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T101: FORMULATION AND EVALUATION OF PIROXICAM EMULGEL FOR RHEUMATOID ARTHRITIS

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The present work includes the formulation and evaluation of Piroxicam emulgel for topical route of administration. It is mainly to avoid the risks and inconvenience of intravenous therapy and the varied conditions of absorption like pH changes in the presence of enzymes and gastric emptying time. This work includes the pre-formulation and formulation parameters. The drug was formulated into 6 batches and evaluated individually. The conclusion shows that the invitro drug release order is F5>F4>F6>F2>F3>F1 that the prepared neem oil based emulgel F5 formulation has shown good emulgel properties.

T102: PREPARATION AND CHARACTERIZATION OF HOLLOW MICROSPHERES CONTAINING AN ANTICOAGULANT LOADED WITHIN HYDROMELLOSE CAPSULE

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A controlled release drug delivery system for Dabigatran Etexilate mesylate was designed to increase its gastric residence without establishing any contact with the gastric mucosa. This was made possible by formulating hollow microspheres using cellulose acetate and acrycoat S100 poly- mers by solvent evaporation method. The prepared hollow microspheres were characterized for physical characteristics such as particle size, particle shape, surface morphology by Scanning electron microscopy. Further micromeritic properties, % yield, drug entrapment efficiency, total drug content, in vitro drug release and kinetics, in vitro buoyancy, cellulose acetate and acrycoat S100 poly- mers by solvent evaporation method. The prepared hollow microspheres were characterized for physical characteristics such as particle size, particle shape, surface morphology by Scanning electron microscopy. Further micromeritic properties, % yield, drug entrapment efficiency, total drug content, in vitro drug release and kinetics, in vitro buoyancy, in vivo radiographic studies were carried out. The obtained microspheres were free flowing, spherical and had a particle size ranging from 263.1 -445.5 µm. The drug entrapment efficiency increased with increasing amount of polymer and 62.29% was the maximum entrapment found. The FTIR and DSC results ruled out the possible incompatibility. The formulation CA1 containing 1:1 ratio of polymers was found to have maximum buoyancy, % drug content and drug release of 75.3%, 82.13% and 85.66% respectively compared to the same parameter of microspheres formulated using a single polymer. The drug release was found to follow Korsemeyer - peppas model showing super case II transport. The in vivo radiographic studies in albino rabbits further showed that the hollow microspheres were able to float in stomach up to 8 hrs. The formulated microspheres were successfully designed to produce controlled drug release. Thus, enhancing bioavailability and increasing patient compliance.

T103: FORMULATION AND EVALUATION OF CURCUMIN LOADED NANOSPONGES FOR COLON TARGETING IN COLITIS

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Government College of Pharmacy, Bangalore Nanosponges represent tiny sponges filled with a wide variety of drugs. The average size of these Nanosponges varies from 250nm – 1µm. Curcumin is a suitable candidate for colon targeting

nanoparticulate drug delivery system, owing its poor solubility and low bioavailability. The primary health benefit of curcumin is its potent anti-inflammatory activity in the colon region. Inflammatory bowel disease (IBD) is comprised of various chronic inflammatory conditions that affect the large and small intestines. Colon has a large amount of lymphoma tissue which facilitates direct absorption of the drug into blood. Curcumin loaded nanosponges (CURNS) were prepared by emulsion solvent diffusion method. From the preliminary trials, the constraints for independent variables, polymer concentration and stirring speed were set and experimental runs were performed by min run screen design. The characterisation study was performed on particle size, particle shape, surface morphology, micromeritic properties, percentage yield, drug entrapment efficiency, in vitro release studies. The accelerated stability studies were carried out for the optimized formulation according to ICH guidelines. The average particle size of the optimized formulation was 166.3 ± 23.32 nm suitable for oral delivery. The drug release mechanism followed Higuchi model. Pharmacokinetic studies of CURNS were compared to pure curcumin in rabbits, AUC of CURNS in plasma was approximately 3.07-fold greater than CUR solution and the mean residence time increased by 1.42 folds. The optimized formulation showed controlled release of drug with enhanced release in colon, indicating colon specific release. The findings revealed that the bioavailability of curcumin was increased. Hence, nanosponges of curcumin was found to be more effective.

T104: DESIGN OF POLYMERIC NANOPARTICLE OF NEBIVOLOL HYDROCHLORIDE BY EXPERIMENTAL DESIGN: OPTIMIZATION AND IN VITRO CHARACTERIZATION

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Nanoparticulate systems like solid lipid nanoparticles and polymeric nanoparticles are widely used to deliver both macro and micro molecules. The experimental formulation design involves an appropriate selection of carriers, delivery systems, and drug molecules which is laborious, expensive and requires lot of chemicals. This can be overcome by the use of Quality by Design which saves time, resources and cost. The aim of the present study was to develop a 'computational tools assisted formulation of polymeric nanoparticle of Nebivolol Hydrochloride' and evaluate its parameters. A 32 factorial design approach were employed to assess the influence of two independent variables, namely amount of Polymer and stabilizer on particle size and entrapment efficiency of prepared polymeric nanoparticle. The drug loaded polymeric nanoparticles were prepared by emulsion solvent evaporation method and characterized for zeta size, zeta potential, entrapment efficiency, and in vitro drug release through cellophane membrane. The optimized polymeric nanoparticles had a particle size of 291nm and entrapment efficiency of 83.4% and which was found to be within 95% of the confidence interval (CI) of the predicted value which is acceptable. SEM studies showed that the formed polymeric nanoparticles were smooth, spherical in shape and uniform in size. In vitro drug release study of optimized formulation showed sustained release for prolonged time period. Hence, the developed Nebivolol hydrochloride loaded in PLGA nanoparticles could be promising formulation in oral drug delivery for the treatment of hypertension.

