In-vitro study was performed on Human Head Lice collected from infested children, on blood feeding membrane surface of an In-vitro louse rearing unit. The results depicted that the formulated oil showed 99.28±1.65% of ovipositional avoidance bioassay after 72hrs of treatments in comparison to control and positive group of treated lice. The hatchability was also found to be decreased to 2.39±0.09 after 72hrs of treatments in comparison to control and positive group of treated lice. Based on results from in-vitro assessment, the prepared formulation was found as effective infestation deterrents against head lice after 72hrs of treatment. Hence, from the present investigation it was found that the formulated herbal hair oil has optimum standards and further standardization and biological screening established the efficacy of formulated herbal hair oil.

KEYWORDS: Herbal oil, physicochemical, Human Head Lice, blood feeding membrane, blood feeding membrane, hatchability

T484: FORMULATION AND EVALUATION OF LANSOPRAZOLE ENTERIC COATED DELAYED RELEASE CAPSULE

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ABSTRACT

Lansoprazole degrades in stomach in acidic environment. It is needed to delay the release of the drug so that it can remain stable and release in the intestine. Pellets are of great interest to the pharmaceutical industry for variety of reasons. Pelletized products are not only offer flexibility in dosage form design and development, but are also utilized to improve safety and efficacy of bioactive agents. In this research work lansoprazole delayed release capsule has been developed by following steps such as, powder layering and solution /suspension layering. The layering step involves deposition of successive layers of dried powder of drug and solution/suspension of drug substance over the prepared inert pellets, a protective seal coating layering and an enteric coating layering stage. HPMC 15cps, HPMC 6cps and HPMC 3cps have been utilized in both the drug layering stage and seal coating stage. Various quality parameters such as tapped density bulk density and sieve analysis were carried out for deferent batches of dried coated pellets. Finally, in-vitro dissolution of the pellets was performed consecutively in acidic (pH 1.2) and buffer (pH 6.8) media. T5 formulation has shown maximum bulk density (0.921gm/ml) in comparison to other formulation (0.856-0.912gm/ml). All the coated pellets passed through sieve 16 and retained 20 and maintained more than 90% retained in sieve 18. T6 and T7 failed to comply the drug release at 1 hour as per USP. T1 and T4 have also been failed to comply the release pro-file because of incomplete release at the end of 120min. In-vitro dissolution of T5 was according to the USP specifications.

KEYWORDS: Lansoprazole, enteric coating, In-vitro dissolution

T485: IN VITRO PHARMACOKINETIC MODIFICATION: ANTI-HYPERTENSIVE DRUG LOADED CONTROL RELEASE SOLID LIPID MICROPARTICLES (SLM)

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ABSTRACT

PURPOSE: Isradipine (ID), a DHP derivative Calcium Channel blocker, has a high therapeutic potential but with very short biological t1/2 and low bio-availability of 15-24%. To overcome these drawbacks, Controlled Release SLM dosage form was developed; to improve the bio-availability and to reduce the dosing frequency to reduce the associ ated toxicity of Isradipine. **MATERIALS AND METHODS:** Solid Lipid Microparticles (SLM) are micro-scale drug carriers possessing a matrix made from fatty acid, glyceride, fatty alcohol, and solid wax (0.75, 1.00 and 1.5%) with high melting points combining many advantages of drug carrier systems. The prepared IDS-SLMs were characterized for particle size, PDI, zeta potential, drug content, entrapment efficiency (EE %). In vitro drug release studied using dialysis bag method in 0.1N HCl and pH 6.8 phosphate buffer solutions. The optimized formulation was stable at refrigerated and room temperature for 6 months**. RESULTS AND DISCUSSION:** The standard stock solution was prepared and scanned by UV spectrophotometer showed absorption maxima at 330 nm. FTIR and DSC studies revealed that no interaction between the drug and lipids. ID-SLMs prepared using Dynasan-116 (IDS8 – SLM), with Particle size of 614.44 nm, PDI of 0.415, ZP of -26.2 mV with 83.88±2.40% of EE was optimized and was stable for 6 months. SEM studies showed nearly spherical shaped particles. The kinetic drug release study data of IDS1 to IDS9 formulations fitted best into Higuchi equation with diffusion mechanism. The result shows that, drug release rate for the F8 formulation followed zero order mechanism. The selected IDS8-SLM formulation was subjected to six months stability studies at Accelerated six months 400C±20C/75%RH±5%RH and showed stability with respect to release pattern and all physical parameters**. CONCLUSION:** Taken together, the results, it is indicative that lipid based SLMs are suit- able carrier system for improving the oral bioavailability of ID-SLMs.

KEYWORD: Isradipine, Solid Lipid Microparticles (SLM), Fatty acid, Glyceridel, Solid wax.

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TRACK 5: PRE-CLINICAL STUDIES

T501: PHYTOCHEMICAL, ANTI INFLAMMATORY & ANTI ULCER ACTIVITY OF ALCOHOLIC POLYHERBAL EXTRACT IN RODENTS.

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ABSTRACT

The present study was designed to investigate the phytochemical Antiulcer activity following indomethacin induced ulceration & Anti-inflammatory activity following histamine induced paw edema of Polyherbal extract in rats. Adult wistar rats (180-250gm) were exposed to inflammation by using formalin induced paw edema. Rat received histamine (0.1ml) in saline solution for 7 days in sub-planter region of left hind paw. Ethanolic Polyherbal extract (400mg/kg, p.o.) given & following parameter were estimated like percentage inhibition paw volume. Polyherbal extract was evaluated for Anti-ulcer activity; ulcer was induced using indomethacin induced model. Animal were treated with indomethacin (5mg/kg, p.o.) for 5 days for induction. Polyherbal extract (500mg/kg, p.o.) was administered & ulceration was evaluated by estimating ulcer index and percentage (%) ulcer inhibition. Polyherbal extract showed significant (*P<0.05) Reduction in paw volume and percentage inhibition (P<0.001) was significantly enhanced with treatment of Polyherbal extract as compare to control group. Polyherbal extract showed potent Anti-ulcer & Anti-inflammatory activity which could be attributed to the presence of glycosides and flavonoids. The optimum dose of Polyherbal extract which produced gastro protective activity was found to be 500mg/ kg & anti-inflammatory activity was found to be 400mg/kg in this experimental study.

KEYWORDS: Anti-inflammatory, anti-ulcer, gastro protective

T502: ANTIDEPRESSANT ACTIVITY OF ETHANOLIC POLYHERBAL EXTRACT IN RODENTS

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ABSTRACT

The present study was designed to evaluate the antidepressant effect of Ethanolic Polyherbal Extract (EPHE) using tail suspension test and forced swim test (FST). The Polyherbals were collected and authenticated. Extraction of dried Polyherbals was carried out using soxhlet apparatus to obtain its EPHE. EPHE was tested for its acute toxicity on mice and found to be safe up to 2g/kg. Hence the therapeutic dose was fixed as 200 and 400mg/kg. p.o. The EPHE showed significant antidepressant activity comparable to the standard drug. The oral administration of EPHE at 200 and 400 mg/kg respectively to the test group of animals showed an anti-de pressant activity comparable (P<0.001) to that of standard drug as compared to control. The antidepressant effects of EPHE seem to be mainly associated with the activation of dopaminergic system.

KEYWORDS: Antidepressant activity, EPHE, forced swimming test, tail suspension test.

T503: ANTI-ANAEMIC ACTIVITY OF ETHANOLIC POLYHERBAL EXTRACT IN PHENYLHYDRAZINE INDUCED ANAEMIC RATS

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ABSTRACT

The aim of the present study is to evaluate the anti-anemic activity of Ethanolic Polyherbal Extract (EPHE) against phenylhydrazine induced hemolytic anaemia in rats. Phenylhydrazine (60mg/kg) was administered intraperitoneally for 2 days to induce anaemia in rats. The animals were divided into four groups of 6 animals each. Group I served as normal control, group II as anemic control, group III as reference control administered with Vitamin B12 and group IV animals were treated with 200mg/kg, of EPHE.

All the treatments were given once daily for 28 days through oral route. On 29th day blood was withdrawn, through tail puncture under light anesthesia and subjected to the estimation of RBC, Hb and percentage Hematocrit. Both the EPHE and Vitamin B12 significantly increased ($P<0.001$) the RBC, Hb and Hematocrit levels which conclude that, EPHE exhibits anti-anemic activity.

KEYWORDS: Anemia, Anti-anaemic activity, phenylhydrazine, Polyherbal, Vitamin B12.

T504: IN-VITRO ANTIUROLITHIATIC ACTIVITY OF ALCOHOLIC POLYHERBAL EXTRACT

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ABSTRACT

The objective of this research was to find the efficiency of alcoholic Polyherbal extract in dissolution of calcium oxalate crystals by using in-vitro dis- solution model. In-vitro dissolution model was prepared by using semi permeable membranes obtained from eggs that served as dissolution bags for the investigation. Dissolution bags containing calcium oxalate and Polyherbal extract were suspended in conical flasks containing TRIS buffer. Percentage dissolution of calcium oxalate by extract was evaluated by titrimetry. Alcoholic extract of different herbals showed effective dissolution of calcium oxalate as compared to standard cystone. Although the dissolution of calcium oxalate by alcoholic extract was less than that of standard drug. Results obtained from this research work indicated promising effects of Polyherbal extract in dissolution of calcium oxalate. Polyherbal Extract can be used for the effective treatment of urolithiasis.

KEYWORDS: Polyherbal, antiurolithiatic activity, calcium oxalate, alcoholic, cystone.

