

CONFERENCE THEME:

**Pharmaceutical Industries:
Future Avenues**



Journal of Pharmaceutical Research (Conference Proceedings) Krupanidhi College of Pharmacy

ABS1: TECHNOLOGICAL ADVANCEMENTS IN ORAL FILMS

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ABSTRACT

The aim of the review was to explore the necessity, advantages and different techniques of oral films for enhancing solubility of poorly soluble drugs with an emphasis on the newer, state-of-the-art technologies, such as 3D printing and hot-melt extrusion (HME). The historical background of oral films is presented along with the regularly used techniques. The modern approach of quality-by-design (QbD) is unraveled, identifying appropriate critical process parameters (CPP) and applied to oral films. A section is devoted to modern technologies such as 3D printing and HME of oral films. Oral films are innovative formulations by which poorly soluble drugs have been found to give positive results in enhancing their solubility and dissolution characteristics. With modern sophisticated techniques, precise mass production of oral films has been given a thrust. Oral films have better patient compliance, improved biopharmaceutical properties, improved efficacy, and better safety. By applying QbD and implementation of modern technologies the newer generation of oral films are yielding promising results.

ABS2: TOPICAL AND TRANSDERMAL BENEFITS OF NANOSTRUCTURED LIPID CARRIERS

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ABSTRACT

Lipid based carriers (solid lipid nanoparticles-SLN and nanostructure lipid carriers-NLC) were developed at the beginning of the 90s and have been extensively used for topical and transdermal delivery of pharmaceuticals and cosmeceuticals. Among them, NLC's are widely accepted for maintaining drug stability, improving drug therapy, solubilizing poorly water-soluble drugs, achieving controlled and sustained drug delivery and reduced toxicity. This review article discusses different formulations and characterization techniques and discusses how NLCs can penetrate the skin barrier. Further, overview on the current state of the art of NLCs as therapeutic and cosmetic formulations are also discussed in detail. The study highlights the reported data on oral bioavailability and toxicological studies and how these NLC's can be employed as promising drug delivery systems for novel treatments in the near future.

ABS3: HPLC METHOD DEVELOPMENT AND VALIDATION FOR DETERMINATION OF GLIBENCLAMIDE IN PHARMACEUTICAL DOSAGE FORMS

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ABSTRACT

Glibenclamide is an oral hypoglycemic agent, which increases the insulin secretion by binding to the sulfonylurea receptors on the beta cells or with ATP sensitive potassium channels on the pancreatic beta cells. The present study includes development of HPLC technique for determination and estimation of glibenclamide in pharmaceutical dosage forms using acetonitrile: phosphate buffer (70:30) as mobile phase. The detection wavelength of glibenclamide was found to be at 235 nm. The developed method was validated for its linearity, precision, accuracy, specificity, robustness and

determination of limit of quantification and limit of detection in the mobile phase. The linearity demonstrated a correlation coefficient of 0.999. Thus, this method can be considered to be precise, reliable, rapid, simple, sensitive and cost effective for determination of glibenclamide in pharmaceutical formulations.

ABS4: ASTHMA CONTROL TEST AMONG TEXTILE WORKERS IN KONGU NADU REGION – TAMIL NADU

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ABSTRACT

Objectives: Respiratory disorder is one of the major health threats to textile workers as they are highly exposed to garment dust for persistently. Therefore, the garment factory workers are engaged in the textile industry shows highly significant morbidity of bronchial airway obstruction than among those who are not working in textile industries. **Materials and Methods:** A clinical investigation of the disease knowledge and adherence among garment unit in a 600 bedded hospital revealed that factory employers are complained of respiratory challenges include tightness of the chest cavity, continues cough, and breathing difficulties. The main of this observational study was access to the pervasiveness of bronchial symptoms and asthma gens concentration in garment industries. The obtained report was compared with the different follow-ups. All workers are responded the asthma control test questionnaire. **Results:** The textile workers (n = 346, including male 588 and female 758). The training level was underneath the optional dimension in 47% of patients and middle school 32%; 56% of patients were fat, and 20% of patients had mild persistent, 19% had mid intermittent, 28% of patients had moderate persistent, and 33% had severe persistent and extreme steady asthma. 31%, of patients, had family atopic; 15% of Kongu Nadu garment workers had cotton dust allergies. **Conclusion:** Knowledge of asthma was low in older patients and regular asthma care was to a great extent lacking.

ABS5: VALIDATED RP-HPLC METHOD FOR THE DETERMINATION OF CLOFARABINE IN BULK AND TABLET DOSAGE FORM

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ABSTRACT

A novel, simple and economic reverse phase high performance liquid chromatography (RP-HPLC) method has been developed for the estimation of Clofarabine in bulk and tablet dosage form with greater precision and accuracy. Separation was achieved on Develosil C18 MG-5 column (150X4.6mm i.d., 5µm) in isocratic mode using Trifluoro acetic acid PH-3.6 buffer, Methanol and Acetonitrile in the ratio of 70:15:15(v/v/v) as mobile phase, pumped in to the column at flow rate of 1.0 mL min⁻¹ and the detection of eluent from the column was carried out using variable wavelength UV detector at 263 nm. The total run time was 10 min and the column was maintained at ambient temperature. The retention time of Clofarabine was 5.578 min. The standard curves were linear over the concentration range of 10-30 µg/ml with R² 0.999 and the LOD and LOQ values for Clofarabine were 0.0007 µg/ml and 0.023 µg/ml, respectively. The percentage recovery was found to be 101.78 – 99.86 %, the % RSD was found to be 0.08. The percentage amount of a marketed tablet formulation of Clofarabine was found to be 101.2 %. The method was validated as per ICH guidelines. Validation studies demonstrated that the proposed RP-HPLC method is simple, specific, rapid, reliable and reproducible. Hence the proposed method can be applied for the routine quality control analysis of Clofarabine in bulk and tablet dosage forms.

ABS6: CLINICAL ASSESSMENT ON KNOWLEDGE OF GARMENTS DUST INDUCED BRONCHIAL ASTHMA AMONG KONGU NADU TEXTILE WORKERS

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ABSTRACT

One of the major factors that influence proper management of asthma is patient's education. Prior knowledge of etiology, usage of medication regarding asthma is a necessity for better patient compliance. Evaluation of knowledge of diseases and attitude is very important for the patient's wellbeing, which hinders asthma complication and also synergises health improvement. Data regarding disease knowledge and drug adherence for occupational asthma is negligible in India. Hence the evaluation of knowledge of garment induced bronchial asthma amongst textile workers which was conducted in a few textile industries adds in to the data. In reference to this regard, patient required information had been taken from 857 patients with a response rate of 96%. Majority of the participants were between 30-60 years of age. Ratio of male and female was found to be 39.08% (334) and 61.02 % (523) respectively. The participants received a score value of 20 and 15 for disease knowledge and attitude towards asthma respectively. Therefore, present clinical study concluded that patients lack the knowledge and medication adherence which also induces misunderstanding in management of disease condition precisely in patients suffering from occupational asthma.