T105: OPTIMIZATION OF PROCESS PARAMETERS FOR EMULSION SOLVENT EVAPORATION TECHNIQUE IN THE PREPARATION OF NANO LIPID CARRIERS USING DEFINITIVE SCREENING DESIGN

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The present study focuses on the optimization of process parameters for preparation of nano lipid carriers (NLC's) by emulsion solvent evaporation technique. A definitive screening design using JMP 13 was used to analyze the effect of critical process parameters on particle size, polydispersity index (PDI) and zeta potential of nano lipid carriers. The nano particles were formed using different ratio of solid lipid and liquid lipid in presence of ethyl acetate as dispersing solvent and poloxamer 188 as aqueous surfactant. The critical process parameters evaluated were solid lipid liquid lipid ratio, phase volume ratio, surfactant concentration and homogenization speed. Each variable was tested at two levels, low (-1) and high (+1). Thirteen formulations were prepared as per the design. Using this design, the magnitude of effect of each variable on particle size, PDI and surface charge were estimated. Model validation was carried out at a significance level of $P<0.05$ and the process was optimized at a desirability of 0.89. Three optimized formulations were prepared in the design space using optimized process parameters. The percentage bias of particle size, PDI and zeta potential of the predicted and the observed values were found to be less than 5%. The optimized formulations were subjected for SEM study, which revealed the formation of nano particles. Gas chromatography of the optimized

formulation showed the residual solvent content was within the limit as per ICH Q3 R6 guidelines. The suitability of the process to improve solubility was proved by formulation of nano lipid carriers of highly lipophilic drugs. Therefore, it can be concluded that the design was effective for production of nano lipid carriers by emulsion solvent evaporation technique.

T106: PREPARATION AND OPTIMIZATION OF FORMULATION VARIABLES USING PLACKETT-BURMAN DESIGN IN TRAMADOL HYDROCHLORIDE FLOATING TABLETS

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The prime objective of our research topic involves formulation and optimization of excipients variables in developing floating tablets of Tramadol Hydrochloride (TH) by using a 3-factor, 2-level Plackett-Burman (PB) statistical design. Floating systems or dynamically controlled systems are low- density systems that have sufficiently buoyancy to float over the gastric contents and remain buoyant in the stomach without affecting the gastric emptying rate for a prolonged period of time. It helps in continuously releasing the drug before it reaches the absorption window, thus the bioavailability of drugs will be improved. We have prepared TH Floating tablet, which is a centrally acting opioid oral analgesic and inhibition of nor epinephrine& serotonin reuptake. The short plasma half-life of 6 hour makes it ideal candidate for developing gastro retentive floating drug delivery system. In this study we have taken different concentrations of sodium bicarbonate and varying number of novel polymers like Chitosan, HPMC, and gum tragacanth to prepare Floating Tablet. During our study we consider different independent factors like sodium bicarbonate, Chitosan, HPMC and Gum tragacanth concentration at their low, high levels and studied how these factors affects the drug release pattern, floating lag time (which is the time taken for dosage form to emerge on surface medium) and total floating time (which is duration of time by which it constantly emerges on surface of medium) using a 3-factor, 2-level Plackett-Burman (PB) statistical design. The present paper mainly explains on the usefulness of Plackett–Burman design in screening different factors. To check drug interaction Fourier, transform infrared spectroscopy (FTIR) study was conducted. From our experimental work we found that the statistical design is now days very much important for identifying factors which affects drug release and also helps in selecting the best formulation. Stability studies (40ºC and 75±5%RH) are conducted for 3 months showing stability of prepared TH tablets.

T107: FORMULATION AND *IN-VITRO* EVALUATION OF MATRIX TYPE LEVETIRACETAM LOADED TRANSDERMAL PATCHES: A NOVEL MEDICATION FOR NOCTURNAL EPILEPSY

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Levetiracetam is used for the treatment of epilepsy (partial onset, myoclonic, or tonic clonic seizures). It binds to a synaptic vesicle glycoprotein, SV2A and inhibits presynaptic calcium channel reducing neurotransmitter release and acting as a neuromodulator. It is rapidly and completely absorbed after oral administration. However, it a short half-life up to 6-8 hrs. In order to prolong the drug release, an attempt was made to develop transdermal drug delivery system for Levetiracetam in the form of matrix diffusion controlled TDDS. The polymers used in this study were a blend of PVA and PVP (F1-F20). The plasticizer used was glycerol. DMSO (F11-F15) and DMF(F16-F20) were used as permeation enhancers. The patches were prepared was casting method and the formulated patches were evaluated for various physicochemical parameters, in vitro release and compatibility studies. The percentage moisture and moisture absorption increased with an increase in the concentration of PVP. No significant difference in thickness among each group indicates that the patches were uniform throughout. The increase in the average weight was due to increase in the plasticizer concentration (F6-F10) and use of permeation enhancers (F11-F20). There was a slight increase in the folding endurance (F6-F10) due to the increase in the plasticizer concentration. There was no significant difference in the drug content among patches indicating the uniformity in drug content. Formulation variables such as polymer ratio, plasticizer and permeation enhancers were found to influence the in vitro drug release behavior of the formulated patches. Increasing the concentration of hydrophilic polymer (PVP) was found to increase the in vitro drug release of the formulated patches. From the studies performed, F15 formulation with PVP to PVA ratio 4:1 showed the best results and exhibited the cumulative percentage of drug release of 40.34% in 24 hrs. I.R studies were performed and reported no abnormal peaks and thus it was concluded that there is no incompatibility between the drug and the polymer blends. An attempt was made to develop the complete transdermal system of the drug by using the backing membrane and release liner. From this study it can be

concluded that it is possible to design a transdermal drug delivery system for Levetiracetam, where therapeutic efficacy and patient compliance are of prime importance. However, long term pharmacokinetic and pharmacodynamics studies are needed to be undertaken to establish the usefulness of these patches.