T506: CITRUS FLAVONOID APIGENIN ATTENUATES MANGANESE-INDUCED MANGANISM IN RATS

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ABSTRACT

Manganese (Mn) is a metal required by biological systems. However, environmental or occupational exposure to high levels of Mn can produce a neurological disorder called manganism. The neuroprotective actions of dietary citrus flavonoid apigenin involve a number of effects within the brain, including a potential to pro-tect neurons against injury induced by neurotoxins. The present study was designed to investigate the effects of long term low-dose exposure to Mn in drinking water on behavioral and biochemical parameters in rats and to determine the effectiveness of apigenin in attenuating the effects of Mn. After 30 days of continuous treatment with MnCl2 (10 mg/kg), rats exhibited clear signs of neurobehavioral toxicity depicted in terms of catalepsy score using standard bar test, activity score using actophotometer, manganese tissue analysis, neurohistopathology, neuroimaging and biochemical analysis. The administration of apigenin (10 mg/kg, PO) improved the motor performance of Mn-treated rats, decreasing the tissue concentration and reversing the histopathological & neuroimaging profile and also decreases the ROS and increasing the antioxidant levels, indicating that the compound could be reverting Mn induced neurotoxicity. Irrespective of the applied dose, the addition of flavonoid in forage decreased tissue Mn concentrations and increased Mn excretion rate in the stool by 20 % to 35 %. All neurobehavioral aberrations were also improved. Our findings show that oral exposure to Mn may cause neurobehavioral abnormalities in adult rats that could be efficiently alleviated by concomitant supplementation of apigenin in animal feed.

KEYWORDS: Manganese, neurobehavioral aberration, apigenin, antioxidant, catalepsy score, activity score

T507 EVALUATION OF AQUEOUS EXTRACT OF VIGNA TRILOBATA SEEDS FOR ITS LAXATIVE ACTIVITY

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ABSTRACT

The aim of present study was to evaluate the laxative activity of seeds of the plant Vigna trilobata (L) verdc. Using various experimental animal models. Aqueous extract of the Vigna trilobata seeds (AEVTS) was used to study the laxative activity using propulsive gut motility in mice and loperamide induced constipation in rats at a dose of 200 and 400 mg/kg of body weight and compared to standard castor oil (0.4 ml/mice, 2 ml /rat, p.o.) The results showed that AEVTS possessed significant laxative activity at a dose of 200 and 400 mg/kg by increasing propulsive gut motility in mice and the weight of faeces in rats in a dose dependent manner. The study justifies the use seeds as laxative in traditional medicine.

KEYWORDS: Aqueous extract, Vigna trilobata seeds, Gut motility.

T508: HALOPERIDOL INDUCED HYPERPROLACTINEMIA AND ASSOCIATED HEMATOLOGICAL AND HISTOPATHOLOGICAL CHANGES IN SPLEEN

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ABSTRACT

OBJECTIVE: Purpose of the study is to evaluate the hematological parameters and histopathology of spleen due to haloperidol (HPL) induced hyperprolactinemia**. METHOD**: To induce hyperprolactinemia, HPL (5 mg/kg/day for 16 continual days) was administered through i.p. route and then hematological parameters and histological changes were observed. **RESULT:** Prolonged administration of HPL (5 mg/kg/day) for 16 days significantly ($p<0.05$) significantly decreased RBC count, Hb count and significantly ($p<0.05$) increased the WBC count, PCV count, platelet count, MCV count, neutrophil count, lymphocyte count and monocyte count respectively. In addition to that, spleen shows loosely packed red pulp (RP) and white pulp (WP), collapsed interlobular matrix, higher melano-macrophages in HPL treated group**. DISCUSSION:** HPL 5 mg/kg/ day continuously for 16 days significantly alters hematological parameters like neutrophils, lymphocyte, monocyte, Hb, MCV etc. These are the markers of inflammation. The histological data of spleen is also in agreement with hematological data reflecting spleen infection/inflammation. **CONCLUSION:** Thus, administration of haloperidol of (5 mg/kg/day) causes associated hematological irregularities. So, a preclinical attempt has been made to confirm the hematological changes associated with hyperprolactinemia.

KEYWORDS: Haloperidol, hyperprolactinemia, spleen, hematology.

T509: EVALUATION OF SERUM PROLACTIN LEVEL OF METHANOLIC EXTRACT OF TINOSPORA CORDIFOLIA AGAINST HALOPERIDOL INDUCED HYPERPROLACTINEMIA

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ABSTRACT

OBJECTIVE: The study aims to determining the serum prolactin level and neurochemical changes seen in brain of albino rat against haloperidol (HPL) induced hyperprolactinemia. **METHOD**: To induce yperprolactinemia, HPL (5 mg/kg/day) for 16 continual days was administred through i.p. route. Prolactin level was then measured in control and treated groups. **RESULT:** Prolonged administration of HPL (5 mg/kg/day) treated group serum prolactin (PRL) level was significantly increased as compared to con-trol group. Again, HPL induced hyperprolactinemia is associated with decrease in dopamine (DA) concentration in brain,whereas, administration of HPL along with methanolic extract of Tinospora cordifolia(200 mg/kg/day and 400 mg/kg/day) significantly decreased serum prolactin level and significantly increased DA concentration in rat brain. **DISCUSSION:** Neuroleptics enhance the release of prolactin in human beings and animals.TC decreases prolactin level in blood and increased DA level in brain significantly. Current study revealed that herbs may play a key role to manage drug induced hyperprolactinemia.

CONCLUSION: So, obtained result indicated that methanolic extract of Tinospora cordifoliahas significant anti- hyperprolactinemia.

KEYWORDS: Haloperidol, hyperprolactinemia, prolactin, serum.

T510: METHOD DEVELOPMENT AND VALIDATION FOR THE ESTIMATION OF VALERENIC ACID CONTENT IN VALERIAN TABLETS USING RP-HPLC METHOD

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ABSTRACT

Valerian (Valeriana officinalis) has been used from so long as a traditional medicine since it has therapeutic effects such as to enhance sleep, anxiolytic for nervous unrest, neuralgia, epilepsy, to relieve digestive and other painful contractions of smooth muscle. For determining the dose of herbal formulations and to estimate the quality of dosage from, we need to develop an effective reproducible validated method for the determination of the bioactive molecules essential for the sedative activity of the vale- rian tablets. So, the primary objective of the present work was to develop an efficient and sensitive method for the determination of valerenic acid content in valerian tablets using reverse phase high performance liquid chromatography technique. There were some assay methods by HPTLC and HPLC, but they have a greater retention time and complex gradient elution method. Valerenic acid which is one of the main constituents in the Valerian formulation, is a stable, robust compound and is easy to detect and quantify, using RP-HPLC. For the method, the column used was Phenomenex C18 Luna® 5 µm C18 (2) 100 Å (250 x 4.6mm) column. The mobile phase used is acetonitrile: ortho-phosphoric -acid in the ratio of 97:3. The chromatographic conditions employed are 1ml/min flow rate and absorbance were observed at 220nm. Retention time was at 4.4 minutes. The selected chromatographic conditions were found to give effective separation of Valerenic acid at 4.4±0.2min. Validation was carried out for linearity, system suitability, accuracy, precision (intra-day and inter-day), and robustness, limit of detection and limit of quantification which was found to be within acceptable limits according to ICH Guidelines. Thus, the method proposed was found to be accurate, precise, reproducible and analyte specific. In this work, based on the observations made from the literature review a relatively suitable method was developed for the estimation of valerenic acid in valerian tablets was developed with shortening the retention time along with better resolution thus, reducing the wastage of solvents and time of analysis.

KEYWORDS: RP-HPLC, Valeriana Officinalis, Valerenic acid, Validation

T511: METFORMIN PREVENTS PHENYTOIN INDUCED COGNITIVE IMPAIRMENT

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ABSTRACT

Cognitive impairment is one of the major problems associated with antiepileptic drugs. Phenytoin is one of the widely used anticonvulsant but it adversely affects learning and memory on prolonged use due to generation of ROS (Reactive Oxygen Species). Metformin which is widely used for type-2 diabetes mellitus additionally pro-motes neurogenesis, enhances spatial memory function and protects the brain against oxidative imbalance. Metformin due to its interference with apoptotic cascade prevents cell death. Hence the present study is undertaken to evaluate the nootropic effects of metformin against phenytoin induced cognitive impairment by using several preclinical models such as actophotometer, rotarod, elevated plus maze, radial arm maze and Y-maze. Adult wistar albino rats (150-200g) of both sexes were divided into 3 groups. Group-I animals were treated as control. Group-II animals were administered with phenytoin whereas Group-III animals were subjected to metformin followed by phenytoin. Metformin (200mg/kg) was administered orally 1hr before administration of phenytoin (25mg/kg) for 21 days. Metformin showed significant ($p<0.05$) increase in locomotor activity in actophotometer, time of fall in rotarod, number of correct entries in radial arm maze, % SAB in Y-maze and decrease time spent in open arm in elevated plus maze thereby reversing the effects of phenytoin. So, use of metformin may prevent phenytoin induced cognitive impairment.

KEYWORDS: Metformin, Nootropic effect, Cognitive impairment, Neurogenesis.