ABS7: ANTIOXIDANT AND ANTICANCER POTENTIAL OF METHANOLIC EXTRACT OF KIGELIA PINNATA FRUITS AGAINST DENA INDUCED HEPATOCELLULAR CARCINOMA IN RATS

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ABSTRACT

The aim of the present study is to study the preventive nature of *Kigelia pinnata* methanolic extract (MEKP) during Diethyl Nitro Amine (DENA) induced hepatocellular carcinoma in rats. Phytochemical screening for the methanolic extract of *Kigelia pinnata* was carried out. The methanolic extract of the fruits was tested for antioxidant property by in vitro DPPH radical scavenging assay and reducing power assay and also anticancer activity of methanolic extract of *Kigelia pinnata* was evaluated in DENA induced Sprague Dawley rats at the doses of 250 and 500 mg/kg body weight orally and both doses were administered for 14 weeks. After 24 h of the last dose, the rats were sacrificed and antitumor effect of KMPE extract was assessed by evaluating biochemical parameters such as

AFP, AST, ALT, ALP and LDH to evaluate anticancer activity of the extract. MDA and SOD levels in the liver tissue of each group were estimated for determining in vivo antioxidant activity of the plant. Histopathological studies were carried out. MEKP showed the presence of alkaloids, glycosides, flavonoids, tannins, saponins, reducing sugars and phenolic compounds. MEKP showed concentration dependent free radical scavenging activity and increase in reducing power activity. Comparative analysis on the KPME treatment groups revealed that high dose (500mg/kg body weight) showed significant reduction in the serum level of enzymes. Also, there was dose dependent effect of MEKP in the MDA and SOD level in the liver tissue. Histopathological studies showed the decrease in the damages to the liver tissue in the MEKP treatment groups. Hence the methanolic extract of *Kigelia pinnata* possesses anti-hepatocellular activity which may be due to its hepato protective action. This may be due to the presence of flavonoids. Further studies can be carried out to elucidate the exact mechanism of its activity as an antioxidant and anticancer agent. The methanolic extract of *Kigelia pinnata* possesses anti-hepatocellular activity which may be due to its hepato protective action. This may be due to the presence of flavonoids. Further studies can be carried out to elucidate the exact mechanism of its activity as an antioxidant and anticancer agent.

ABS8: COTTON DUST INDUCED PNEUMONIA IN GERIATRIC PATIENTS IN KONGU NADU REGION: A CASE HISTORY

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ABSTRACT

Ceaseless introduction to cotton residue may result in different respiratory disorders like pneumonia, Acquired Respiratory Distress Syndrome (ARDS) and so on. Such occupation initiated disarranges are in the ascent right now. Here is an instance of a 70-year-old male patient who is experiencing network procured pneumonia brought about by presentation to cotton dust gained because of working at a material industry. The essential causative living being for the

equivalent was observed to be *Acinetobacter* and *E. coli*. He is known to have no co-morbidities on affirmation and has boss grumbings of hack with expectoration, blood-decolored sputum, fever and shortness of breath for around about fourteen days. The patient was found in a condition of respiratory trouble amid confirmation, which was basically treated with Non-Invasive Ventilation. The patient was observed to be unreasonably hypoxic because of declining ARDS. The patient's chest x-beam uncovered combination and the patient were at first treated within-toxins and given nor adrenaline for hemodynamic help. Antimicrobial treatment included Colistin and Cotrimoxazole. The patient additionally hinted at different organ harm, in particular hinted at Acute Kidney Damage. The condition was recognized because of anomalous creatinine levels orpee yield. Steps were taken to control and treat the equivalent.

ABS9: EVALUATION OF BEHAVIORAL AND COGNITIVE EFFECTS AGAINST DIABETIC MODEL IN YOUNG AND ADULT RATS

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ABSTRACT

The present work was carried out to study the behavioral and cognitive effects in young and adult diabetic rat models. Diabetes was induced in young and adult rats by using two different doses of STZ (40mg/kg & 60 mg/kg. Behavioral studies were carried out on 1st, 14th and 28th day by using various psychopharmacological tests like elevated plus maze, hole board test, forced swim test. The body weight and fasting blood glucose level were also assessed. The STZ induced groups showed a decrease in body weight after the induction of diabetes. The fasting blood glucose level was found increased in whole groups irrespective of the doses. The time spent and the number of entries in the open arm of elevated plus maze was decreased during the course of the study with an increase in the transfer latency in adult group than that in young groups. The light dark test too showed similar results to that of elevated plus maze with a decrease in the time and number of entries to the light chamber. The hole board test showed a decrease in number of poking in those groups administered with STZ. The forced swim test showed a significant increase in the immobility time in adult groups whereas the younger groups didn't show any significant changes.

ABS10: FORMULATION AND EVALUATION OF IMMEDIATE RELEASE FILM COATED TABLETS OF AN ANTICANCER DRUG (DASATINIB)

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ABSTRACT

The objective of the present study was to develop an immediate release tablet of Dasatinib using different concentration of super disintegrants with a view to obtain rapid action for myelogenous leukemia and acute lymphoblastic leukemia. Dasatinib is a chemotherapy medication used to treat certain cases of leukemia's. Materials and Methods: Various formulations were prepared by direct compression technique using super disintegrants (cross carmellose sodium, sodium starch glycolate and crospovidone). Effect of different super disintegrants on drug release was studied. Optimized formulation was selected on the basis of drug release and its in-vitro release profile compared with the reference product (Sprycel). Results and Discussion: The dissolution results showed gradient increase in the drug release with the increase in concentration of the super-disintegrants. Conclusion: Among all the formulations F3 containing croscarmellose sodium (4.5%) was found to show best results with 98.3% release within 45 minutes and it exhibited a release profile comparable to the reference product.

ABS11: NOVEL APPROACHES IN NANO PARTICULATE DRUG DELIVERY SYSTEM TO OVERCOME HUMAN IMMUNODEFICIENCY VIRUS

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ABSTRACT

The development of antiretroviral medication has considerably modified the perception of Human Immunodeficiency virus /acquired immunodeficiency syndrome (HIV/AIDS) as a fatal to a last stage manageable sickness. The convenience and organization of antiretroviral medicinal consideration has essentially diminished mortality and horribleness related to HIV and AIDS. Antiretroviral drug deficiency remains a serious drawback in underserved populations worldwide. Partnerships among pharmaceutical

corporations, tutorial investigators and government and

nongovernment agencies are necessary to boost access to life-saving regimens. Nanomedicine opens new restorative roads for assaulting viral diseases and for enhancing treatment achievement rates. Significantly, nanomaterials like dendrimers and numerous other inorganic nanoparticles like gold, silver, zinc, and iron can be utilized for HIV treatment. Moreover, nanoparticles could best go about as adjuvants, convoys throughout vaccine delivery, nanomedicine could also be an appropriate methodology in HIV/AIDS treatment by methods for offering lower dose and aspect impact, better patient-to-persistent consistency and HIV diagnosis. This article explores the varied applicable methods for delivery of antiretroviral drugs within the style of liposomes, dendrimers, solid lipid nanoparticles, microspheres and polymeric nanoparticles. These approaches of delivery are verified to supply innovative and direct delivery of antiretroviral medication by enhancing the therapeutic effectiveness, targeting the location of action and increasing the activity and safety of the medication.

ABS12: A STUDY ON GENERALIZED ANXIETY DISORDER AND INTOLERANCE OF UNCERTAINTY IN YOUNG WORKING ADULTS IN BENGALURU

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ABSTRACT

Anxiety disorders follow a chronic course affect daily life and are associated with significant global burden. The cardinal feature of GAD is excessive and uncontrollable worry regarding future events and outcomes. The Intolerance of Uncertainty has been associated predominantly (conceptually and empirically) with generalized anxiety disorder. The aim of this study was to analyze the generalized anxiety disorder as well as the intolerance of uncertainty in young working people. Cross sectional study, Online Survey was conducted for a period of six months. The survey was elaborated through Google Forms and disseminated through social networks. Questionnaires used were generalized anxiety disorder scale

(GAD7) scale and Intolerance of Uncertainty scale (IUS-12). A total of 150 participants data were collected from different places of Bengaluru between 18 to 30 years. When analyzing the results from Generalized Anxiety Disorder Scale we can see that female respondents have shown more anxiety than Men and when analyzing the results from Intolerance of uncertainty scale we can see that females are more vulnerable to uncertainty than males. Anxiety disorders tend to start early in life. Early recognition of symptoms is important so that treatment can be administered. Anxiety disorders are often treated with counseling, medicine, or a combination of both. Dealing with uncertainty is an unavoidable part of daily life. If you can't get rid of uncertainty in your life, the only way to manage your intolerance of uncertainty is by learning to be more tolerant of uncertainty.