T108: FORMULATION AND EVALUATE ION OF MICROSPONGES FOR TOPICAL DELIVERY OF SILVER SULFADIAZINE

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Silver sulfadiazine is the drug of choice in the treatment of burns and skin infections, but suffers from low patient compliance due to poor release of silver, lack of penetration and staining (argyria). The purpose of the present work is to formulate and evaluate microsponges using silver sulfadiazine along with Eudragit S100 to maximize the amount of time the active ingredient is in contact with the skin, control the release of the actives, and reduce irritation of the drug without reducing its efficacy. Microsponges loaded with drug were prepared by quasi emulsion solvent diffusion technique. Eudragit S100, a polymethyl methacrylate copolymer was used for encapsulating the drug particles, ammonia was used as a solvent and poly vinyl alcohol as a surfactant. Drug: polymer ratio of 1:1 was considered to be optimized formulation with a yield of 70.84%, entrapment efficiency of 73.62%, particle size ranging from 30.32 – 315.96µm, and in-vitro drug release of 68.34% at the end of 8 hours. FTIR and DSC studies suggested absence of drug-excipients interaction. Creams prepared by incorporating microsponges exhibited an in vitro drug release of 73.15% at the end of 8 hours. The SEM of final formulation revealed that the microsponges remained intact even after incorporation into cream. The release was found to fit into the Peppas model, exhibiting non-Fickian diffusion mechanism. The results obtained suggested that effective control on the release rate was achieved for silver sulfadiazine by formulating as microsponge based delivery system.

T109: DESIGN AND DEVELOPMENT OF NANOPARTICULATE BASED TOPICAL DRUG DELIVERY SYSTEM FOR THE EFFECTIVE TREATMENT OF PSORIASIS

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Psoriasis is a chronic inflammatory autoimmune disease which appears as erythematous, indurated, scaly plaques over the skin. Topical tacrolimus (TAC) although effective in the treatment of psoriasis, is a challenging molecule due to its low-solubility. Encapsulation of TAC into solid lipid nanoparticles (SLNs) makes it amenable to topical dosing as their small size promotes its penetration into the skin. Drug loaded SLNs were prepared using Glyceryl monostearate (GMS) as the lipid and Tween-80 as surfactant by hot homogenization method. Further, the drug loaded SLNs were optimized by 32 full factorial design where the drug to lipid ratio (X1) and concentration of surfactant (X2) was selected as independent variables. Particle size (Y1), PDI (Y2) and % entrapment efficiency (Y3) were selected as dependent variables. In-vitro drug release study was carried out for the optimized formulation F9 which showed the particle size of 111.1 nm and 82.37±1.12% EE. Optimized drug loaded SLNs can be incorporated into commonly used dermal carriers like gels or creams. Gels are normally preferred because of their improved targeting to the viable epidermis and dermis with good tissue compatibility. The drug loaded SLN gels were investigated by ex-vivo skin permeation studies where the selected CF5 formulation showed the highest cumulative percentage drug release of 83.78% at end of 24 hours which was optimum when compared to other formulations (i.e., CF4 and CF6). The potential of selected CF5 formulation was compared with the conventional marketed formulation by ex-vivo skin permeation studies where, the CF5 formulation showed 85.78 %CPR which was better than that of the conventional marketed formulation which showed 65.12 %CPR. Thus, it can be concluded that the TAC-SLNs loaded in Carbopol gel represents a promising topical drug delivery system and has the potential to increase dermal penetration of tacrolimus into the thick, hyperkeratotic, psoriatic skin lesions. It is also, a safe and effective alternative to the existing conventional topical drug delivery systems by minimizing drug administration frequency and patient compatibility.

T110: DEVELOPMENT OF NOVEL SOLID SELF EMULSIFYING DRUG DELIVERY SYSTEM OF A BCS CLASS 4 FLUROQUINOLONE IN A QUALITY BY DESIGN FRAME WORK AND VERIFICATION OF ITS CRITICAL QUALITY ATTRIBUTES

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Drug discovery studies reported that about 40% of all new chemical entities are poorly aqueous soluble and a great risk is involved in launching them in market, in spite of their potent pharmacokinetic activity, even they show marked physiological effect on target. In spite of having solubility and permeability issues, BCS class IV drugs show a good therapeutic effect. The present aim of this study was to develop the novel Solid-Self Emulsifying Drug Delivery System (S-SEDDS) of Norfloxacin and to implement the predefined CQAs through QbD approach. Risk assessment was performed to identify the Critical Material Attributes and Critical Process Parameters affecting the responses of drug loaded SEDDS. Pseudo ternary diagram constructed by water titration method for the screening of best Smix ratio that can give faster and wider emulsion range. Mixture design based on its utility and applicability to the formulation problem was selected for the study. The CQAs selected for optimization was droplet size and % drug release in 30 min. The factors considered in the design are oil, surfactant and cosurfactant. As per the design six formulations were prepared and evaluated to check the model fit. The prediction profiler was drawn and the same was used for selecting optimized SEDDS formulation which was validated and reported. The optimized liquid SEDDS was converted into solid SEDDS and characterized. The liquid SEDDS of Norfloxacin prepared was thermodynamically stable with good self-emulsification efficiency with a smaller globule size falling in the range of 200-400 nm. The optimized liquid SEDDS was found to have globule size of 371.1 nm and zeta potential of -50 nm. The solid SEDDS prepared from the optimized liquid SEDDS was found to have the particle size of 369.73 nm and Zeta potential of -38.46 mV with the % release of 84.63. SEDDS were a promising approach for the formulation of Norfloxacin, where all the CQAs were achieved with the implementation of QbD through the process.

T111: DESIGN AND EVALUATION OF EUDRAGIT BASED TRANSDERMAL PATCHES OF NICORANDIL

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Background: The transdermal route of administration is recognized as one of the potential routes for the local and systemic delivery of drugs. They offer many advantages such as elimination of the first pass metabolism, sustained drug delivery; reduced side effects associated with conventional oral therapy and improved patient acceptance. Nicorandil is an antihypertensive drug with vasodilator activities. The half-life of the drug is reported to be 2 hours. Objective: To retain the medication within the therapeutic window for a longer period of time, frequent administration is required. Hence transdermal patches of nicorandil were formulated to reduce the frequency of dosing and associated adverse effect. Method: This work focuses on preparation and evaluation of transdermal patches of nicorandil for controlled drug delivery. The patches were prepared by solvent casting using Eudragit RL 100 polymer. The ratio of drug: polymer concentration studied, ranged between 1:1- 1:6. The patches were evaluated for physical properties and drug content. In vitro diffusion profile of drug from the patches in phosphate buffer pH 6.8 was carried and compared with pure drug. The selected formula (F4) was studied for its permeation properties through rat abdominal skin. Results: The results of study suggested a good physical property of patches with satisfactory drug content. Surface morphological studies indicated a uniform distribution of drug in the polymeric patch formulation. The in vitro diffusion studies showed that the drug release was in a controlled manner from all six formulations in comparison to pure drug. The cumulative release of the drug in phosphate buffer pH 6.8 from formulations (F1-F6) ranged between 89.55±0.62-78.52± 0.63 % in a 12-hour study. Ex vivo results exhibited a good correlation with in vitro study results. About 89.55±0.62% of the drug from F4 (drug: polymer 1:4) was found to be permeated through the rat abdominal skin sample over a period of 12 hours. Conclusion: The results of the characterization and evaluation established the suitability of the prepared novel nicorandil transdermal patch.