T512: SYNERGESTIC EFFECT OF COENZYME Q10 AND MAGNESIUM SULPHATE ATTENUATES ISOPROTERENOL INDUCED MYOCARDIAL INFARCTION BY MODULATING THE EXPRESSION OF A-SMOOTH MUSCLE ACTIN

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ABSTRACT

The objective of the study aims to evaluate the combined protective effects of Coenzyme Q10 and Magnesium sulphate on isoproterenol induced myocardial infarction in rats. CoenzymeQ10 (50mg/kg) and Magnesium sulphate (10mg/ kg) were administered orally to Wistar Albino rats in individual or in combination for 30 days. At the end of this period, rats were administered isoproterenol (85mg/kg i.p.) for two consecutive days to induce myocardial damage. After induction, rats were anaesthetized and plasma was collected to analyze various biochemical parameters. Further, immunohistochemistry and histopathology of the heart tissue was performed. Induction of rats with isoproterenol resulted in a marked (P<0.001) elevation of infarct size, level of serum marker enzymes (AST, ALT, LDH and CK- MB), lipid peroxidation, protein expression of alpha- smooth muscle actin (α SMA) along with alterations in histopathology. Pretreatment with combination of Coenzyme Q10 (CoQ10) and Magnesium sulphate (MgSO4) exhibited a significant (P<0.001) decrease in serum marker enzyme, infarct size, lipid peroxidation, protein expression of α- smooth muscle actin (α-SMA) and showed preservation of cardiomyocytes histoarchitecture when compared with individual treated groups. The study demonstrated the synergistic cardio protective effect of CoenzymeQ10 (CoQ10) and Magnesium Sulphate (MgSO4) in isoproterenol induced myocardial damage in rats. The mechanism might be associated with the enhancement of antioxidant defense system as well as reduction in expression of α-smooth muscle actin. It could provide experimental evidence to support the rationality of combinatorial use in the prevention of the onset and progression of myocardial injury.

T513: EFFECT OF SHODHANA ON NOOTROPIC ACTIVITY OF SEMECARPUS ANACARDIUM

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ABSTRACT

Semecarpus anacardium (bhallataka) is an upavisha dravya (semipoisonous drug) and the toxicity is due to the presence of chemical called urashiol. But semecarpus anacardium has so many therapeutic effects including neuroprotective activity. It is sug- gested that shodhana (an Ayurvedic purificatory procedure) of semecarpus anacardium should be carried out before its internal administration. Earlier studies have shown the efficacy of semecarpus anacardium as a nootropic agent. We have reported a decrease in nootropic activity of methanolic extract of semecarpus anacardium due to shodhana in scopolamine induced model. In the present study we have used aluminium chloride (40mg/kg p.o.) induced amnesia model to evaluate the effect of shodhana on nootropic activity of methanolic extract of semecarpus anacardium nuts. The nootropic activity is found to be reduced due to shodhana.

KEYWORDS: semecarpus anacardium, nootropic activity, shodhana, aluminium chloride

T514: DEVELOPMENT AND VALIDATED FOR ESTIMATION OF B-ASARONE IN ACORUS CALAMUS EXTRACTS BY USING GC METHOD

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ABSTRACT

A simple, sensitive analytical methods have been developed and vali-dated for analysis of β-Asarone in Acorus Calamus extracts by using GC. The GC was performed on Rtx-5 capillary column (cross bond 5% diphenyl/95% dimethyl polysiloxane) using nitrogen as carrier gas at column flow rate 1 mL/min. The column temperature was maintained at 100 ºC, Injection temperature at 250 ºC, detector temperature at 300 ºC and pressure was maintained at 94.2 K pascal. The

eluents were monitored with FID detector. In this method, β-Asarone elutes at retention times of 7.6 min. The proposed method is having linearity in the concentration range from 50 to 250 µg/mL. All the above proposed method were validated with respect to sys-tem suitability, linearity, precision, limit of detection (LOD) and limit of quantification (LOQ), accuracy (recovery) and robustness according to ICH guidelines. The conents of β-Asarone present in ethanolic and ethyl acetate extracts was analysed and reported.

KEYWORDS: β-Asarone, GC-FID, Analytical method development, ICH Guidelines.

T515: DEVELOPMENT AND VALIDATION OF UV SPECTROPHOTOMETRIC METHOD FOR SIMULTANEOUS ESTIMATION OF EPALRESTAT AND PREGABALIN IN PHARMACEUTICAL DOSAGE FORM

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ABSTRACT

A new sensitive, simple, rapid and precise spectrophotometric method has been developed for simultaneous Estimation of Epalrestat (EPAL) and pregabalin (PGB) in pharmaceutical dosage form using ninhydrin as a derivatization agent. This method was based on UV spectrophotometric determination of two drugs, using simultaneous equation method. It involves measurement of absorbance's at two wavelengths 388nm (λmax of Epalrestat (EPAL)) and 405 nm (λmax of Pregabalin (PRB)) in methanol for the simultaneous quantitative determination of Epalrestat and Pregabalin in the binary mixture without previous separation. The linearity was observed in the concentration range of 2-10µg/ml for both Epalrestat and Pregabalin. The accuracy and precision of the method was determined and validated statically. Method was found to be rapid, specific, precise and accurate, can be successfully applied for the routine analysis of Epalrestat and Pregabalin combined dosage form without any interference by the excipients. The method was validated according to ICH guidelines.

KEYWORDS: Epalrestat, Pregabalin, UV spectrophotometric method; Simultaneous equation method.

T516: EVALUATION OF SERUM URIC ACID AND C- REACTIVE PROTEIN AS BIOMARKERS OF LONG TERM TREATMENT RESPONSE IN PATIENTS WITH ASTHMA AND COPD

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ABSTRACT

Asthma and chronic obstructive pulmonary disease (COPD) are characterized by Structural remodeling of trachea-bronchial smooth muscles often associated with inflammation. Asthma is caused due to inflammation of the larger conducting airways whereas COPD affects the small airways and the lung parenchyma, which leads to reduced airflow due to inflammation of the airway causing hypoxic conditions. Tissue hypoxia results in net degradation of adenosine triphosphate which leads to the release of purine intermediates and the purine catabolic end product, uric acid. Uric acid derived from serum is found at high concentration in the human epithelial lining fluid of the upper and lower respiratory tracts, which increases significantly during hypoxia. So, this uric acid levels can be used as biomarker in COPD and asthma patients who are on long term treatment response. **AIM AND OBJECTIVES:** To assess the potential of uric acid over spirometry with broncho- dilators and corticosteroids. **METHODOLOGY:** A total of 91 patients were randomly selected from a tertiary care hospital, who signed informed consent and satisfied all the inclusion criteria. Patient's demographics, medical conditions and other details necessary for the study were collected with Uric Acid levels on baseline, 1st month and 3rd month. The results were analyzed for statistical correlation. **RESULTS & DISCUSSION:** The end-points showed that there is a potential effect of Serum uric acid on Asthma and COPD in long-term treatment response (P = 0.01). The study showed negative correlation between spirometry readings and uric acid levels, which states that when the uric acid levels reduce due to treatment, the lung function improves. ROC curve was also derived for cut-off values. **CONCLUSION:** Serum Uric acid can be a biomarker for the long-term treatment response in patients with asthma and COPD.

T517: ISOLATION, CHARACTERISATION AND INSILICO ANALYSIS OF LUTEOLIN IN THE MANAGEMENT OF ALZHEIMER'S DISEASE

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ABSTRACT

In the present study, luteolin was isolated from Momordica charantia and characterized by IR and NMR spectroscopy, undergone Insilco docking to study its anti- Alzheimer's role. In silico molecular docking is a computational system employed to predict the interaction vitality between two particles and the best introduction of ligand that shapes a complex with general least vitality. In this Protein Ligand Docking, we have used HEX 8.0.0 as a Docking Software. The receptors (PDB ID: 4PQE, 1P0I, 5O3L, 1J1C, 3NYJ, 2FJZ) were retrieved from the RCSB Protein Data Bank (PDB) Database while the ligand structure was retrieved as mol format from ChEBI database and it was converted as .pdb format using Chimera1.12 and docking was done according to the specified parameters. The molecular docking process for the luteolin was performed with the receptors and the E-value was determined. Further, the result of the binding site of ligand with the target proteins was interpreted by using Chimera 1.12 software. Luteolin was proved to have good affinity for target protein and it is having multitarget activity that is responsible for AD.

KEYWORDS: Momordica charantia, Luteolin, Insilico molecular Docking, PDB data- base, ChEBI database, Ramachandran plot, Hex 8.0.0 Software

T518: ANALYTICAL METHOD DEVELOPMENT, VALIDATION OF NEWLY FORMULATED ANTIHYPERTENSIVE TABLET DOSAGE FORM

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ABSTRACT

The primary objective of the present work was to formulate a controlled release tablet 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 in-vitro dissolution studies showed that the formulation - F4 showed a controlled release which extended up to the 12th hour. The percentage drug release was found to be up to 97% of the three drugs. The formulated controlled release tablet dosage form was subjected to an analytical method development and validation. A simple, sensitive and specific RP-UFLC method was developed for the simultaneous estimation of hydrochlorothiazide, amlodipine besilate and losartan potassium in the formulated controlled release tablet dosage form. Separation was achieved using Phenomenex Kinetex C18 (5µ, 100A, 250X4.6mm) column with mobile phase containing ACN: 0.1% OPA in water pH 2.3 (40:60). The flow rate was 1.0mL/min, the eluent was monitored at 230nm. The selected chromatographic conditions effectively separate hydrochlorothiazide, amlodipine besilate and losartan potassium with retention time of 2.8 min, 4.1min and 4.5 min respectively. The drugs were found to be linear in the range of 0.025–0.8µg/ml for hydrochlorothiazide and 1.25–40 µg/mL for amlodipine besilate and losartan potassium. The developed method was validated following ICH guidelines. The developed method could also be used for routine quality-control analysis of these three drugs in combination tablets.

KEYWORDS: Controlled release formulation, Natural gum, Hydrochlorothiazide, Amlodipine besilate, Losartan potassium.