ABS13: DRUG UTILIZATION EVALUATION OF OLANZAPINE AND ASSESSMENT OF ADVERSE DRUG REACTIONS ASSOCIATED IN PSYCHOTIC PATIENTS IN A TERTIARY CARE HOSPITAL

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ABSTRACT

To review the drug utilization and evaluation pattern of olanzapine and assessment of adverse drug reaction associated in psychotic patients in a tertiary care hospital. Methodology: A prospective Observational study was conducted in Department of Psychiatry, MVJ Medical College and Research Hospital, Bangalore, South India. Study was conducted for 6 months in In-patients who are diagnosed as suffering from psychosis which includes schizophrenia, delusional disorders, schizo-affective disorders, acute and transient psychosis and BPAD as per ICD 10 criteria. The utilization pattern of olanzapine therapy were assessed using case record forms with overall demographic data information was collected and ADR is assessed using standard scales. Result: Among 108 patients enrolled into the study 68 patients were under olanzapine therapy and rest were under other antipsychotics. A total of 68 patients olanzapine therapy patients out of which 51% were females and 49% were males. Majority of the patients belong to the age group of 28-37 years and 18-27 years and 66% patients were married. Schizophrenia was

found to be the common type of psychotic disorders with 63%. Even among the various psychotic disorders there was a slight female predominance. The hospitalization period was 12.43 ± 8.4 days. Majority of the patients had normal body mass index. Out of 68 patients 16 patients had switch over from olanzapine to other second-generation antipsychotics. Conclusion: This study has assessed for prescribing pattern of olanzapine in psychotic patients using a specially modified case reporting form. Olanzapine is most commonly prescribed antipsychotic compared to other antipsychotics for the treatment of paranoid schizophrenia and also in certain cases of bipolar affective disorder with mania or mixed episodes. Maximum patients were having paranoid schizophrenia.

ABS14: STUDY ON KNOWLEDGE AND BEHAVIORS OF YOUNG PEOPLE IN RURAL BANGALORE TOWARDS PEOPLE WITH MENTAL ILLNESS

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ABSTRACT

Background of the study: Psychiatric disorders exist worldwide, affecting about 10% of the adult population, at any given point in time. This study aims to estimate the magnitude or prevalence of mental-health-related public stigma among young people in rural areas of Bangalore. **Objectives:** To study the knowledge and behavior of young people in the community towards mentally ill people using MAKS and RIBS Questionnaires. **Results and Discussion:** In our study 60% of the respondents agreed that Medication can be an effective treatment for people with mental health problem and 90% of the respondents agreed that Psychotherapy can be an effective treatment. 90% of the respondents in our study agreed that depression was a type of mental illness. 92% agreed that schizophrenia was a type of mental illness. 90% agreed that bipolar disorder was a type of mental illness. 48% of respondents reported they have a close friend with a mental health problem. 30% reported that they had lived with someone with a mental health problem. 92% of respondents said they intended to continue a relationship with a friend with a mental health problem. 80% said that they intended to work with someone with a mental health problem. **Conclusions:** In a country where mental health disorders and stigma prevail, it was important to assess the factors that contribute to public stigma. Our results showed relatively moderate levels of stigma toward people with mental illness among community in rural areas of Bangalore. Improvement of public MHK

could contribute to reduction of public stigma.

ABS15: 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 tertiary care hospital. **Methodology:** A descriptive-observational study was carried out in the psychiatry department of MVJ medical college and research hospital for six months. 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 were 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 28-37 years (47.6%). 93% of our sample population was married. Schizophrenia was found to be the most common psychotic disorders with prevalence 26.7%. On analyzing 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 an antidepressant immunotherapy (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 the UKU scale. Majority of the patients experienced side effects under psychic class (82%). The side effects were found to be statistically significant with $**P\text{-value} < 0.0001$ (CI=95%) using logistic bivariate fit analysis. **Conclusion:** Our study showed that dry mouth, sedation, headache, weight gain, and constipation are the most common yet serious side effects of antipsychotics. Among these, weight gain is one of the predominant side effects in our study and second-generation antipsychotics are the offending agents. The side effects associated with antipsychotics are confounded by various factors like drug-drug interactions and poly pharmacy.

ABS16: COMPARATIVE STUDY ON ANGIOTENSIN CONVERTING ENZYME INHIBITOR AND ANGIOTENSIN RECEPTOR BLOCKER THERAPY IN PATIENTS WITH HYPERTENSION AND DIABETES MELLITUS

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ABSTRACT

Aim: To monitor the effect of ACEIs and ARBs alone or in combination with other drugs on blood pressure and to assess adverse drug reactions caused by these drugs. **Objectives:** The objectives were to compare the efficacy of Angiotensin converting enzyme inhibitor and Angiotensin receptor blocker in the patients suffering from hypertension alone and hypertensive diabetes and to compare the adverse drug reactions of Angiotensin converting enzyme inhibitor and Angiotensin receptor blocker in the patients suffering from hypertension alone and hypertensive diabetes.

Methodology: A Prospective Observational study was conducted in Department of General medicine, MVJ Medical College and Research Hospital, Bangalore, South India. Study was conducted for six months. In and outpatients who were diagnosed with hypertension and gave the inform consent were enrolled in the study. The effectiveness of anti-hypertensive drugs as alone Telmisartan (40mg) and Enalapril (2.5mg) or in combination with other hypertensive drugs in lowering blood pressure were monitored. The patient blood pressure was monitored on daily basis by using electronic sphygmomanometer on 0, 3rd and 6th day. The adverse drug reactions associated with these drugs were assessed based on causality using Naranjo's scale and severity using Hart wig and Siegel scale. The obtained data was analyzed using descriptive analysis for demographic data, MANOVA for monitoring reduction in BP, logistic fit model test for duration of ADR, ADR severity and relation to drug by H/o medication intake (days) and NIPALS is used for knowing the various factors effect on ADR. **Results:** A total of 200 hypertension patients participated in the study in which 100 were receiving Enalapril and remaining with Telmisartan. The overall means of systolic blood pressure for participants receiving Enalapril was shown to be reduced from 147.76mmHg to 134.77 mm Hg(-12.99mmHg) by the end of 6th day. The

overall means of systolic blood pressure for the participants receiving Telmisartan was shown to be reduced from 149.37mmHg to 131.71mmHg (-17.66mmHg) by the end of the 6th day. The participants receiving Enalapril was having ADRs such as 10% dry cough and 11% hypoalbuminemia were as participants receiving Telmisartan was having fewer ADRs such as 3% dry cough and 5% hypoalbuminemia. **Conclusion:** Telmisartan and Enalapril therapy was found to be effective in lowering systolic blood pressure in the participants. The Telmisartan was found to have less adverse drugs reactions than Enalapril.