T112: TIZANIDINE LOADED MICROSPONGES FOR TOPICAL DELIVERY- FORMULATION AND EVALUATION

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The main objectives of the study were to prepare and assess microsponges loaded gel containing Tizanidine hydrochloride for the treatment of spasticity. FT-IR and DSC analysis confirmed no drug and polymer interactions. Water in oil in water two-fold emulsion technique was carried out to develop the microsponges employing different concentrations of Eudragit RS-100. Chosen formulation was subjected to SEM for surface morphology studies which revealed the porous, spongy, rough surface of the particles and zeta potential analysis results revealed the stability of the formulation. In-vitro dissolution study exhibited 80.99% drug release at the end of 24 h. The release kinetics of microsponge formulation followed higuchi model as well as super case II transport. The microsponges gel was obtained by fusing microsponge particles into Carbopol (2%) gel base. The developed gel was characterized for viscosity, pH, drug content, content uniformity and in-vitro diffusion studies were carried out using Franz diffusion cell through cellophane membrane as a barrier. Microsponge gel containing Tizanidine hydrochloride indicated prolonged drug release due to its entrapped form in the porous structure.

T113: FORMULATION AND EVALUATION OF FLOATING BEADS OF LEVOFLOXACIN AND SUCRALFATE

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Levofloxacin is an antibacterial used in the treatment for gastroenteritis with the eradication of helicobacter pylori from the stomach. Sucralfate is an antacid and it suppresses helicobacter pylori infection and reduces gastric acid secretion. The reasons behind development of Floating Drug Delivery Systems (FDDS) include drug delivery to the site of action without variable gastrointestinal transit time which leads to variable absorption profiles, incomplete drug release and shorter residence time of the dosage form in the stomach. Floating drug delivery system (FDDS) or hypo-dynamically balanced system (HBS) have a bulk density, lower than gastric fluids and thus remains in the stomach without affecting the gastric emptying rate for a prolonged period of time. While the system is floating on the gastric contents, the drug is released slowly at a desired rate from the system. This results in an increase in gastric residence time (GRT) and a better control of fluctuation in plasma drug concentrations. The main goal in developing FDDS of Levofloxacin and Sucralfate combination is to develop delivery system where retention of drugs could be achieved for increased local action in gastric region. In all ten formulations of were prepared by using guar gum [GG], karaya gum [KG], xanthan gum [XG], low methoxy pectin [LMP] and rice bran oil. On the basis of in-vitro dissolution studies formulation F1 containing LMP:GG ratio of 9:1 and 3% w/v of rice bran oil was chosen as the best formulation giving 87.51 ± 1.14% of drug release till 8 hr. The beads containing 3% of rice bran oil demonstrated instantaneous floating ability and remained afloat throughout the study period of 8 hr. Thus, it can be concluded that the present study will be beneficial for the formulation of FDDS of Sucralfate and Levofloxacin.

T114: FORMULATION AND EVALUATION OF ORO-DISPERSIBLE TABLET OF ANTIRETROVIRAL DRUG

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In the current research, Oro-dispersible tablets (ODT) of tenofovir disoproxil fumerate using banana peel powder as natural Super disintegrant were formulated to treat HIV infections. This property of rapid disintegration in the mouth is not only beneficial for the pediatric and geriatric population commonly suffering from HIV but for patients who are suffering due to HIV induced dysphagia. Nine formulation batches (F1–F9) were prepared and optimized by 3 2 factorial designs using the Design-Expert software. On the basis of preliminary experiments conducted, two factors as independent variables (X1-amount of mannitol and X2-amount of banana peel powder) were taken with three levels (+1, 0, −1) and their effect on three dependent variables (disintegration time, wetting time, and in vitro drug release after 30 min) were studied. The active blends of all batches were subjected for pre compression parameters as angle of repose, Carr's index, Hausner's ratio, and porosity and the prepared tablets were evaluated for post compression parameters as weight variation, hardness, friability, wetting time, disintegration time, water absorption ratio and in vitro drug release studies. Formulation F5 was selected as optimized formulation with disintegration time (16 sec), wetting time (12 sec) and in vitro drug release (89%) within 30 minutes. The

optimized batch was further used for short term stability studies for one month indicating stability of the formulation at room temperature. Thus, banana peel powder as a eco-friendly, 'green' agricultural waste material is helpful in ODT formulation of TDF, antiretroviral drug as super disintegrant and additionally can show beneficial effects in improving the immune system in the patient.