T519: NEUROPROTECTIVE ACTIVITY OF HYDNOCARPUS PENTANDRA AGAINST HALOPERIDOL INDUCED PARKINSONISM

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ABSTRACT

The present study evaluates anti-Parkinson's activity of ethanolic extract of leaves and stems of Hydanocarpus Pentandra in haloperidol induced Parkinson's model. In this study, effects of Hydanocarpus Pentandra (200, 400mg/kg, p.o) were studied using in vivo behavioral parameters like catalepsy, muscle rigidity and locomo-tor activity and its

effects on neurochemical parameters (dopamine, serotonine, and L-Glutamate) in rats. The experiment was designed by giving haloperidol in induce catalepsy to induce Parkinson's disease like symptoms. The increased cataleptic scores (Induced by haloperidol) were significantly ($p<0.01$) found to be reduced, with EEHP at dose of 200mg/kg and 400mg/kg (ip). Haloperidol administration showed significant increase in dopamine level and significant reduced in serotonin and L-glutamate level. Daily administration of EEHP (400mg/kg) significantly improved motor performance. Thus, the study proved that Hydanocarpus Pentandra treatment significantly attenuated the motor defects and also increased the neuro chemical dopamine level.

KEYWORDS: Hydanocarpus Pentandra, Anti-Parkinson's activity, Ethanol extract, L- Dopa, Carbidopa and Haloperidol.

T520: ANTI- NEOPLASTIC APPROACH OF PHYTOLCACA DECANDRA BY UPREGULATION OF P53 AND DOWN REGUALATION OF BCL-2 IN HEPATOCELLULAR CARCINOMA

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ABSTRACT

Hepatocellular carcinoma is the most common primary hepatic malignancy worldwide. N- Nitroso compounds are strong carcinogens in various animals, including primates. Diethylnitrosamine (DENA) (200mg/kg) is a well-known carcinogenic substance, which induces hepatic carcinoma by administrating through i.p route for 3days/ week followed by treatment with Phenobarbital (PB) as promoter. The theme of the study was to evaluate the therapeutic efficacy of Phytolaca decandra PDE by combating DENA-induced hepatocarcinogenesis in rats. The rats were exposed to PDE treatment for 5 weeks prior to initiation and treatment was continued for 24 weeks. There was decrease in body weight of the DENA/PB treated group due to functional impairment that was improved by PDE treatment. But the DENA induced group shows substantial increase in relative liver weights due to proliferation and development of hyperplastic nodules that was improved by PDE treatment. A significant increase in hepatocellular markers like serum Aspartate transaminase, Alanine transaminase, Total protein, creatinine and bilirubin was observed in DENA-treated animals. Maximum protection from such toxicity was provided by Phytolacca decandra. Elevated levels of conjugated diene in DENA-treated rats were lowered significantly by Phytolacca decandra. Antioxidant levels in hepatic cells were reduced significantly by the induction of DENA. PDE was found most potent for complete prevention of DENA-induced reduction in antioxidant levels in the liver. Histological findings showed substantial repair of hyperplastic lesion. There was a significant decrease in tumor incidence, tumor multiplicity ($p<0.05$) after the treatment with PDE extract. Immunohistochemistry analysis in-vivo indicated strong expression of p53 and down regulation of Bcl-2 protein in liver tissue of PDE treated animals. Results of in-vivo and in- vitro study demonstrate that PDE has the potential to be developed into an anti-liver cancer drug in the near future.

T521: EVALUATION OF DIURETIC ACTIVITY OF ETHANOLIC EXTRACT OF LEAVES OF OXALIS LATIFOLIA KUNTH

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ABSTRACT

The present study was carried out to evaluate the Diuretic activity of the leaves of the plant Oxalis latifolia kunth based on the traditional use of the plant. The plant leaves were collected, dried and then subjected to Soxhlet extraction with various solvents from non-polar to polar. The extraction was carried out for 72 hrs with petroleum ether and ethanol. The aqueous extraction was carried out by cold maceration process. Then the extracts were subjected to preliminary phytochemical screening. Based on the preliminary phytochemical studies, the ethanolic extract was selected for the evaluation of Diuretic activity by in -vivo, Lipschitz test method using Frusemide as the standard drug. The ethanolic extract of Oxalis latifolia kunth showed a dose-dependent increase in both water (urine) excretion and excretion of Na+, K+, Cl- ions. From the results, both the doses of ethanolic extract (200mg/kg & 400mg/kg) showed significant diuretic activity by increasing the total urine output and increasing the excretion of Na+, K+, Cl- salts. Thus, this plant can be used as a diuretic drug source and it seems to have lesser side effects when compared to that of the synthetic drugs.

KEYWORDS: Diuretics, Oxalis latifolia kunth Soxhlet extraction, Lipschitz test, Frusemide.

T522: EVALUATION OF ANTI-ULCER ACTIVITY OF ETHANOLIC EXTRACT OF LEAVES OF CALOPHYLLUM INOPHYLLUM (CALOPHYLLACEAE) IN RATS

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ABSTRACT

Osyris quadripartita (OQ) Salzm. ex Decne. has been used to treat pep-tic ulcer disease in Ethiopian folk medicine, but its efficacy has not been validated. The present study was therefore carried out to evaluate the anti-ulcer activity of 80% methanol leaf extract of OQ in rats. The effect of OQ extract on gastric ulcer in rats in pylorus ligation-induced and ethanol-induced models was studied using single dosing (100, 200, 400 mg/kg) and repeated dosing (200 mg/kg for 10 and 20 days) approaches. Ranitidine (50 mg/kg) and sucralfate (100 mg/kg) were used as the standard drugs. Depending on the model, outcome measures were volume and pH of gastric fluid, total acidity, ulcer score, percent inhibition of ulcer score, ulcer index as well as percent inhibition of ulcer index. Data were analyzed using one-way analysis of variance followed by Tukey's post hoc test, and $P<0.05$ was considered as statistically significant. OQ significantly ($P<0.001$) reduced gastric ulcer index by 55.82% and 62.11%, respectively, in pylorus ligation-induced and ethanol-induced ulcer models at the 400 mg/kg dose, which is comparable to the standard drugs. Ten- and 20-days pre-treatment with OQ200 exhibited significant ($P<0.001$) ulcer inhibition by 66.48% and 68.36% (pylorus ligation-induced model) as well as 71.48% and 85.35% (ethanol-induced model), respectively. OQ possesses both dose-dependent and time-dependent anti-ulcer effect in the two models. The oral median lethal dose (LD50) is estimated to be higher than 2000 mg/kg for the crude hydroalcoholic extract, and secondary metabolites such as flavonoids, tannins, and saponins were present. The findings of this study confirmed that OQ has anti-ulcer pharmacologic activity due to one or more of the secondary metabolites present in it. Therefore, this study validates its anti-ulcer use in Ethiopian folk medicine. Further investigations on isolation of specific phytochemicals and elucidating mechanisms of action are needed.

KEYWORDS: anti-ulcer activity, in vivo, Osyris quadripartita, rat

T523: IN-VITRO ANTIOXIDANT ACTIVITIES OF VARIOUS EXTRACTS OF COCCINIA INDICA LEAVES: A COMPARATIVE STUDY

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ABSTRACT

Many Indian medicinal plants are considered potential sources of anti- oxidant compounds. In some cases, their active constituents are known. There is an increased quest to obtained natural antioxidants with broad-spectrum actions. The present study was aimed at investigating the antioxidant activities of the various fractions of various crude extracts of Coccinia indica leaves (Cucurbitaceae). Leaves were subjected to successive extraction with methanol, acetone and water. The antioxidant activities of crude extracts have been evaluated by using in-vitro assays and were compared to standard antioxidants such as ascorbic acid. All the fractions showed effective free radical scavenging activity (hydroxyl & nitric oxide). The antioxidant property depends upon concentration and increased with increasing amount of the fractions. From IC50, aqueous extract was found to have high scavenging activity than methanolic and acetonic extracts. The free radical scavenging and antioxidant activities may be attributed to the presence of phenolic and flavonoid compounds present in the fractions. The results obtained in the present study indicate that the leaves of C. indica are a potential source of natural antioxidant.

KEYWORDS: Coccinia indica (Cucurbitaceae), hydroxyl free radicals, nitric oxide free radical, antioxidant

T524: EVALUATION OF CELASTRUS PANICULATUS FOR ANTIULCER ACTIVITY IN EXPERIMENTALLY INDUCED ULCERS IN RATS

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ABSTRACT

AIM: Celastrus paniculatus (Celastraceae) is a widely growing and cultivated traditional medicinal plant. The different parts of this plants have reported to be traditionally used for treatment of various conditions such as brain tonic, for headache, skin infections, and wound healing. The present research was aimed to explore the unreported anti-ulcer activity of the aqueous seed extract of Celastrus paniculatus (ASCP) in experimentally induced ulcers in rats. **METHOD:** ASCP was prepared by maceration using distilled water. The extract was subjected to preliminary phytochemical analysis using standard procedures. Anti-ulcer activity was carried out using Wistar rats. Ulcer protective effect was investigated in ethanol, indomethacin and pylorus ligation induced ulcer models. The ASCP was given orally at different doses as 200 mg/kg, and 400 mg/kg. 50mg/kg of Ranitidine was used as a standard drug for all these gastric ulcer models. The parameters analyzed were ulcer score, free acidity, total acidity and total protein to determine the gastroprotective effect. **RESULT:** Preliminary phytochemical evaluation revealed the presence of alkaloids, flavonoids, saponins, carbohydrates, steroids, glycosides and tannins in ASCP. ASCP significantly ($p<0.001$) inhibited ulcer score, free acidity, total acidity and total protein in all the different ulcer induced models compared to positive control group. The protection may be due to enhancement of the gastric mucosal defensive factors in ethanol induced ulcer model. In Indomethacin induced model the alleviation of ulcers may be due to inhibition of the indomethacin induced suppression of prostaglandin synthesis and the antisecretory effect of ASCP may be due to protection against pylorus ligation induced ulcer model. **CONCLUSION:** From the results obtained with the present study it is confirmed that ASCP possessing a significant anti-ulcer activity. Phytoconstituents like sterols, alkaloids, flavonoids, glycosides, tannins, saponins are already reported for their anti-ulcer activity. Some of the above mentioned phytoconstituents were identified with ASCP extract. Hence these can be accounted for the anti-ulcer activity.