ABS17: A STUDY ON THE UTILIZATION OF ANALGESICS IN POST-OPERATIVE PATIENTS

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ABSTRACT

Objective: The objective of this study was to evaluate the drug utilization pattern, therapeutic effect, and safety of analgesics among post-operative patients in a tertiary care teaching hospital, Bengaluru. **Methods:** A prospective observational cross-sectional study was conducted for 6months. Data were collected from the Departments of Orthopedics, Obstetrics, and Gynecology and Intensive Care Units, after getting approval from the Institutional Research and Ethics Committee and were analyzed by descriptive statistics. Most frequently prescribed analgesics with their pain-relieving effect and duration of sleep were assessed using the Wong- Baker Faces Rating Scale and the Pain and Sleep Questionnaire three-item index. **Results:** We observed 158 post-operative patients, of which 42.4% (67) were male and 57.5 (91) were female. The mean age of all the patients was between 18 and 80 years. Among all the analgesics (tramadol, paracetamol, and diclofenac) that were prescribed, intramuscular administration was the most preferred route. Diclofenac as alone and its combinations were found to be the frequently prescribed analgesic with a pain score of 82% as alone, and while in combination, it reduced the pain by 85% from its baseline value in post-operative patients. 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 subsided. **Conclusion:** Thus, this study suggested that post-operative pain control was able to be achieved by no opioid drug diclofenac alone itself and opioid analogs had been added to patients for whom pain relief could not be achieved.

ABS18: PARENT RELATED FACTORS INFLUENCING THE IMPROPER USE OF ANTIBIOTICS IN CHILDREN

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ABSTRACT

Background: Antibiotics are the drugs used for treating most of the infections. Parents' knowledge and practices to use medicines mainly antibiotics as prescribed by physicians have important effects on the management of childhood illness. Improper use of the antibiotics could be because of some strongly influenced parent related factors. Some factors like residing area, parent's age, education level of parents plays important role in the knowledge level of parents on antibiotic use and some other factors like income status, occupation level increase in number of children may influence on practice of antibiotic use in children. Improper use of antibiotics may result to antibiotic resistance and many other side effects for children. Hence our study aims to analyze the parent related factor leading to inappropriate use of antibiotic in children. **Objective:** To determine the parent related factors which are influencing the improper use of antibiotics in children. **Method:** A prospective study was conducted in 200 subjects from the randomly chosen communities in Bangalore. CRF and questionnaire were prepared along with ICF. CRF contains the demographic data and KAP questionnaire which was prepared by using Likert scale. Questionnaire was prepared in both English and local language Kannada in accordance with previously available literatures. Questionnaire consisted of questions to assess Knowledge and Practice of parents towards antibiotic use in children. Questionnaires were validated and either of the parents was asked to answer the questionnaire. The

responses were framed as strongly agree, Agree, Neutral, Disagree and strongly disagree to allot in categories like good, medium and poor. Door to door visit was done by the investigators. All parents who met the inclusion criteria were enrolled in the study after taking the informed consent form (IC). Parents of children below 12 years were selected by convenience sampling technique. The basic demographic data of parents and their children including other details were collected by researcher. CRF was given to parents who are educated and were asked to fill. However Investigators interviewed and filled CRF for parents who were un-educated or who had difficulty in reading. If both parents were present, only one of them was supposed to answer the questionnaire and was selected based on who was responding more. 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 practices 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 etc. Improper guidance by retail pharmacist in choosing alternative antibiotic based on availability of the prescribed one also controls parents' practice of antibiotics.

ABS19: A STUDY ON COMPLICATIONS OF POLY PHARMACY 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 drugs 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 condition. 41% of the patients showed medium adherence while 17% and 32% showed high and low 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 participants developed adverse drug reactions. One ADR was moderate and five ADRs were mild. The ADRs were metformin induced hypoglycemia (in 3%), glimepiride induced dyspepsia (in 2%), and metformin induced diarrhea (in 1%). 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 reactions, a greater number of potential drug-drug interactions and cognitive impairment.

ABS20: IMPACT OF PATIENT COUNSELLING IN IMPROVING KNOWLEDGE, ATTITUDE, PRACTICE AND HEALTH RELATED QUALITY OF LIFE IN COPD PATIENTS

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ABSTRACT

Objective: The objectives were to assess the baseline KAP and HRQoL among COPD patients, to provide educational/patient counseling interventions to study population and to assess the impact of pharmacist-assisted patient counseling to improve KAP and HRQoL in COPD

patients. **Methods:** 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 assessed for the patients who met the inclusion criteria. Patient-centered pharmacist counseling was done for all patients using various counseling aids and was reviewed after 2 months for follow-up purpose. The impact of pharmacist's counseling in improving the KAP and HRQoL was determined by comparing the baseline and follow up data. **Results:** 100 patients were included in the study. After patient counseling, it was observed that there was a significant improvement in certain domains of KAP and HRQoL from the baseline scores. **Conclusion:** Pharmacist assisted patient counseling had a significant impact on improving KAP and HRQoL in COPD patients. However, a more comprehensive approach should be adopted that addresses solutions for better patient education on smoking cessation, counseling the patient's family members, providing special care for geriatric patients

ABS21: ASSESSMENT OF PARENTAL KNOWLEDGE, ATTITUDE, PRACTICE TOWARDS 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 children 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 questionnaire. 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 parents 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 excellent 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; and attitude 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.

ABS22: EPIDEMIOLOGY OF SCHIZOPHRENIA IN AN INDIAN HOSPITAL

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ABSTRACT

According to WHO estimates, schizophrenia affects approximately 24 million people worldwide. As epidemiological studies on schizophrenia are sparse in India, present study was undertaken to analyze the Sociodemographic profile and distribution pattern of schizophrenia in India. Demography of the patients like age, sex, family history, ICD – 10 sub class, outcome as clinical status of patient at the time of discharge and length of hospital stay were also studied. Marital status and family history of psychiatric illness were also studied. Majority of

the patients were males 81(58.27 %) The average age was 34.4 ± 11.9 years. Predominance of males below 40 years

and females above 40 years were observed. Paranoid schizophrenia was the major subclass (63.3%). The present study revealed an increasing trend of schizophrenia among the patients admitted in a tertiary care hospital.

ABS23: PRESCRIPTION PATTERN OF ANTIPSYCHOTICS POLYPHARMACY IN PATIENTS WITH SCHIZOPHRENIA IN AN INDIAN HOSPITAL

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ABSTRACT

Background: Schizophrenia is a burdensome illness which virtually affects all aspects of the patient's life. There is a lack of national level data from India on prescription pattern of Antipsychotics Polypharmacy and other drugs combination in the treatment of Schizophrenia. **Aim and Objectives:** To evaluate Prescription pattern of Antipsychotic Polypharmacy in schizophrenia. **Methodology:** The medication records of patients admitted from August 2006 to May 2007 were reviewed to evaluate the prescription pattern of antipsychotics poly pharmacy, Demography of the patients like age, sex, were also evaluated. **Results:** The medical records of 139 schizophrenic patients were reviewed, out of 139 patients 30.93% (n = 43) patients received combination therapy. In combination therapy 28.77% (n=40) were prescribed two antipsychotics and 0.007% (n= 3) were prescribed three antipsychotic drugs. The average age was 34.4 ± 11.9 years. F 20.0 Paranoid schizophrenia received maximum prescriptions for combination therapy 18.71 % (n=26). Comparison of adjunct medication showed Anxiolytics & Anticholinergics 17.26% (n=25) received maximum prescriptions for combination therapy A total of 20.86% (n=29) received combination of Second-Generation Antipsychotics SGA + First Generation Antipsychotics FGA, maximum patients 18 was in the combination of Haloperidol + Risperidone **Conclusion:** The present study revealed an increasing trend of polypharmacy among schizophrenia patients admitted in a tertiary care hospital. The present study demonstrates the rate of antipsychotic polypharmacy is relatively low in India.