T115: FORMULATION AND EVALUATION OF VESICULAR CARRIER LOADED RIZATRIPTAN BENZOATE GELS FOR INTRANASAL DELIVERY

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Rizatriptan benzoate is a potent and selective 5HT1B/1D receptor agonist used for the treatment of migraine headache. Rizatriptan benzoate is incompletely absorbed from the gastrointestinal tract and has an oral bioavailability of only 45%. This is because of its poor absorption in lower gastrointestinal tract. It undergoes hepatic first pass metabolism and its elimination half-life is 2 to 3 hours and causes gastrointestinal irritation. Therefore, the development of Rizatriptan benzoate formulation that improves bioavailability is highly desirable. Hence, aim of the present study was to prepare transferosomes (TRS) of RZB to increase its permeability and to develop RZB loaded TRS based in-situ nasal gel for nasal administration, to achieve a double targeting approach that would have the potential to enhance the bioavailability of the drug, avoiding the first pass effect and gastrointestinal irritation caused, while at the same time deliver the drug at its site of action. The TRS were prepared using thin film hydration technique and incorporated into in-situ nasal gel which could be administered as drops. FTIR, Differential scanning calorimetry studies revealed no drug excipient incompatibility. The transferosomes of RZB was developed and optimized by 32 full factorial design. The drug: (lipid + EA) ratio (X1), and concentration of Tween 80 (X2) was selected as independent variables. The dependent variables selected for study were particle size (y1), PDI (Y2), % Drug entrapment (Y3) and (Y4) elasticity. In-vitro drug release and release kinetics, further studies like SEM, IR, DSC were carried for the optimized formulation with particle size 101.2 nm, PDI 0.444, encapsulation efficiency of 68.54 ± 3.87%. Since the target route of delivery was olfactory bulb of the nasal cavity, an in-situ nasal gel loaded with RZB TRS's with different grades of gellan gum provided a gelling time less than 65sec and an optimal viscosity. The developed gel had required mucoadhesive strength. Thus, it can be concluded that in-situ nasal gel loaded with RZB TRSs represents a promising drug delivery system having sustained drug release, potential to increase permeability of RZB, reduce systemic and gastro-intestinal side effects of the drug and would achieve targeting of the drug to the brain.

T116: FORMULATION AND EVALUATION OF IN-SITU HYDROGELS OF NORFLOXACIN FOR OPHTHALMIC DRUG DELIVERY

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The present work aims at formulating in-situ hydrogel of Norfloxacin for ophthalmic drug delivery. Three different gelling agents such as Carbopol 940 (pH sensitive), Gelrite (ion sensitive), and Pluronic (temperature sensitive) were employed for formulating in-situ hydrogel. All the prepared formulations were evaluated for physiochemical properties and the best among them were further evaluated by in-vitro drug release in-vivo drug release, sterility and stability studies, and it was found that NF12 (formulated ion-sensitive gelling agent Gelrite) has shown good transparency, flowability and in-situ gelling capacity. The in-vitro drug release from NF12 has been extended for a period of 10 hrs. From in-vivo pharmacokinetics studies it was observed that Cmax (31.54 µg/ml), Tmax (60 min) and AUC (12844.9 µg.hr/ml), t1/2 (124.96 min) of the formulation NF12 has considerably greater than those of conventional marketed eye drop. The results indicate that Norfloxacin in-situ gels formulated using Gelrite (0.3%) could be effective in maintaining therapeutically effective drug concentration for a prolonged period by increasing the contact time, minimising frequency of drug administration, extending its half-life and patient compliance.

T117: DESIGN AND EVALUATION OF NANOCRYSTALS OF CURCUMIN FOR WOUND HEALING BY TOPICAL ADMINISTRATION

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Curcumin is a polyphenolic constituent obtained from the rhizomes of Curcuma longa belonging to the family Zingiberaceae". Curcumin has been used as antifungal, antioxidant, anti-tumor, anti-inflammatory and for diseases such as atherosclerosis, allergies, Alzheimer's disease etc. Curcumin has restrictive pharmaceutical role because of its

extremely low aqueous solubility, inadequate tissue absorption and degradation at alkaline pH, which severely reduces its availability. Nanocrystals have size less than 1µm. To improve the absorption of curcumin, nanocrystals of curcumin were prepared and incorporated into gel for topical application. CUR nanocrystals were prepared by Sonoprecipitation method. Box-Behnken design along with Response surface method is used to obtain the optimized CUR nanocrystal. The prepared CUR nanocrystal was characterized for Particle size, Zeta potential, PDI, SEM, Powder X-Ray diffraction, practical yield and percentage cumulative drug release. CUR nanocrystal was incorporated into gel which was evaluated for spread ability, pH, drug content, ex vivo drug permeation study, in vivo skin irritability study and in vivo wound healing study. Results showed that concentration of stabilizer, time of sonication and amplitude plays important role in preparation of CUR nanocrystals. The optimized CUR nanocrystal which has particle size of 180 nm and practical yield (70%). SEM images revealed that CUR nanocrystal are irregular shaped particles with rough surface. Powder X-Ray diffraction (PXRD) of nanocrystal showed good crystallinity when compared with curcumin powder. On carrying out in vitro drug release studies, CUR nanocrystal showed a significant improvement in percentage cumulative drug release compared to pure drug which followed first order kinetics. The final gel formulation had readability of 2.9 cm, pH was 7 and 93.86 % drug content. In vivo study skin irritation showed no irritation. Wound healing activity was carried out in albino rats using excision animal model. The study showed that Test group 2 (1% CUR NC) had faster wound contraction then test group 1 (0.5% CUR NC) and control (untreated) when compared with standard (Povidone ointment). CUR nanocrystal gel was subjected to stability studies for a period of 60 days. The subjected formulation showed no appreciable changes with respect to readability, pH and drug content.

T118: LORNOXICAM LOADED STEALTH LIPOSOMES FOR THE TREATMENT OF RHEUMATOID ARTHRITIS

Faby Raju, Akhilesh Dubey, Srinivas Hebbar, Ravi G.S

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Lornoxicam, a new non-steroidal anti-inflammatory drug (NSAID) belongs to oxicam class which is effective in relieving symptoms of rheumatoid arthritis (RA) and for the management of other painful conditions. Conventional liposomal formulations reduced the toxicity of compounds in vivo, through modifying pharmacokinetics and biodistribution to enhance drug delivery to diseased tissue in comparison to free drug. However, conventional liposomal system is prone to rapid elimination from the bloodstream, therefore limiting its therapeutic drug concentration in the circulation for required period of time. This can be overcome by formulating newer generation of liposomes that improves targeting and preciseness of drug delivery. Further, several approaches have been taken in an effort to increase the circulation time of liposomes and thus ensure delivery of the liposomal contents to the target tissue. One such approach is stealth liposomes in which the conventional liposomes are attached to hydrophilic polyethylene glycol (PEG) polymer covalently. Such PEG-coated liposomes are known as stealth liposomes. Thus, the aim of the study was to develop stealth liposomes of lornoxicam and to investigate its efficiency in the treatment of RA. Drug loaded stealth liposomes were formulated by thin-film hydration technique using phospholipid and MPEGDSPE. The liposomal formulations were then evaluated for particle size, zeta potential, drug encapsulation efficiency, in vitro studies and stability profile. The results showed that the stealth liposomes had particle size of 195.5 nm. The zeta potential values exhibited a positive value, indicating a successful coating with PEG. Entrapment efficiency of stealth liposomes was found to be 44.37% which was higher than that of conventional liposomes. Stability study showed higher drug content at refrigeration temperature when compared to the formulations stored at room temperature, after a period of 4 weeks. In vitro studies were carried out and it was found out that PEGylated formulation showed a higher burst release of 74.1% within 8h. Further, the formulated liposomes were evaluated for their anti-rheumatoid activity in vivo in rats. The in vivo study results demonstrated that there was a significant reduction in edema volume in the rat group administered with the PEGylated liposomal formulation. Therefore, the presence of PEG on the surface of the liposomal carrier has been shown to extend blood-circulation time while reducing mononuclear phagocyte system uptake. Therefore, for the treatment of rheumatoid arthritis, stealth liposomes were successfully formulated as a key strategy for improving circulation time and preventing removal by the RES through steric stabilization.