KEYWORDS: Peptic ulcer, Ranitidine, Celastrus paniculatus, indomethacin, pylorus ligation.

T525: ANTI –FERTILITY ACTIVITY OF BARK EXTRACTS OF CAESALPINIA PULCHERRIMA LINN IN RATS

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ABSTRACT

AIM: The plant C. pulcherrima was reported for its varied medicinal uses and contains phytochemical constituents like flavonoids, tannins, resins and di-terpenoids. The present study was conducted to explore the anti-fertility activity of alcoholic extract with bark of C. pulcherrima (AEBCP) and aqueous extract with bark of C. pulcherrima (AQEBCP) in male and female rats with three different doses on the basis of their individual LD50 values. **METHOD:** AEBCP was prepared using Soxhlet apparatus and AQEBCP was prepared by maceration process using distilled water with 10 ml of chloroform used as a preservative. Preliminary phytochemical tests were conducted for both AEBCP and AQEBCP following standard analytical procedures. LD50 studies for both the AEBCP and AQEBCP was conducted in mice (16-20g) using up and down method of OECD Guidelines No-425 up to the maximum dose level of 2000 mg/Kg body weight. Three doses were selected as 1/20th (low), 1/10th (medium), 1/5th (high) with respect to their LD50 doses tested for each extract. Contraceptive activity was tested using anti-fertility model in female and male rats; anti- ovulatory, abortifacient and anti-fertility activities in female rats only. In 1st model parameters like testes, ovary body weights and in 2nd model uterine and ovary weights, in 3rd model number of litters and % resorption and in 4th model number of litters, live litters, dead litters, % anti-implantation and % resorption were noted**. RESULTS:** Preliminary phytochemical evaluation revealed the presence of alkaloids, flavonoids, steroids, triterpenes, tannins, glycosides, saponins, carbohydrates, proteins and amino-acids in both AEBCP and AQEBCP. No mortality/abnormal behavior was observed in mice after treatment with each of the extracts even at the highest dose. After treatment with standard and both the extracts no significant alteration in body weight was noted with respect to normal control. A significant reduction in number of litters were noted with a significant increase in % resorption and % anti-implantation with both the extracts. **CONCLUSION**: From the results obtained with the present study it is confirmed that both AEBCP and AQEBCP possess a significant anti-fertility activity. Phytoconstituents like sterols, alkaloids, phenols, saponins and glycosides are already reported for their anti-fertility activity. Some of the above mentioned phytoconstituents were identified with both AEBCP and AQEBCP.

T526: A NEW METHOD DEVELOPMENT AND ANALYTICAL METHOD VALIDATION FOR CHLORPHENIRAMINE MALEATE

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ABSTRACT

Allergies are caused by hypersensitivity of the immune system to typically harmless substances in the environment. Non-sedative, anti-histamines are unlikely to be useful in the treatment of common cold symptoms since they do not have clinically significant anti-cholinergic effects (drying effects on nasal mucosa). Some of the anti-histamines drugs include Brompheniramine, Cetirizine, Chlorpheniramine, Diphenhydramine, Fexofenadine, Loratadine. Chlorpheniramine maleate (CPM) is an anti-histaminic drug (H1 blocker) available as OTC medication for the symptomatic relief of common cold, cough and allergies. CPM is available in various pharmaceutical formulations like tablet, capsules and syrups. In the present study, an attempt was made to develop a new analytical method by HPLC and it was validated for the crude CPM. Chromatographic determination was performed on C18 column (150mm×4.6mm), using Phosphate buffer: methanol as mobile phase at a flow rate of 1 ml/min with UV detection at 215nm.

KEYWORDS: anti-histamines, HPLC, Chlorpheniramine, validation.

T527: IN VITRO & IN SILICO ALPHA AMYLASE & ALPHA GLUCOSIDASE INHIBITORY ACTIVITY OF BAICALEIN

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ABSTRACT

Diabetes mellitus is a chronic endocrine disorder that affects the metabolism of carbohydrates, proteins, fat, electrolytes and water. The oral antidiabetic drugs include sulphonyl-ureas, meglitinides, biguanides, thiazolidinediones and α-glucosidase inhibitors. Alpha glucosidase and alpha amylase are the important enzymes involved in the digestion of carbohydrates. Alpha amylase is involved in the breakdown of long chain carbohydrates and alpha glucosidase breaks down starch and disaccharides to glucose. Baicalein is a flavone glycoside and is found in several species in the genus Scutellaria, including Scutellaria baicalensis and Scutellaria lateri flora. It is purchased from Sigma. The present study was carried out to investigate the α-amylase and α-glucosidase inhibitory activity, anti-oxidant activity, and molecular docking studies of Baicalein. The alpha amylase assay showed 92.3% of inhibition using the standard Acarbose. The alpha glucosidase assay showed 33.8% inhibition using the standard acarbose. The antioxidant assay was performed by four methods using quercetin as standard namely DPPH scavenging activity and its percentage inhibitions were found to be 41.86%, 70.98%, 83.83%, 87.8% ,88.02%, 97.27% respectively at the concentrations. of 5, 10, 20, 40, 80, 160 µg/ml. Nitric oxide free radical scavenging activity and its percentage inhibitions were found to be 50.02%, 48.2%, 48.24%, 41.4%, 35.46%, 19.9% respectively at the concentrations of 5, 10, 20, 40, 80, 160 µg/ml. Reducing power method and its percentage inhibitions were found to be 80.3%, 68.44%, 59.24%, 45.62%, 38.35%, 27.12% respectively at the concentrations of 5, 10, 20, 40, 80, 160 µg/ml. Phospho-molybdenum activity and its percentage inhibitions were found to be 74.54%, 66.11%, 53.29%, 41.09%, 30.82%, 19.71%. From the molecular docking studies, Baicalein was found to have good binding affinity with the molecular targets (α-amylase and α-glucosidase) as compared to the standards (Acarbose and Voglibose). Thus, the results of the work clearly indicate great potential of baicalein to manage post prandial hyperglycemia.

KEYWORDS: Diabetes, Bacalein, alpha amylase, antioxidant, alpha glucosidase.

T528: DESIGN, SYNTHESIS AND ANTI-TUBERCULAR ACTIVITY OF SOME NOVEL PIPERINE ANALOGUES

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ABSTRACT

Piper species is known as king of spices because of its principle constituent piperine, isolated from Piper nigrum Linn and Piper longum Linn, belonging to family Piperaceae. Piperine is an alkaloid and has known to possess many pharmacological activities like antifungal, antimicrobial, anticancer, anti-inflammatory, anxiolytic, antiproliferative, trypanocidal, antidepressant, insecticidal, antiasthmatic, antileishmanial, antihyperlipidemic, antioxidant, analgesic

and UV protective. Piperine also acts as activity potentiator or bioenhancer of some classes of drugs such as those employed in the treatment of tuberculosis, depression, anxiety and epilepsy. Piperine, has received enormous attention in the last two decades as a versatile bioactive molecule with structural components: methylenedioxyphenyl ring, side chain with conjugated double bond and basic piperidine moiety attached through a carbonyl amide linkage to the side chain. The present study was done with an aim to explore the docking potential of 70 novel piperine analogues for their anti-tubercular activity against Mycobacterium Tuberculosis using Glide tool of Schrodinger. Molecular docking studies were performed on these novel piperine derivatives using protein with PDB ID: 5DUC to understand the binding interactions between ligands and target protein. The binding energies of the compounds ranges from – 7. 155 kcal/ mol to -6.547 kcal/ mol. The results suggested that the ligand with good binding energy interacts through hydrogen bonding as well as pi-pi interactions with amino acids of protein. Ligands which showed lowest binding energy with high stability are Schiff's bases having carbonyl amide benzene ring substituted with electronegative atoms. On the basis of these docking results, we have synthesized a series of these analogues. The anti-tubercular activity was done for all synthesized compounds by using Micro plate Alamar Blue Assay (MABA). All the compounds of the series showed significant activity as compared with standard drugs Pyrazinamide, Ciprofloxacin and Streptomycin but interestingly, p604, p707 and p689 compounds with their lowest binding energies (-7.155 kcal/ mol, -7.08 kcal/ mol and -6.967 kcal/ mol) exhibited highest activity with MIC = 3.12 µg/ml, 3.12 µg/ml and 6.25 µg/ml respectively which is an evidence that these compounds can be good candidates against Mycobacterium Tuberculosis (Vaccine strain, H37 RV strain) as anti-tubercular agents.

T529: PHYTOCHEMICAL ANALYSIS OF BRASSICA NIGRA L.SEEDS

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ABSTRACT

Alzheimer's disease rises with predictions of 115 million being affected by 2050 due to aging of the population, continuing lack of progress in identifying, effective treatment modalities and lack of predictive diagnostic techniques. Clinical treatment for this disease relies mostly on prolonging the availability of acetylcholine release into the neuronal synaptic cleft. Inhibition of acetylcholinesterase leads to breakdown of acetylcholine and it is considered as a promising strategy for the treatment of Alzheimer's disease. An enormous source of acetylcholinesterase inhibitors is provided by the abundance of plants in nature and also supportive for the development of new drug substances with amended targeting activity and reduced side effects. In the present work phytochemical analysis of the Brassica nigra L. showed the presence of carbohydrate, alkaloids, steroids, sterols, glycosides, saponins, tannins, phenolic com-pounds, proteins, amino-acids and fixed oil. Alkaloids and volatile oils are present in the seed which may be useful in the treatment of Alzheimer's disease.