ABS24: PRESCRIPTION PATTERN AND DISTRIBUTION PATTERN OF SCHIZOPHRENIA: A NATURALISTIC STUDY

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ABSTRACT

Background: Schizophrenia is a burdensome illness which virtually affects all aspects of the patient's life. There is a lack of national level data from India on prescription pattern of Antipsychotics and other drugs in the treatment of Schizophrenia. **Aim and Objectives:** To evaluate distribution and Prescription pattern of schizophrenia. **Methodology:** The medication records of patients admitted from August 2006 to May 2007 were reviewed to evaluate the prescription pattern of antipsychotics, Demography of the patients like age, sex, family history, type of schizophrenia based on ICD – 10 sub class, outcome of patient at the time of discharge and length of hospital stay were also evaluated. **Results:** The medical records of 139 schizophrenic patients were reviewed, majority were males 81(58.27 %) The average age was 34.4 ± 11.9 years. Predominance of males below 40 years and females above 40 years were observed. Paranoid schizophrenia was the major subclass (63.3%). Second generation antipsychotics were the major class (93.5%) used, among which tablet olanzapine was prescribed maximum (54.7%). Inj. haloperidol was the major (15.8%) first generation antipsychotic used. Anxiolytics (57.5%) and anticholinergics (56.8%) were the major adjuvant drugs used. The average hospitalization period was 12.4 ± 8.4 days and majority (92.1%) improved at discharge. **Conclusion:** The present study revealed an increasing trend of schizophrenia among the patients admitted in a tertiary care hospital. Increased application of second-generation antipsychotics can improve outcomes like hospitalization period and clinical status at discharge.

ABS25: PRESCRIPTION PATTERN OF SECOND-GENERATION ANTIPSYCHOTICS AND OUTCOMES OF PATIENTS WITH SCHIZOPHRENIA IN AN INDIAN HOSPITAL

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ABSTRACT

A cross-sectional observational study was carried out to assess the clinical characteristics of patients with schizophrenia, treatment pattern and outcomes in a tertiary care hospital of South India. A retrospective evaluation of the prescription pattern of second-generation antipsychotics and the clinical outcome of patients diagnosed with Schizophrenia in a tertiary care Indian hospital. The influence of patient demographics like age, sex, and family history, type of schizophrenia and treatment on the outcome of patient at the time of discharge and length of hospital stay were also evaluated. Among a total of 139 schizophrenic patients, majority were males 81(58.27 %) and the average age was 34.4 ± 11.9 years. Predominance of male patients below 40 years and females above 40 years were observed. Paranoid schizophrenia was the major subclass (63.3%). Paranoid schizophrenia was the most prevalent subclass. Second generation antipsychotics were the major class (93.5%) used, among which tablet olanzapine was prescribed maximum (54.7%). Inj. haloperidol was the major (15.8%) first generation antipsychotic used. Anxiolytics (57.5%) and anticholinergics (56.8%) were the major adjuvant drugs used. The average hospitalization period was 12.4 ± 8.4 days and majority (92.1%) improved at discharge. An overall male predominance of schizophrenia among male population, especially more in age group below 40 years and the female domination above 40 years of age was observed. Second generation antipsychotics were the major class of treatment provided among which olanzapine received maximum prescriptions. Haloperidol was the major drug used among first generation antipsychotics. For the management of schizoaffective disorders, mood stabilizers like lithium, anxiolytics like lorazepam, antidepressants like fluoxetine and sertraline were commonly prescribed. Anticholinergics like benhexol was prescribed for controlling the extrapyramidal side effects of antipsychotics. The increasing trend of prescribing second generation antipsychotics reflect the efficacy and safety profile as compared to first generation antipsychotics.

The present study revealed an increasing trend of Paranoid schizophrenia and the use of second-generation antipsychotics improved outcomes like hospitalization period and clinical status at discharge.

ABS26: AMORPHOUS SOLID DISPERSION BASED ORAL DISINTEGRATING FILM OF EZETIMIBE: DEVELOPMENT AND EVALUATION

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ABSTRACT

Background: Ezetimibe is a cholesterol-lowering agent with an oral bioavailability of 50% by virtue of its poor solubility and extensive hepatic and intestinal metabolism. **Objective:** The study aimed to overcome low bioavailability issues of ezetimibe by formulating an oral disintegrating film. **Methods:** The low solubility of ezetimibe was undertaken, preparing solid dispersions using mannitol, β -cyclodextrin, and urea. The mannitol solid dispersion assimilated oral disintegrating film was prepared and optimized using 23 factorial designs, where the concentration of film formers hydroxypropyl methylcellulose (K5& K15) (X1and X2) and super disintegrant, sodium starch glycolate (X3) was used as factors on the response disintegration time (Y). The films were evaluated for physical properties, time of disintegration, and drug release profiles. **Results:** Mannitol solid dispersion (1:2 ratio) based on the superior drug content, solubility and in vitro release profile was preferred in film formation. The low crystalline nature of the solid dispersion was very evident by the absence of prominent peaks in the X-Ray diffraction pattern and the reduced peak intensity of melting endotherms. The correlation coefficient (R²) and statistical parameter analysis of variance specify the implication of linear factors on responses, which is apparent from confidence intervals (P-values) less than 0.05. The in vitro release profile of all the eight formulations (F1-F8) in a phosphate buffer solution of pH 6.8 revealed a significant increment in comparison to ezetimibe. The study revealed that the formulation approach.

ABS27: QUALITY BY DESIGN BASED DEVELOPMENT OF ETRAVIRINE SELF MICRO EMULSIFYING DRUG DELIVERY SYSTEM

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ABSTRACT

Objective: The main objective of the present research work was to develop systematically the Self Micro Emulsifying Drug Delivery system of BCS Class IV drug in a Quality by Design framework. **Methods:** The quality by design-based formulation development proceeds with defining the Quality Target Product Profile and Critical Quality Attributes of dosage form with appropriate justification for the same. The statistical Mixture design was used for the development of the formulation. The independent variables selected for the design were Oleic acid, Labrasol and PEG 6000, whereas droplet size (nm), emulsification time (sec), % drug loading and % drug release at 15 min were considered as the potential quality attributes of the Self Micro Emulsifying System. The eight different batches of Etravirine-Self Micro Emulsifying systems (ETV-SMEDDS) were prepared and checked for the Critical Quality Attributes. The simultaneous optimization of the formulation was done by the global desirability approach. **Results:** The characterization report obtained for all the different batches of formulation was analyzed statistically by fitting into regression models. The statistically significant models determined for droplet size (nm) (R²= 0.96 and p-0.1022), emulsification time (sec) (R²= 0.99 and p-0.0267), % drug loading (R²= 0.93 and p-0.1667) and % drug release at 15 min (R²= 0.96 and p-0.0911) and were statistically significant. The maximal global desirability value obtained was 0.9415 and the value indicates, the selected factors and responses have a good correlation and are significant enough for optimization and prediction of best formulation. **Conclusion:** The QbD approach utilized during the development of ETV-SMEEDS facilitated the identification of Critical Material Attributes and their significant impact on the Critical Quality Attributes of SMEDDS. The concept of building quality into product through the QbD application was utilized successfully in the formulation development.

ABS28: FUNDAMENTAL OF A COMPARATIVE TREATMENT IN RHEUMATOID ARTHRITIS: A BRIEF REVIEW

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ABSTRACT

Rheumatoid arthritis (RA) is a debilitating chronic systemic autoimmune inflammatory disease, a long-term condition and affects 1-3% of population worldwide that causes severe pain, inflamed bone erosion, unsteadiness, stiffness in the joints and deformity. It gradually deteriorates over the course of many years. The exact causes of RA are still unknown but

genes, environmental factor, hormone, obesity, smoking; age may be involved in autoimmune development and progression. Pathophysiology of RA is usually due to synovial membrane inflammation, chemokine involvement leading to swollen joints. In the early hours, diagnosis and management can help to prevent damage to the joints. To understand the recent advances in physiology of RA, several biologics DMARDS include TNF-inhibitor, anti-CD20 antibody, IL-6 receptor antibody are implemented in current therapies and these advances are based on disease modifying therapy that includes with a goal where drug should reach targeted site and focused on pain relieving. Therapies are normally personalized with patients need including their general well-being. This review provides a modern appraisal from current literature on different RA treatment regimes.