T119: INVESTIGATION OF TASTE MASKED FAST DISSOLVING ORAL FILMS OF FENUGREEK SEED EXTRACT FOR THE CONTROL OF DIABETES

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Fenugreek seed extract is well known for its potential antidiabetic effects. Fast dissolving oral films are a novel mode of drug delivery and fenugreek seed extract has been incorporated in the formulation for this study. The current study was aimed at formulating fast dissolving oral films containing fenugreek seed extract and characterizing for its physico-chemical and taste masking properties. Crude extract of fenugreek seed was prepared by Soxhlet extraction method using ethanol. External appearance, pH, active drug concentration in terms of Trigonelline and the percentage of yield were analysed. Preliminary quantitative phytochemical analysis on fenugreek seed extract was conducted. Fast dissolving films containing the extract were prepared by a solvent casting method and films were subjected to physico-chemical evaluation. The in vitro residence time was determined using the disintegration apparatus. The in vitro drug release studies were conducted using the USP Type 1 Dissolution Apparatus and the taste evaluation was done on healthy human volunteers. Preliminary quantitative phytochemical analysis of the fenugreek seed extract showed the presence of alkaloids, proteins, carbohydrates, starch, flavonoids and saponins. The films were subjected to physico-chemical evaluation and the results were found to comply with the acceptable range. In vivo disintegration was performed and all formulation did not show significant variation in disintegration time. In vitro drug release studied was found to be 99.631% within 60 seconds. In vivo taste evaluation was done on healthy human volunteers using the rated score chart. F3, F6 and F9 gave the highest score among all other formulations with a score of 2.00 to 2.33. Therefore, these formulations were considered to have the most pleasant taste.

T120: DESIGN AND CHARACTERIZATION OF ETHOSOMES OF ZALTOPROFEN GEL FOR SUSTAINED RELEASE TOPICAL DELIVERY

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The objective of the present study was to design and characterize the ethosomal gel containing zaltoprofen for sustained drug delivery and also to reduce the side effects. Zaltoprofen was chosen here as the drug candidate because of its short half-life and increased dosing frequency. The drug loaded ethosomes were prepared by using cold method. The ethosomal formulation were prepared by varying the concentration of soyaphosphatidyl choline, cholesterol and the concentration of ethanol. Using DoE an optimized formulation of ethosomes loaded with Zaltoprofen was obtained. The prepared ethosomes were characterized by Scanning Electron Microscopy, PDI, zetapotential, vesicle size, percentage drug entrapment efficiency, percentage cumulative drug release and stability studies. The results showed that the vesicle size, entrapment efficiency and zeta potential play an important role in the preparation of ethosomes. The SEM images showed that the ethosomes had a good morphology and a smooth surface, unlike the pure drug. The optimized formulation was prepared and further it was incorporated into Carbopol gel base. The in vitro drug release studies of the ethosomal gel formulation showed sustained drug delivery when compared with the plain gel containing the pure drug. And the stability studies data showed that formulation had significant stability. It was concluded that the ethosomes containing zaltoprofen showed sustained drug release and improved bioavailability.

T121: ORODISPERSIBLE FILMS CONTAINING SOLID LIPID NANOPARTICLES FOR CONTROLLED DELIVERY OF LEVODOPA

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Dysphagia, the difficulty in swallowing is a common but lesser addressed problem in Parkinson's disease. A controlled release of anti-Parkinson's agent is found much beneficial in the therapy but often they are formulated as tablets that may not suit the need of a dysphagic patient. Mouth dissolving films have gained popularity as it dissolves in mouth leaving a drug solution which is easy to swallow. The present study aims to combine mouth dissolving technology with controlled drug release that can have a greater impact on Parkinson's therapy enabling to reach the therapeutic goal easier. Solid Lipid Nanoparticle (SLN) of Levodopa was formulated using glyceryl monostearate (GMS) and tween 80. Varying concentrations of tween 80 was tried as a stabilizing agent and a stable formulation (F5) was achieved at 7.5% V/V. The formulation F5 was characterized for its physical nature, particle size, zeta potential, drug entrapment efficiency, drug release pattern and ex vivo permeation. The particles were distributed in a size range of 17 to 208 nm with a lower zeta potential of -2.69 mV. The particles showed adequate stability for weeks together which may be due to the combination of different stabilizing mechanisms. The drug entrapment was shown to be 88% and the drug was released in a controlled manner for 11 hours. In ex vivo permeation study, SLN were found permeating the goat intestinal tissues

in 7h showing a high permeation rate. The TEM studies revealed the formation of spherical nanoparticles of GMS containing levodopa with varying particle size. SLN dispersion was incorporated in fast dissolving films made up of HPMC E-15 with sodium starch glycolate and were evaluated for its pharmaceutical properties. MDF2 formulations with 300 mg of HPMC and 70 mg of SSG were chosen ideal based on disintegration and other physical characteristics. The formulation was found to release the SLN in the medium in 35 ± 0.22 seconds making it a suitable formulation in Antiparkinson's therapy.