KEYWORDS: Plants, Acetylcholinesterase Inhibitors, Alzheimer's disease, Brassica nigra L. cholinergic neuron, Cognition.

T531: ROLE OF ANIMAL STRAIN ON IMQ-INDUCED PSORIASIS

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ABSTRACT

Psoriasis is a chronic inflammatory, autoimmune disease that develops by the complex mechanisms involving genetic and immune factors. Despite various advances in the treatment, an ideal therapy for the cure is not been established. Parallelly on the other side lack of good animal model compromised the research in psoriasis. Imiquimod (IMQ) - induced psoriasis is most widely used murine model that produces psoriasis like skin lesions in mice. Strain dependent aspects of IMQ-induced derma-titis in some mice strains was demonstrated previously but the strain effect of IMQ between C57BL/6 and Swiss Albino mice is never been investigated. Therefore, in the present study we aimed to check the influence of animal strain on IMQ-induced psoriasis between C57BL/6 and Swiss Albino mice. Our study comprised of four treatment groups (n=6) in each stain. The models were developed by the topical application of 5% IMQ (62.5mg/dorsal skin, 5mg/right ear). To validate the models, anti-psoriatic drug 0.05% clobetasol (120mg /dorsal skin, 10 mg/right ear) and antioxidant 1% curcumin (150mg/dorsal skin, 12.5mg /right ear) was used. The psoriasis severity was assessed by measuring PASI score, skin thickness, % change in body weight and histopathology studies. The systemic effect of IMQ was observed by measuring spleen size and spleen index. The involvement of redox status was investigated by

the activity of enzymes SOD, catalase and levels of GSH. In both the strains IMQ application induced psoriasis-like skin inflammation which was confirmed by increased PASI, decreased body weight, increased skin thickness and histopathological alterations. However, the diseased stability and severity between the strains was not identical. Although IMQ application caused spenomegaly, IMQ + curcumin treated C57BL/6 mice showed another increment in spleen index. Activity of SOD, catalase and levels of GSH was declined indicating the participation of redox system in the genesis of the disease. These find-ings indicate the strain-dependent effect in IMQ-induced psoriasis between C57BL/6 and Swiss mice. Secondly, Swiss model was found to be better in terms of severity and stability than C57BL/6 model. Further, detailed mechanistic study will help to explain the pathological difference between these strains.

T532: LEAD MOLECULE IDENTIFICATION FOR HELMINTHIASIS FROM *VITEX TRIFOLIA*. LINN

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ABSTRACT

The attempt of this study is to discover the lead molecule for helminthiasis through sterile effect, in-vitro and in-silico evaluation of total methanolic leaves extract of Vitex trifolia Linn. The Antibacterial activity was done by Kirby-Bauer disc diffusion method in three different concentrations of the extract. In-vitro anthelmintic activity was carried out by petri dish and organ bath method. In silico docking studies were carried out using the 11 phytoconstituents against phosphoethanolamine methyltransferase (4FGZ) using AutoDock4.2, its working based on the Lamarckian genetic algorithm principle. In the docking studies, three important parameters like binding energy, inhibition constant and intermolecular energy were determined. Results obtained from this extract showed an antibacterial effect in three concentrations, at 16mcg/disc having a significant effect, when compared to blank and ciprofloxacin 5mcg/disc. For anthelmintic activity in petri dish method, the mean paralyzing time of Pheretima posthuma with the dose of 25, 50 and 100mg/ml were showed 13.78, 5.79 and 4.57minutes respectively. In case piperazine citrate (10 mg/ml) shows paralysis in 21.58 minutes. In organ bath method the time for paralysis of the worm was recorded on a slow-moving Sherrington rotating drum. The paralyzing time was decreased at increasing concentrations of the extract. From the in-silico docking studies abietatriene-3-ol binding energy, inhibitory constant (Ki), intermolecular energy is (-10.25kcal/ mol, 30.91nM, -10.84kcal/mol) lesser than the standard ligand phosphoethanolamine (- 6.03kcal/mol, 38.29µM, -7.82kcal/mol). This study author concludes that the active constituents in Vitex trifolia Linn having better anthelmintic activity, so these active constituents were optimized and made into a new moiety to treat helminthiasis condition.

KEYWORDS: Vitex trifolia, helminthiasis, binding energy, inhibitory constant, inter- molecular energy, phosphoethanolamine methyltransferase, abietatriene-3-ol, phosphoethanolamine

T533: IDENTIFICATION OF POTENTIAL CANDIDATE FOR TREAT DIABETES FROM SCHLEICHERA OLEOSA (LOUR) OKEN LEAVES

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ABSTRACT

Diabetes mellitus is a major health growing problem in most countries. The purpose of the study was to evaluate the antidiabetic activity of Schleichera oleosa (SO) leaves extracts. The in vitro anti-diabetic activity of the SO extracts was measured by using α-glucosidase and α-amylase enzyme inhibitory activity. For in vivo studies diabetes was induced in Wistar albino rats (150–250 g) by using nicotinamide (110 mg/ kg/p.o) and single intraperitoneal injection of streptozotocin (55 mg/kg/i.p). Diabetic rats were treated with ethanolic and aqueous extracts, which was compared with the positive, negative control and glibenclamide treated groups. The changes in body weight, oral glucose tolerance test, hypoglycemic effects, OGTT and serum lipid pro-file, biochemical analysis, and histopathological examination were assessed. In in vitro anti-diabetic study, the ethanol and aqueous extracts were found to be a potent inhibitor of α-glucosidase and α-amylase activity. Oral administration of SO extracts and standard drug for 28 days caused a significant decrease in the concentrations of Fasting blood glucose level, total cholesterol (TC), serum triglycerides (TG), low-density lipo-protein-cholesterol (LDL-C), malondialdehyde (MDA) and significant increase in the concentrations of high-density lipoprotein cholesterol (HDL-C), body weight and anti-oxidative enzymes were enhanced dose dependently with SO. Preliminary mechanisms were also elucidated. In this study, a novel flavonoid extracted from an ethanolic extract of SO was isolated and purified using column & TLC. The preliminary structure features of

SMK/SO/01 were investigated by FT-IR, 1H NMR, 13C NMR, LC-MS. Hence SMK/SO/01 can be considered for developing into a potent antidiabetic drug.

KEYWORDS: Diabetic rats; Schleichera oleosa; α-glucosidase; α-amylase, Pancreas, SMK/ SO/01

T534: EXTRACTION AND PHYTOCHEMICAL SCREENING OF AZADIRACHTA INDICA. A (NEEM) FOR ANTI MICROBIAL ACTIVITY

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ABSTRACT

The plant Azadirachta indica was selected for the anti-microbial activity against gram negative bacteria. The major microbial effects are produced by Salmonella and E. coli and hence it was selected to perform the activity. The leaves from the plant were collected and some amount of leaves were dried under shadow and some fresh leaves were kept. The plant barks were extracted with three different solvents like ethanol, n-hexane, chloroform. The phytochemical analysis such as test for alkaloids, triterpenoids, flavonoids, saponins, glycosides, tannins were performed. The separation of alkaloids, flavonoids and lipids from neem was performed by TLC with different solvents. The active compounds were retrieved and used for the determination of anti- microbial effect by cup diffusion method. The micro-organisms were evaluated for inhibition of the activity and compared with the standard Mac- Farland as recommended by WHO. Escherichia coli and Salmonella species showed larger zone of inhibition in ethanol extraction. The separated active compound alkaloids, flavonoids, lipids from TLC were found to be more effective against all tested organisms in shade dry samples and fresh neem lipid were ineffective against the tested organisms.

T536: FORMULATION, STANDARDIZATION AND IN VITRO ANTIDIABETIC EVALUATION OF POLYHERBAL SIDDHA FORMULATION (VILVA KUDINEER CHOORNAM)

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ABSTRACT

Diabetes is a chronic, metabolic disease characterized by elevated levels of blood glucose (or blood sugar), which leads over time to serious damage to the heart, blood vessels, eyes, kidneys, and nerves. The most common is type 2 diabetes, usually in adults, which occurs when the body becomes resistant to insulin or doesn't make enough insulin. There is a globally agreed target to halt the rise in diabetes and obesity by 2025.Diabetes was known to Indians from Vedic period by the name Asrava. In Ayurveda Diabetes is also referred to as Madhumeha. In Ayurveda, Prameha is caused due to sedentary lifestyle, lack of Exercise, Diwaswap (Day time Sleeping.) Choornam is a mixture of powdered herbs and or minerals used in Ayurvedic medicine. Choornam is chosen because they help to rectify the three doshas in the body, and to restore homeostatic balance that builds up in the body's digestive system and spreads to the tissues. Herbal medicine has witnessed a renaissance among the customers throughout the world. The recent upsurge in siddha system, an ancient system of Indian medicine practised in Southern parts of India can be seen by large scale manufacture of siddha formulations. Vilva kudineer Choornam is a Traditional Polyherbal formula-tion in Siddha used for the treatment of Diabetes. It comprises of Azadirachta Indica, Aegle Marmelos, Mangifera Indica, Syzgium Cumni, Gymnema Sylvestre, Andrographis Paniculata, Adhatoda Vasica. The formulation was made by taking required proportion of each powdered drugs. All the procured and authenticated drugs were dried in Shade and cleaned by hand sorting. The extract was prepared by macerating 200g of each formulation by cold maceration with ethanol and water with occasional shaking. There is no literature evidence of standardization of Vilva kudineer choornam. Our aim is to formulate and standardize the Vilva kudineer choornam. The organoleptic evaluation and physicochemical evaluation have been performed. On addition to that in-vitro anti-diabetic Evaluation of the formulation has also been carried out by alpha amylase inhibition assay. The phytochemical studies of the formulation were carried out and it revealed the presence of alkaloids, tannins and many others. In-vitro anti-oxidant activity of the formulation was established using DPPH free radical scavenging assay.