ABS29: A NIOSOMAL GEL OF CEFOPERAZONE SODIUM FOR TOPICAL APPLICATION

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ABSTRACT

The present study endeavors to prepare a niosomal gel of Cefoperazone sodium (CFS), as a novel dermal delivery for the treatment of skin infections. CFS loaded niosomes were prepared using different molar ratio of Tween 80 and Cholesterol by ether injection method using experimental design. The optimized formula was evaluated for DSC, XRPD and AFM. A niosomal gel with the optimized formulation was prepared in Carbopol 934 and were evaluated for gelling properties, in-vitro release, ex-vivo permeation and skin irritation study on rats. Quality by design was successfully executed to get stable (Zeta potential -30mV), nano sized (365.3 nm) niosomal vesicles. The niosomal gel of CFS showed a pH around 5.5, and a viscosity of 84.13±0.25 cps, enhanced permeation and no skin irritation. Hence, the study depicts that a superior site-specific delivery of CFS can be achieved with a niosomal gel of the drug in the treatment of skin infections.

ABS30: EXPERIMENTAL DESIGN SUPPORTED LIPOSOMAL AZTREONAM DELIVERY: IN VITRO STUDIES

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ABSTRACT

Purpose: The present study focuses on a systemic approach to develop liposomal aztreonam as a promising dosage form for inhalation therapy in the treatment of pneumonia and explores the in-vitro antimicrobial and cell uptake efficacy. **Methods:** Liposomes were prepared by ethanol injection method using the lipids - soya phosphatidylcholine (SP) and cholesterol (CH). A central composite design (CCD) was employed to optimize the lipid composition to evaluate the effect on vesicle size, zeta potential and entrapment efficiency of the formulation. A numerical and graphical optimization was carried out to predict the optimized blend. The optimized formulation was characterized for vesicle size, surface charge, encapsulation, surface morphology, differential scanning calorimetry (DSC), powder X Ray Diffraction (PXRD), thermogravimetric analysis (TGA), in vitro diffusion, accelerated stability studies, antimicrobial studies on *Pseudomonas aeruginosa* NCIM 2200 and in vitro cell uptake studies. **Results:** The optimized formulation was found to have a particle size of 144 nm, a surface charge of -35 mV, with satisfactory drug entrapment. The surface morphology study proved the formation of nanosized vesicles. The drug release from liposomal matrix was biphasic in nature. The solid-state study revealed the reason for good encapsulation of drug. The moisture retention capacity was found to be minimum. The anti-microbial study revealed the potential antibacterial activity of the optimized formulation over the pure drug. The formulation was found to be safe on the epithelial cells and showed a marked increase in cellular uptake of aztreonam in a lipid carrier. **Conclusion:** It can be concluded that the optimized liposomal aztreonam could be considered as a promising approach for the delivery of aztreonam through inhalation.

ABS31: STATISTICAL OPTIMIZATION AMALGAMATED APPROACH ON FORMULATION DEVELOPMENT OF NANO LIPID CARRIER LOADED HYDROPHILIC GEL OF FLUTICASONE PROPIONATE

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ABSTRACT

Introduction: Formulation of a nano lipid carrier loaded hydrophilic gel of a corticosteroid; fluticasone propionate (FP) was investigated systemically with response surface model (RSM) for promising dermal delivery of the drug.

Objectives: To achieve a better penetration of the drug and to overcome the generally associated adverse reactions of corticosteroids, the present study, explored the formulation and evaluation of nano lipid carriers (NLCs) of FP in a hydrophilic gel base. **Methods:** A central composite design was proposed to study the effect of processing materials on the physicochemical properties of the NLC. High shear homogenization method with stearic acid, isopropyl myristate and poloxamer 407 was used to make different batches of FP-NLCs. The model was optimized at a significance level of $P < 0.05$. FTIR, DSC and surface morphology studies were carried out for the optimized product. The optimized product was incorporated in the Carbopol P940 gel base and was evaluated for its mechanical and rheological properties, ex-vivo permeation and skin irritation study. **Results:** It was observed that using the proposed model, a nano size (179 nm) stable (Zeta potential -26 mV) optimized product of FP-NLC with 85% entrapment efficiency was achieved. The nanogel exhibited a spread ability of 4.2 gm.cm/sec and a viscosity of 92.6 cp. Approximately 3.5 times improvement in ex-vivo permeation and no skin irritations on animals were reported on application of the nanogel of FP. **Conclusion:** Hence the investigation created a paradigm to explore the efficacy of nanogel of FP for dermal application with improved permeation and promising therapy for dermatitis.

ABS32: NOVEL HERBAL DRUG FORMULATIONS - A REVIEW

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ABSTRACT

Recently the use of herbal medicines has been improved all over the world due to their astounding therapeutic effects and fewer adverse effects as compared to the modern medicines. However, delivery of herbal drugs also requires modifications with the purpose to attain sustained release, to increase patient compliance etc. The basic thought behind it is treatment of each disease is hidden in nature. Previously herbal drugs could not attract scientists towards the development of novel drug delivery systems due to processing, standardizing, extracting and identification difficulties. But now days with the advancement in the technology, novel drug delivery systems (NDDS) open the door towards the development of herbal drug delivery systems. Great advancement has been made in the uses of plant therapeutics, on development of novel herbal formulations like polymeric nanoparticles, nano capsules, liposomes, phytosomes, nano emulsions, microsphere, transferosomes and ethosomes. These formulations have

reported to have several advantages over the traditional preparations such as improved solubility & bioavailability, reduced toxicity, controlled drug delivery, protections of plant actives from degradation. The present review highlights the current status of the development of novel herbal formulations and summarizes their method of preparation, type of active ingredients, size, and entrapment competence, route of administration, biological activity and uses of novel formulations.

ABS33: A REVIEW ON AYURVEDIC MEDICINAL PLANTS FOR EYE DISORDERS FROM ANCIENT TO MODERN ERA

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ABSTRACT

The management of eye disorders by chemical drugs without any side effects is still a challenge to the medical system. But the herbal medicines have potential to overcome the limitations associated with conventional drugs. Therefore; many efforts have been made to identify new medicinal plants from different sources because of their effectiveness, fewer side effects and relatively low cost. Approximately 200 plants worldwide have been documented to support treatment of eye disorders and several plant species have been advocated in Traditional Indian Medicine for their ophthalmic effects. In the present review it is proposed to highlight the medicinal plants used from ancient time for the treatment of eye diseases, their merits and demerits and role of Modern medicines over demerits of medicinal plants traditionally used for eye disorders. Review concluded that by using techniques and polymers of modern era, the best Herbal formulations may be developed.

ABS34: GLOBAL REGULATORY AFFAIRS - ROLE IN THE BIOPHARMACEUTICAL INDUSTRY

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ABSTRACT

The demand for globally acceptable products heightens the imperative for harmonization of regulatory requirements to

lend efficiency and cost effectiveness to the process of product development, manufacturing and expediency to global access. In addition, biopharmaceutical companies have continued to expand their frontiers to attain a global reach, with presence in many regions and countries, and therefore exposed to myriad, and sometimes diverse, regulatory requirements and operating standards. The challenges of globalization in a heterogeneous world with an evolving regulatory landscape and expectations of multiple stakeholders have increased the complexity, unpredictability and intensity of the biopharmaceutical product development and registration process. These challenges likewise reinforce the crucial role of the regulatory team and underscore the need for enhanced global regulatory function with regulatory professionals who are strong leaders, business partners and strategic contributors. The scope of the regulatory affairs group function spans the entire spectrum of product development, manufacturing, registration, post-marketing activities and lifecycle optimization. The regulatory team and professional hold a unique position of importance with impressive diversity in function and significant breadth and depth of responsibility.