T122: IN SITU GELLING IMPLANTABLE SYSTEM FOR THE SUBCUTANEOUS ADMINISTRATION OF INSULIN

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The aim of the present work was to formulate and evaluate thermo reversible injectable in situ gelling system of insulin in order to provide prolonged release of drug thereby avoiding disadvantages such as frequent dosing, patient non-compliance. Injectable in situ gelling system was formulated by using cold method, using the thermosensitive polymer Pluronic F127 along with Pluronic F68. The drug polymer compatibility was studied by FTIR. Drug free thermo reversible gelling solutions and drug incorporated thermo reversible gelling solutions were prepared and evaluated for appearance, pH, gelation temperature, gel strength, rheological studies, drug content and in vitro drug release studies. All the developed formulations had a clear appearance. The pH of all the formulations was found to be in the range of 6.4 to 7.2. Gelation temperature increased with the increase in concentration of Pluronic F68 in the formulation. The gel strength of all the formulation was in the range of 19- 70 sec. All the developed formulations passed the syringe ability and injectability studies. From the rheological studies it was found that the viscosity of formulation increased with increase in the percentage of Pluronic F68 from 0.8% [FA1] to 1.2% [FA3] both in solution and gel form. The drug content of the formulations was found in the range of 92- 96%. The in vitro release profiles of the drug from all the formulations appeared to follow zero order kinetics. Ex vivo drug release from the formulations was slow when compared with in vitro release. The formulations were found sterile from the test for sterility. The results showed that the developed system had the potential for prolonging drug release and improving bioavailability.

T123: OPTIMIZED TRANSFERSOMAL GEL OF ADAPALENE FOR THE TREATMENT OF ACNE

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Acne is a cutaneous pleomorphic disorder of the pilosebaceous unit occurring due to irregular sebum production. Retinoids are most commonly used for the treatment of acne. Adapalene is a third-generation topical retinoid used for the treatment of acne. The main mechanism of retinoids is targeting microcomedone. The problem with conventional adapalene gel is, it cannot deliver the drug effectively through the narrow pores of the skin which can be avoided by formulating it in the form of transfersomes. Transfersomes are elastic, flexible and self-optimized lipid vesicular systems which are known for permeating through stratum corneum. Transfersomes are highly stress-adaptive, stress-responsive complex aggregate having a complex lipid bilayer surrounding the aqueous core. They are mainly composed of phospholipids and an edge activator. Hence the aim was to prepare and characterize the transfersomal gel of adapalene for the treatment of acne and to compare with conventional gel. The transfersomes were prepared by reverse phase evaporation. The vesicles were optimized by using Design Expert software. The optimized transfersomes were investigated for particle size, PDI, zeta potential, entrapment efficiency, TEM, Turbidity measurement. Further, the optimized formulation was incorporated into the Carbopol gel and investigated for measurement of pH, spread ability, in vitro drug release pattern, ex vivo skin permeation and skin irritation. The optimized transfersomes had particle size of 128.8 nm, PDI of 0.364, zeta potential of -40.3 and entrapment efficiency of 68.33 %, vesicles found to be bilayerd in TEM and turbidity was 230, pH was 6.81 ± 0.01, spread ability was 23.026±3.178 g/cm2. The gel containing optimized adapalene transfersomes exhibited 84.88 % drug release. Ex vivo study showed 67.98 % of the drug release from the system. The transfersomal gel of adapalene was found to be promising in the acne treatment in comparison with conventional gel.

T124: DEVELOPMENT AND CHARACTERIZATION OF BRAIN TARGETED FORMULATION OF CENTELLA ASIATICA USING BETA – CYCLODEXTRIN AND THIOLATED EUDRAGIT

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Centella asiatica also known as Mandukaparni or Gotu kula is used in Ayurveda for a number of ailments. Majorly used as a substitute for Brahmi, C. asiatica is best owned with neuroprotective, memory and brain function enhancement properties. These activities of C. asiatica is mainly due to the presence of terpenoids like Asiatic side, Asiatic acid, centelloside, saponin glycoside, centallic acid, volatiole oils and flavonoids. However, the extract with immense pharmacological activity is hygroscopic in nature and has poor bioavailability. Hence, the present study was designed for the development of nanoparticles that could improve the stability of this herbal drug and also deliver it to brain in sufficient quantity that would be beneficial for the management of brain ailments. A preliminary docking studies using Auto dock vina was performed for selecting the polymers. Docking study showed the high affinity of β-cyclodextrin to receptors like Sphingosine 1- phosphate receptor (SIP-1) and Lipoprotein receptor related protein-1 (LRP-1) with a binding energy of -8.5 and -5.1 respectively. SIP-1 promotes barrier function in peripheral vessels and inhibition of SIP-1 may lead to opening of BBB. Similarly, LRP-1 exhibit transcytosis capacity and acts as a receptor for ligand mediated delivery of drug to brain. The extract of C. asiatica was first encapsulated into β- cyclodextrin by acid-base precipitation method. This βcyclodextrin encapsulated C. asiatica was used for preparing nano formulation and was in turn covered with thiolated eudragit (TE) by acid-base precipitation method. TE was used, as the formulation was intended to be administered intranasally and TE is a good mucoadhesive agent. The prepared formulation was subjected to FTIR, SEM, AFM, XRD and DLS characterization. SEM and AFM studies confirmed the spherical nano size of the particles (84 – 114 nm). XRD studies revealed the crystalline nature of the nanoparticles and characterization by DLS showed a pdi of 0.280 indicating stable formulation. The results showed the successful preparation of a brain targeted formulation. However, in vitro and in vivo studies should be performed to confirm the brain targeting efficacy.

T125: LIPOSOMAL FORMULATIONS OF ZIDOVUDINE FOR ANTIRETROVIRAL THERAPY

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Liposomes are spherically shaped biodegradable nano carriers, which are phospholipid bilayer structures with an ability to encapsulate both hydrophilic and lipophilic drugs. This study aimed to formulate and evaluate liposomes enclosing Zidovudine. Zidovudine is an antiretroviral medication used to prevent and treat HIV/AIDS. It has particularly found safe usage in pregnant ladies who suffer from HIV/AIDS. The liposomal formulations of Zidovudine were prepared by film hydration technique. In this technique the lipid (soyaphosphotidycholine and cholesterol + drug) is mixed with an organic solvent (chloroform), the solvent is removed and the dry film of lipids is hydrated by an aqueous medium (phosphate buffer of pH 7.2). The obtained multilamellar vesicles (LMV) was further size reduced by sonication. The liposomes were characterized for mean vesicle size, drug loading capacity and in vitro release characteristics of the drug. The mean vesicle size of the selected formulation was found to be 520 nm and the zeta potential was found to be 41.3 mV. The drug loading capacity of the formulation was found to be 35.08±2.08% to 64.02±1.04 %, related to overall volume of aqueous phase encapsulated during liposomes formulation. The in vitro release of drug from all the formulations in phosphate buffer PH 7.2 exhibited a controlled release of drug over a period of 24 hours. The drug release kinetics displayed Higuchi release mechanism.