KEYWORDS: Diabetes, Vilva kudineer choornam, antioxidant, Alpha amylase, DPPH.

T537: A STUDY ON NOOTROPIC ACTIVITY OF SEED EXTRACTS OF ARTOCARPUS HETEROPHYLLUS LAM (MORACEAE) IN MICE AND RATS

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ABSTRACT

OBJECTIVES: The present study was aimed to explore the nootropic activity of A. heterophyllus (Moracea) in experimental animals like mice and rats. In traditional system of medicine this plant is extensively used to treat various disorders and the activity may be attributed to its phytochemical constituents. **MATERIALS AND METHODS**: Both alcoholic extact of seeds of A. heterophyllus (AESAH) and aqueous extract of seeds of A. heterophyllus (AQESAH) were prepared by maceration process. The extracts were subjected for LD50 studies by following OECD guidelines NO-425 and the maximum dose level of 2000 mg/kg, p.o. has not produced any abnormal behavior or mortality. Three different doses were selected for the present study like 100 mg/kg (low), 200 mg/kg (medium) and 400 mg/ kg (high) with respect to the highest LD50 dose tested with each extract. The nootropic activity of AESAH and AQESAH was evaluated by using Shuttle box, Elevated plus Maze models. Diazepam, Scopolamine and Sodium nitrite induced amnesic models in mice and Sodium nitrite induced hypoxia model in mice were also used. The behavioral study was tested by Lithium induced head twitches in rats. Piracetam was used as standard reference for all the above-mentioned models. **RESULTS:** Preliminary phytochemical studies revealed the presence of phytoconstituents like carbo- hydrates, flavonoids, tannins, triterpenes, saponins, proteins and amino acids in both the extracts. All the doses of AESAH and AQESAH (except low dose of AESAH) have shown a significant nootropic activity noted by increased step-down latency (SDL), decreased time spent in shock zone (TSZ) and number of errors (SDE) in passive avoidance paradigm. The two extracts except low dose of AESAH have significantly decreased the time spent in shock zone (TSZ) and number of step-down errors (SDE) in active avoidance model. A significant increase in inflexion ratio was noted with all doses of AESAH and AQESAH in Diazepam, Scopolamine and Sodium nitrite induced amnesic models respectively. In Lithium induced head twitches model in rats AESAH and AQESAH at all the 3 dose levels have significantly reduced the number of head twitches and further in Sodium nitrite intoxication model they have shown a significant increase in time for cessation of respiration in mice. **CONCLUSION:** Phytoconstituents such as flavonoids, tannins, triterpenes, saponins, essential oils, proteins and amino acids were already reported for their nootropic activity. Some of the phytoconstituents such as flavonoids, tannins, triterpenes, saponins, essential oils, proteins and amino acids were present in both the AESAH and AQESAH. Hence these can be accounted for the observed nootropic activity.

T538: A STUDY ON NEPHROPROTECTIVE ACTIVITY OF LEAF EXTRACTS OF ANNONA MURICATA LINN IN RATS

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ABSTRACT

AIM: To study the nephroprotective activity of the leaf extracts of Annona muricata Linn (Annonaceae) in Paracetamol, Cisplatin and Gentamycin induced nephrotoxicity in rats. **BACKGROUND:** In literature A. muricata is reported for its good source of antioxidants, vitamins B and C, tranquilizing and sedative activities. The oil from the leaves is externally used for neuralgic, rheumatism and arthritic pain. Further no scientific data is available on the nephroprotective activity of leaf extracts of this plant. Hence, the present study was aimed to explore the nephroprotective activity of leaf extracts in different nephrotoxic models in rats. **MATERIALS AND METHODS:** A. muricata leaf powder was extracted with 95% alcohol (Soxhlet method) and with chloroform water (maceration process) to get alcoholic (AELAM) and aqueous (AQELAM) extracts. Both the extracts were subjected to LD5o studies in mice following OECD guidelines No. 425 by 'up and down method'. Further the two extracts were subjected for preliminary phytochemical evaluation. Then both extracts were evaluated for their nephroprotective activity in various experimental models like Paracetamol, Cisplatin and Gentamycin induced nephrotoxicity in rats. Different parameters like serum Alkaline phosphatase, BUN, CRE, CHO, ALB, and UAC were noted in all the three models. Standard drug like Rutin was used as reference compound in all the models. **RESULTS:** Preliminary phytochemical studies with AELAM and AQELAM revealed the presence of phytoconstituents like alkaloids, glycosides, tannins, flavonoids and carbo- hydrates in both the extracts. When these two extracts are subjected for LD50 studies none of them produced abnormal behavior or mortality even at the highest dose level of 2000 mg/kg body weight in mice. Three different doses like 100 mg/kg (low), 200 mg/kg (medium)

and 400 mg/kg (high) were selected with respect to their LD50 tested dose i.e., 2000 mg/kg. Rutin, AELAM and AQELAM treated groups in all the three models have significantly reduced the biochemical parameters like ALP, BUN, CHO and CRE but the ALB levels were significantly increased. The histopathological changes i.e., congestion of glomeruli and necrosis were moderately prevented with Rutin and both the extracts. **CONCLUSION:** The present study confirmed the nephroprotective activity with AELAM and AQELAM. Several phytoconstituents like alkaloids, glycosides, flavonoids, tannins and carbohydrates were already reported for their nephroprotective activity. Some of the phytoconstituents mentioned above are present with both the extracts and these can be accounted for the nephroprotective activity.

T539: PAPAIN, AN ACTIVE CONSTITUENT OF CARICA PAPAYA AMELIORATES NEUROPATHIC PAIN IN RATS SUBJECTED TO SCIATIC NERVE LIGATION BY MITIGATING OXIDATIVE DAMAGE AND EXCITOTOXICITY

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ABSTRACT

Neuropathic pain (NP) is a disability disorder mainly affects one's quality of life. Free radicals and oxidative stress have been implicated in the pathogenesis of NP. Carica papaya, a neutraceutical with wide range of medicinal properties. Papain (PN) is the active constituent of Carica papaya with potent antioxidant property. Hence, we aimed to evaluate the antioxidant activity of PN in sciatic nerve ligation (SNL) induced neuropathic pain in rats. We assessed a battery of behavioral and biochemical changes after SNL in rats. Male Wistar rats were divided into four groups of eight rats in each group; Sham control, SNL control, PN 50 mg/kg/p.o treated group, PN 100 mg/kg/p.o group. The drug or vehicle was administered orally by gavage once daily for 14 days. Nociceptive threshold was assessed on 15th day. Biochemical markers namely total pro-tein, reduced glutathione, myeloperoxidase, lipid peroxidation, superoxide dismutase, Catalase, glutamate, calcium was measured in sciatic nerve homogenate. PN 100 mg/ kg significantly ($p<0.001$) attenuated the SNL induced nociceptive threshold and bio-chemical changes which was supported by histological changes in sciatic nerve. These findings suggested that PN attenuated neuropathic pain in rats through mitigating oxi-dative stress and excitotoxicity.

KEYWORDS: Neuropathic pain, oxidative damage, excitotoxicity, papain, Carica papaya

T540 HYPOGLYCEMIC AND ANTI-DIABETIC EVALUATION OF VERNONIA DIVERGENS (DC.) EDGEW. IN STREPTOZOTOCIN INDUCED DIABETIC RATS

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ABSTRACT

The term diabetes mellitus (DM) describes a metabolic disorder of multiple etiologies characterized by chronic hyperglycemia with disturbances of carbo-hydrate, 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. Diabetes mellitus may present with characteristic symptoms such as thirst, polyurea, blurring of vision and weight loss. Many herbal products have been described for diabetes mellitus in ancient literature of Ayurveda in India. The current investigation for anti-diabetic activity of the plant Vernonia divergens (DC.) Edgew. have not been reported till date. However, to enlighten the folkloric claim of the plant, the study was carried out on various animal models like albino mice, albino rabbits, Wister rats, rabbits, hamsters, dogs and monkeys. The whole plant of Vernonia divergens was studied on various animal models. Screening methods generally have been carried out on rodents and non-rodents respectively. As per the concept the mice and rats have been chosen. The methanol and aqueous extracts of vernonia divergens showed maximum control in blood sugar in hyperglycaemic Wister rats than other experimental extracts. The test extract also reduces blood sugar level to a maximum extent in case of normal animals. Among the study, the effects of MEVD (methanolic extract of Vernonia divergens) and AEVD (Aqueous extract of Vernonia divergens) in both normoglycemic and hyperglycemic model were done through oral route. Toxicological study revealed that the MEVD and AEVD were safe and does not alter normal physiological and behavioral effect even at a higher dose level of 3000mg/kg body weight. The whole protein, whole cholesterol, AST (Aspartate aminotransferase), ALT (Alanine aminotransferase), Alkaline phosphatase enzyme

activity of streptozotocin administered rats showed significantly higher than normal rats, the test extract treated rats significantly reduced the elevated levels. The results of the present study indicate that MEVD and AEVD may have a place in the therapy of DM as anti-diabetic and/or hypoglycaemic agent. Thus, it may be concluded that the methanol and aqueous extract of Vernonia divergens (DC.) Edgew might be beneficial in lowering the blood sugar concentration and management of other diabetic complications. However, in comparison between both the extracts, the methanol extract was found to be significantly more potent than that of the aqueous extract in all aspects.

KEYWORDS: Vernonia divergens, normoglycemic, hyperglycemic, Wister rats.