ABS35: GMP MEETS REGULATORY AFFAIRS

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ABSTRACT

For getting a drug approved it is required to demonstrate its quality efficiency and safety. For that purpose, the format of the Common Technical Document (CTD) which is mandatory in Europe since more than 10 years now has to be used. It is also used to apply for a marketing authorization in the US and Japan. Therefore, a good understanding of the CTD structure is inevitable and a basic requirement for all persons from GMP regulated departments involved in providing and compiling documents for a marketing authorization application. For the maintenance of a marketing authorization, it is very important to know how to handle all the changes and variations occurring during the life cycle of a medicinal product. The rules for handling variations in Europe are laid down in the variation's regulation, being applicable as well for national marketing authorizations from August 3rd 2013 – and supporting guidelines. For handling changes in the US rules are provided in different guidance's for industry and for approval of changes in Japan there are specific procedures in place to be followed. Maintaining marketing authorizations in a global scenario is a challenge and requires strategic planning and a good knowledge of the

different regulations and timelines.

ABS36: SOLUBILITY AND STABILITY ENHANCEMENT OF AZITHROMYCIN

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ABSTRACT

Azithromycin has 37% bioavailability when given in oral route, because of its poor water solubility; this decreases its effectiveness for optimal delivery of drug and clinical effect. Its reduced solubility is therefore a difficulty in design and development of dosage form. During this study, amorphous forms of azithromycin were prepared via quench cooling, technique and desolvation of chloroform- and ethyl acetate solvates. These amorphous forms were characterized by means of several techniques. Solubility studies confirmed the superior solubility of the azithromycin glass (prepared through quench cooling) and amorphous forms (desolvation of solvates) over the azithromycin monohydrate in water. The solubility in water improved in the order of azithromycin monohydrate < azithromycin glass < azithromycin glass powder < amorphous chloroform desolvate. The azithromycin monohydrate, as well as the amorphous forms of azithromycin demonstrated stability over a one-month period of exposure 40°C and relative humidity (RH) of 75%. The azithromycin glass at lower temperatures of 25°C and 30°C (both at 75% RH) tended to transform into the more crystalline form at week 4 of the study. These transformations were, however, not as significant as during the 40°C / 75% RH study.

ABS37: FORMULATION AND EVALUATION OF KETOPROFEN PRESS COATED TABLETS FOR CHRONOTHERAPY

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ABSTRACT

The objective of the current study is to develop and evaluate Chrono therapeutic drug delivery system of ketoprofen for the treatment of rheumatoid arthritis with distinct pre-determined lag time of 5.5 hr. The basic design of the system consisted of an inner core, which is surrounded by the polymers by compression coating. Core composed of drug, lactose, potassium bicarbonate. The outer layer composed with hydrophilic and hydrophobic polymers in different

ratios. The effect of level of swelling layer and rupturable coating was investigated. Lag time and dissolution tests were performed using the USP type II paddle apparatus at 50 rpm in 0.1 N HCl and phosphate buffer 6.8 pH. The obtained results showed the capability of the system in delaying the drug release for programmable period of time which improves the anti-inflammatory therapy in the management of arthritis. From the results the formulation which is composed with EC & Xanthus gum shows 5.5 hr lag time with 98% drug release. It was observed that lag time decreases with increasing concentration of hydrophilic polymer. The drug release follows first order kinetics with non-diffusion mechanism which was confirmed from tepeppas plot. This work demonstrated the possibility of development of the press coated tablet in order to obtain a Chrono therapeutic drug delivery system with the desired drug release profile.

ABS38: PULLULAN BASED NOVEL SELF ASSEMBLING NANOPARTICLES FOR ORAL INSULIN DELIVERY

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ABSTRACT

Polymeric nanoparticles delivery systems have emerged as a promising approach for peroral insulin delivery. In this research work, we have prepared anionic pullulan and cationic polymer-based nanoparticles by a mild polyelectrolyte ion gelation method. As pullulan is a neutral polysaccharide, carboxymethylated and sulphated derivatives of the polymer were synthesized to provide pullulan with a negative charge. These polymers were characterized by FTIR and ¹H-NMR. These derivatives were then complexed with cationic polymer to produce the Nano complexes. Insulin encapsulated nanoparticles were prepared by the ion gelation method and characterized. The particle size distribution, polydispersity index and zeta potential of nanoparticles were determined. The % Encapsulation efficiency of insulin was determined by HPLC method. The particle sizes of insulin loaded nanoparticles were obtained in range of 170 to 270 nm. Encapsulation efficiency of insulin was found to be greater than 55%. The electrostatic interactions between negatively charged groups of pullulan and the positively charged group of cationic polymer plays an important role in the encapsulation efficiency of insulin in nanoparticles. In-vitro insulin release studies showed an initial burst followed by a slow release of insulin. This insulin loaded pullulan-based nanoparticles were successfully developed and subjected for

further characterizations for oral delivery.

ABS39: FORMULATION AND EVALUATION OF MICROPARTICLES OF METRONIDAZOLE

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ABSTRACT

In the present study it was aimed to formulate delayed release Metronidazole micro particles, which will have enteric as well as sustained release properties. For the preparation of Metronidazole micro particles CAP, HPMCP, Eudragit L-100 and Eudragit S-100 were used as coating materials. Among the prepared micro particles the best formulation is reported by in-vitro release studies. Micro particles of Metronidazole were prepared using cellulose acetate phthalate as the retardant polymer by emulsion-solvent evaporation method. The micro particles formed were collected by filtration. They were evaluated for morphology, melting point, size distribution, drug content and percentage drug entrapped, flow property, in-vitro drug release and comparative drug release studies with commercial dosage forms. Drug content and percentage of drug entrapment were found to good in all the batches, as the entrapment values were not less than 85%. All batches of micro particles were found to have enteric release property as it was expected. The drug release from all batches of micro particles was found to be concentration dependent (first order release kinetics). The mechanism of drug release was found to be erosion as it was revealed by (1-Mt/M) ^{1/3} versus time plots. Comparative drug release study revealed that the formulated product (micro particles) have more sustained effect than the marketed product.

ABS40: BUCCAL BIO ADHESIVE DRUG DELIVERY - A PROMISING OPTION FOR ORALLY LESS EFFICIENT DRUGS

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ABSTRACT

Buccal drug delivery is a promising area for continued research with the aim of systemic delivery of orally inefficient drugs as well as a feasible and attractive alternative for non-invasive delivery of potent peptide and protein drug molecules. Buccal cavity was found to be the most convenient and easily accessible site for the delivery of

therapeutic agents for both local and systemic delivery as retentive dosage forms delivery. Buccal delivery offers a safer mode of drug utilization, since drug absorption can be promptly terminated in cases of toxicity by removing the dosage form from the buccal cavity. Since the above reasons, delivery of the desired drug as buccoadhesive drug delivery systems has been subject of interest since last three decades. However, the need for safe and effective buccal permeation, absorption enhancers is a crucial component for a prospective future in the area of buccal drug. Transmucosal is relatively new drug delivery strategy; in this traditional polymer are replaced by novel bio adhesive polymers such as thiomers (e.g. chitosan) and lectins etc. to overcome limitations of traditional polymers. Some of the buccoadhesive products like Nitrostat, Buccastem, Striant, Suscard are commercially available in the market to play a vital role in the treatment of various diseases. The buccoadhesive products are increasing day by day in the market, so they have steady growth rate of above 10 % in the world market.