T541 COMPARATIVE IN VITRO STUDY OF PHLOROTANINS FROM RED ALGAE (*Gelidiella Acerosa*) AND BROWN ALGAE (Sargassum ilicifolium)

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ABSTRACT

Phlorotanins are a type of tannin consists of phloroglucinol units linked to each other in various ways and are of wide occurrence among marine plants, especially found in brown algae such as kelps and rockweeds or sargassacean species and red algae. On isolation of phlorotanin from Sargassum illicifolium and Gelidiella acerosa, Sargassum was found to have more Phlorotanin content. On FT-IR spectra of Phlorotannin which is present in Brown and Red algae was dried with KBR and which formed discs, in which frequencies were analyzed. In DPPH Scavenging activity, DMSO-Dimethyl sulphoxide and extracts in addition of ethanol were prepared for test and standard to find %DPPH inhibition. The Percentage DPPH inhibition of ascorbic acid, and red algae and brown algae are compared in this activity. The phlorotanins showed the presence of phenol, tannin also gave positive result for specific test of phlo rotannins.

KEYWORDS: Phlorotanins, DMSO, Ascorbic acid

T542: INVESTIGATION OF IN-VITRO ANTHELMINTIC ACTIVITY OF PENTAHYDROXY FLAVONE- MORIN HYDRATE

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ABSTRACT

Morin Hydrate is a flavonoid popularly known for its antioxidant property that can be isolated from Maclura pomifera (Osage orange), Maclura tinctoria (old fustic) and from leaves of Psidium guajava (common guava). The 2′,3,4′,5,7- Pentahydroxyflavone was evaluated for anthelmintic activity using distinct worms like earthworm (Pheretima posthuma), tapeworm (Raillietina spiralis) and round worm (Ascaridiagalli). Parasitic diseases caused by Helminthes lead to significant health hazards to animals resulting in enormous economic impact. While a number of anthelmintics are currently available, all are encountering resistance and one with a mode of action are needed. The present study reveals the paralysis followed by death of different worms at the selected concentration. Albendazole was used as reference standard drug whereas distilled water was used as control. The various concentration 0.5mg/ml, 1.0mg/ml, 1.5mg/ml, 2.0mg/ml and 2.5mg/ml of standard drug and Morin Hydrate exhibited a dose- dependent inhibition of worm response to pin-prick. Determination of paralysis time and death time of worms were recorded. From the observation, Morin hydrate showed similar potential activity at concentration 1.5mg/ ml with the standard drug, and optimal activity at 1.0mg/ml concentration ensuring the anthelmintic property of Morin Hydrate. Hence the lower concentration of flavone produces desired result which helps in optimization of the dose. The result shows that Morin Hydrate possesses potential vermicide activity and thus, can be applicable as an anthelmintic.

KEYWORDS: Anthelmintic activity, Flavone, Morin Hydrate, Intestinal parasites, vermicidal.

T543: SYNTHESIS, CHARACTERIZATION AND EVALUATION OF PYRAZOLINE DERIVATIVES AS POTENTIAL ANTITUMOR AGENTS.

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ABSTRACT

INTRODUCTION: Cancer is a general term used to refer to a condition where the cells begin to grow and reproduce in an uncontrollable way. Medically it is known as malignant neoplasm. There are about 200 known cancers which can affect humans. Chemotherapy is an important method of treatment for cancer. The research in the area of chemotherapy is of continuous interest for medicinal chemists as the chemotherapy suffers from major drawback of causing side effect and target specificity. In view of this the search for new chemotherapeutic agent continues to be an active area of research. Pyrazolines are well-known and important heterocyclic compound and the ring is five membered with a nitrogen atom. These molecules have diversified pharmacological properties and have gained lot of attention in the field of research. Pyrazolines demonstrate various types of biological activities including cytotoxic and anticancer activity. **AIM:** This work is aimed at synthesis of some pyrazole derivatives, characterization of synthesized compounds and Evaluation of anticancer activity of the compounds by in vivo method using DLA model. **EXPERIMENTAL:** The synthesis of pyrazolines was carried out by synthesizing various chalcones. The synthesized compounds were characterized by IR, NMR and Mass spec-troscopy. The compounds were screened for invitro cytotoxic activity by Tryphan blue dye exclusion method. Out of the ten derivatives which were screened, two compounds showed good cytotoxic activity and these two compounds were further screened for anticancer activity by in-vivo method using DLA model**. RESULTS AND DISCUSSION:** In-vivo antitumor studies were done using Dalton's Lymphoma ascites tumor model (DLA) model and Swiss albino mice of either sex were used. Parameters analyzed were Average life Span, Percentage increase in life span (% ILS), Body weight analysis, Packed cell volume and Hematological parameters. Two derivatives namely Phenyl-3-hydroxy Phenyl and 4-Chloro Phenyl- 3-Nitro Phenyl which exhibited good cytotoxic activity by Tryphan blue dye exclusion method were evaluated for antitumor activity by DLA model and they showed a prolonged life span of cancerous mice by 31.03 and 21.11%. Conclusion: The pyrazoline derivatives were synthesized and characterized. As two derivatives showed significant anticancer activity, they are potential molecules as anti- cancer agents and further studies can be carried out.

KEYWORDS: pyrazolines, chalcones, anti-tumor activity synthesis, characterization, in- vitro screening, in-vivo dla.

T544: RP-UHPLC FOR THE SIMULTANEOUS ESTIMATION OF PARACETAMOL AND TOLPERISONE IN COMBINED DOSAGE FORM

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ABSTRACT

A RP-UHPLC method was developed and validated for the simultaneous determination of PCM and TOL in pharmaceutical dosage form. The chromatographic separation was achieved on a Zorbax Eclipse Plus C18 column (50 x 4.6mm, 1.8µm), the mobile phase consisting a mixture of 0.1% aqueous triethylamine (pH adjusted to 3.0 with orthophosphoric acid, acetonitrile and methanol in the ratio of 50:25:25v/v/v at flow rate of 0.3ml/min and UV detection was done at 256nm. The retention time was found to be 2.07 and 3.06min for PCM and TOL respectively. The validation of the developed method was carried out and the linearity was found to be in the concentration range of 80.84 to 242.52µg/ml for PCM and 37.39 to 112.18µg/ml for TOL with correlation coefficient of 0.999 for both PCM and TOL respectively. The % accuracy was found between the range of 99.32-100.42 for PCM and 99.16-100.05 for TOL. System precision and method precision was determined and % RSD values were within the limits (<2.0). The proposed method was found to be specific, linear, accurate, precise, rugged and robust. Hence the developed and validated method can be used routinely for the simultaneous determination of PCM and TOL in combined dosage form.

KEYWORDS: Paracetamol, Tolperisone, UHPLC and Validation.

T545: SIMULTANEOUS ESTIMATION OF PARACETAMOL (PCM) AND ZALTOPROFEN (ZLT) BY HPTLC

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ABSTRACT

The method employed TLC aluminum plates precoated with silica gel G60 F254 as the stationary phase. The mobile phase consisted of Hexane: Chloroform: Methanol in the ratio of 3.5:5.5:1 v/v/v. The linear response was found to be in the concentration range of 0.8-4 µg/spot for PCM and 0.2-1 µg/spot for ZLT and the correlation coefficient were found to be 0.996 for PCM and 0.998 for ZLT. The %RSD value obtained for intraday precision were 0.237 and 0.377 and for inter-day precision were 0.259 and 0.766 respectively, the low % RSD indicates that proposed method is precise as per ICH guidelines. The accuracy of the method was determined and the mean recovery of PCM was 99.73-100.15% and ZLT was 99.57-100.18%. LOD and LOQ values were found to be 0.034 µg/spot and 0.105 µg/spot for PCM, 0.0034 µg/spot and 0.018 µg/spot for ZLT and pointed towards adequate sensitivity of the method. The drug content was found to be 99.90% and 99.8% with standard deviation.

KEYWORDS: Paracetamol, Zaltoprofen, HPTLC

T546: GREEN SYNTHESIS OF OLEUROPEIN FROM OLIVE LEAF AND INVIVO CHARACTERIZATION OF OLEUROPEIN IN MENINGITIS INDUCED ANIMALS

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ABSTRACT

Currently, the developments in the area of Phytomedicine will foster the need of herbal medicine as a biomolecule to revert various pathological uncertain-ties. The extraction methods used for isolation of biomolecule from olive leaves were associated with a risk of residual solvent & lack in extraction efficiency. Henceforth, there is a need to develop or introduce some novel techniques which can encapsulate all the risks headed with extraction process. The current investigation, sketched to unravel the effect of process parameters on the extraction efficiency of Oleuropein from Olea europaea, a major secoirodoid resided in olive leaf. Olive leaf was collected, authenticated and subjected to proximate, phytochemical analysis to contemplate the source of active moiety. The précised solvent was functionalized to depict the influence of independent variable on response by using central composite design. The independent factor selected were treatment temperature (50-70°C), steam duration (10-30min) and response in % extraction efficiency. The data projected from the experimental runs was fit to stepwise regression analysis, which suggests a linear model with R2 of 0.95. from the design space, the model is stable at the range of 0.002 to 0.80 which indicates lack of fit is very less and more curvature effects are clearly visualized with P value at 5% level of significance. From the perturbation plot, we observed that two-way interactions play a pivotal role i.e., temperature and steam duration together show a significant effect on extraction efficiency of Oleuropein from Olive leaf. The validation of the model is confirmed by check point analysis which showcases that the differences between actual and predicted values were less than 2% (%RSD < 2%). Steam blanching technique shows a significant upswing in the concentration of Oleuropein and the maximum extraction efficiency was obtained under optimal experimental conditions of 60-65°C temperature and 20-25 min of steam duration. Henceforth, an effectiveness of this technique will pave a way to design higher protocols for the isolation of biomolecules from Olive leaves.

KEYWORDS: Steam blanching; Polyphenol; Oleuropein; Central Composite design.

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