ABS41: PULSATILE DRUG DELIVERY SYSTEMS: NOVEL DRUG DELIVERY

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ABSTRACT

Traditionally, drugs are released in an immediate or extended fashion. However, in recent years, pulsatile drug release systems are gaining growing interest. A pulsatile drug release, where the drug is released rapidly after a well defined lag-time, could be advantageous for many drugs or therapies. Pulsatile release systems can be classified in multiple-pulse and single-pulse systems. A popular class of single-pulse systems is that of rupturable dosage forms. Other systems consist of a drug-containing core, covered by a swelling layer and an outer insoluble, but semi permeable polymer coating or membrane. The lag time prior to the rupture is mainly controlled by: (i) the permeation and mechanical properties of the polymer coating and (ii) the swelling behavior of the swelling layer. As is frequently found in the living body, many vital functions are regulated by pulsed or transient release of bioactive substances at a specific site and time. Thus, it is important to develop new drug delivery systems to achieve pulsed delivery of a certain number of drugs in order to mimic the function of the living systems, while minimizing undesired side effects.

Special attention has been given to the thermally responsive poly (N-isopropyl acrylamide) and its derivative hydrogels.

Thermal stimuli-regulated pulsed drug release is established through the design of drug delivery devices, hydrogels, and micelles. Therefore, Pulsatile drug delivery is one such systems that, by delivering drug at the right time, right place and in right amounts, holds good promises of benefit to the patients suffering from chronic problems like arthritis, asthma, hypertension.

ABS42: FORMULATION AND EVALUATION OF RAPID DISINTEGRATING TABLETS OF DIPHENHYDRAMINE HCL USING POLYMER CARRIER SYSTEM

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ABSTRACT

The present study was aimed to mask the intensely bitter taste of Diphenhydramine HCl and to formulate a rapid disintegrating tablet (RDT) of the taste masked drug. In this work Diphenhydramine HCl complexed with amino alkyl methacrylate copolymer (Eudragit EPO) in different ratios by the precipitation method. The complex which not release drug in simulated salivary fluid was considered taste masked and selected for formulation of Rapid Disintegrating Tablets. Thus, this complex was used for further studies. Change in molecular properties of Diphenhydramine HCL was studied by FTIR spectroscopy. An FTIR study was suggest the complexation of drug with polymer. The complexes were successfully formulated into Rapid Disintegrating Tablets. Three super disintegrant were evaluated for rapid disintegration i.e. croscopovidone, croscarmellose sodium, and sodium starch glycolate. Among these croscopovidone induces rapid disintegration at 8% w/w. The prepared tablets were evaluated for various tablet properties such as hardness, friability, weight variation, drug content, disintegration time, and dissolution time. And all the batches were found to be within acceptable limits. All the tablets show disintegration time in the range of 15 to 32 seconds. Tablets with disintegration time of 15.16sec was selected as optimize formulation. This optimized formulation was studied for dissolution behavior. Dissolution of optimized tablet shows rapid release of drug (t₉₀ for tablet is ≈ 1min). Therefore, study concluded that successful masking of taste and rapid disintegration of the formulated tablets in the oral cavity.

ABS43: NANOMEDICINE AND DRUG DELIVERY -REVOLUTION IN HEALTH SYSTEM

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ABSTRACT

Nanomedicine seeks to deliver a valuable set of research tools and clinically helpful devices in the near future. The National Nanotechnology Initiative expects new commercial applications in the pharmaceutical industry that may include advanced drug delivery systems, new therapies, and in vivo imaging. Neuro electronic interfaces and other nano electronics based sensors are another active goal of research. Nanomedicine is the medical application of nanotechnology. The approaches to Nanomedicine range from the medical use of nanomaterials, to Nano electronic biosensors, and even possible future applications of molecular nanotechnology. The speculative field of molecular nanotechnology believes that cell repair machines could revolutionize medicine and the medical field. Nanotechnology's health implications can be split into two aspects: The potential for Nano technological innovations to have medical applications to cure disease, and the potential health hazards posed by exposure to nanomaterials. Current problems for Nanomedicine involve understanding the issues related to toxicity and environmental impact of nanoscale materials.

ABS44: IMPACT OF CLINICAL PHARMACIST'S EDUCATIONAL INTERVENTIONS ON QUALITY OF LIFE OF DIABETIC FOOT PATIENTS

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ABSTRACT

One of the long-term complications of diabetes mellitus is foot ulcers, a leading cause of hospital admissions, amputations and mortality in diabetic patients. Pharmacists can educate these patients and increase their awareness on the importance of routine foot care and screenings. We undertook the study to assess the impact of clinical pharmacist's educational interventions on the quality of life of diabetic foot patients. Two hundred patients satisfying the inclusion-exclusion criteria were randomly assigned into control and intervention groups. Baseline knowledge and

quality of life (QOL) of the patients were assessed using validated knowledge assessment questionnaire and RAND-36 Item Health Survey questionnaire respectively. The patients were then counselled about proper foot care measures, of coding etc. using a standard patient counselling leaflet. The patients were then re-evaluated using the same questionnaires in their follow up visits. Patient's base line knowledge about diabetic foot care was low. Only 5% of patients in the intervention group had 'high knowledge' at base line but this improved to 100% at the third follow up visit due to regular educational interventions by the clinical pharmacists. For control group patients this improvement was from 7 to 53%. There was significant increase in the QOL scores of the intervention group patients at the study end period in all the domains except social functioning, pain and general health. Less number of patients in the intervention group required toe amputations (15% vs. 31%) as compared to the control group. Pharmacist initiated patient education can increase patient knowledge regarding diabetic foot care and significantly enhance their QOL.

ABS45: KNOWLEDGE ATTITUDE AND PRACTICE ON SAFE USE OF MEDICINES IN THIRUVALLUR DISTRICT – A CROSS SECTIONAL STUDY

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ABSTRACT

Self-medication is common all over the world except developed countries. Self-medication causes serious hazard due to over-the-counter medication and also factors such as socio-economic status, satisfaction of the patient, gender etc., which led to several interactions and adverse drug reaction due to the lack of knowledge on drugs. Factors including poverty, cultural perception of certain diseases' entity and their perceived responses to indigenous medications have been widely reported as indicators in developing countries making the practice a necessity. This can have severe consequences like adverse drug reaction, drug resistance, protracted illness and even death. KAP study measures the Knowledge, Attitude and Practice of a community. The main use of KAP study is to explore changes in knowledge acquiring medicines. Understanding the levels of Knowledge, Attitude and Practice will enable a more efficient process of awareness creation as it will allow the program to be tailored more appropriately to the needs of the community. In this project we done that awareness

programs through the medication instruction and get the knowledge details from the public through the questionnaire. Then after the counselling the percentage of knowledge, attitude and practice are noted through the six-month duration. As a result of this study helps to now the today self-medication practice and giving educational programs through the pharmacist leads to reduce the negative health issues.

ABS46: PHARMACOVIGILANCE & REGULATORY AFFAIRS: INTERDEPENDENCE

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ABSTRACT

Pharmacovigilance (PV) is the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem. The Regulatory Affairs department is an important part of the organizational structure of a pharmaceutical company. To be effective the remit of drug regulatory authorities needs to go further than the approval of new medicines, to encompass a wider range of issues related to the safety of medicines. In order to achieve their respective objectives pharmacovigilance programs and drug regulatory authorities must be mutually supporting. On one hand, pharmacovigilance programs need to maintain strong links with the drug regulatory authorities to ensure that the latter are well briefed on safety issues in everyday clinical practice, whether these issues are relevant to future regulatory action or concerns that emerge in the public domain. On the other, regulators need to understand the pivotal role that pharmacovigilance plays in ensuring the ongoing safety of medicinal products. Hence, the present article depicts that regulatory affair create a comprehensive medicine safety system through careful strategic planning that envelope all aspects of pharmacovigilance