T126: HOLD TIME STABILITY STUDIES: SIGNIFICANCE IN PHARMACEUTICAL INDUSTRY AND CURRENT STATUS OF REGULATIONS

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Manufacturers must assure that the products that they manufacture are safe and effective. The manufactured products must have Quality standards as required for their intended use and also as required by the marketing authorization. Manufacturing processes should be shown to be capable of consistently producing pharmaceutical

products of the required quality that meet their specifications. There should be provisions to ensure that materials used, intermediate goods, bulk and finished items are processed under suitable conditions. Storage should have no negative effect on the processing, stability, safety, efficacy or quality of materials, intermediates, bulk and finished products. Good manufacturing practices require the maximum allowable holding time to be defined in order to ensure that the in-process or bulk product can be preserved without any adverse effect on the performance of the material until the next processing stage. Sufficient time periods must be supported by adequate data to demonstrate that the product will be stable throughout the approved shelf-life. Therefore, total appropriate holding periods should be defined to ensure that intermediates and bulk product can be stored without producing results beyond the acceptance criteria for the performance of the material until the next processing stage. Generally, intermediate and bulk products should not be stored beyond the established hold time. Bulk products should not be stored for a period of 25% or more of the approved shelf-life unless these are tested, with stability indicating methods, prior to packaging.

T127: COST OF QUALITY: THE MONEY SAVING TOOL IN PHARMACEUTICAL INDUSTRIES

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Cost of quality is summation of cost of conformance and cost of non-conformance; in this cost of conformance, it is the cost for preventing poor quality such as inspection while cost of nonconformance is the cost of poor quality caused by product and service failure such as reworking and returns. The cost of quality of today is an important tool in the pharmaceutical industries as it leads to customer satisfactions which increases the profit and maintain survival of the organization. In those pharmaceutical industries that have adopted the idea of cost of quality, they are successful for reducing the cost of service and improving the quality of the product used by their clients. In many pharmaceutical industries the organizations spend a lot of money to build a quality product to overcome this different methods or models for improving cost of quality are available such as prevention- appraisal- failure (P-A-F) model, Crosby's model etc. However most useful model is prevention- appraisal-failure (P-A-F) model but all other different models can be implemented and leads to better results. The main thing is that the model chosen must suit the company's circumstances, environments, intent and needs in order to become an effective systemic tool in the process of quality management.

T128: ADVANCEMENT IN TARGETED DRUG DELIVERY FOR THE TREATMENT OF MIGRAINE: CURRENT PERSPECTIVE

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Migraine is a common and highly disabling neurological disorder associated with a high socioeconomic burden. According to World Health organization, headache disorders, are characterized by recurrent headache, are associated with personal and societal burdens of pain, disability, damaged quality of life, and financial cost. In accordance with 2016 statistics, about 50% of adult globally is having headache, in which 30% or more is migraine. Triptan class of drug are considered the first line drug for the treatment of migraine. This class act specifically on 5HT1 target by mechanism of triptans are mediated by 5-HT(1B/1D) receptors and include vasoconstriction of painfully dilated cerebral blood vessels, inhibition of the release of vasoactive neuropeptides by trigeminal nerves, and inhibition of nociceptive neurotransmission. Conventional treatment strategies fail to address treatment of migraine properly due to the involvement of a plethora of physiological factors and the drug factor. Unfortunately, migraine treatment outcomes are disappointing despite research efforts, which highlight the gaps that exist between promising research outputs and proper administration. Notably, the drugs can used conventionally to target the central nervous system have limitations that include an inability to cross the 'blood-brain barrier' effectively. Nanotechnology appears to offer an innovative means of advancing research efforts by specifically modulating different pathways in targeted locations. As nanotechnology utilization in the drug delivery has rapidly spread out, the nasal delivery has become attractive as a promising approach. Nanoparticulate systems facilitate drug transportation across the mucosal barrier, protect the drug from nasal enzyme degradation, enhance the delivery of vaccines to the lymphoid tissue of the nasal cavity with an adjuvant activity, and offer a way for peptide drug delivery into the brain and the systemic circulation, in addition to their potential for migraine treatment. This review article aims at discussing the potential benefit of the intranasal nanoparticulate systems, including nanosuspensions, lipid and surfactant, and polymer-based nanoparticles as regards productive intranasal delivery.

T129: NOVEL APPROACHES OF LINCOSAMIDE ANTIBIOTICS FOR THE TREATMENT OF FLESH -EATING DISEASE

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Dermal and subdermal bacterial infections, caused mainly by Staphylococcus aureus, are currently treated by systemic antibiotics. The aim of the present study was to investigate a new approach to treat deep skin and soft tissue bacterial infections by dermal application of lincosamide antibiotic - Clindamycin Phospahte. With the advent of newer biocompatible and biodegradable materials like phospholipids, and cutting-edge drug delivery technologies like liposomes, solid lipid nanoparticles (SLNs), microemulsions, and nanoemulsions, the possibility to improve the efficacy and safety of the topical products has increased manifold. Improved understanding of the dermal delivery aspects and that of designing and developing diverse carrier systems have brought in further novelty in this approach. Clindamycin belongs to BCS class III that is high solubility, low permeability and a topical bioavailability of 4-5%. Flesh-eating disease known as 'Necrotising Fascitis', is an infection that results in the death of parts of the body's soft tissue. This review describes novel approaches of Clindamycin phosphate antibiotic which has been formulated using a particulate vesicle system nanogels based drug delivery system. It is highly biocompatible and biodegradable including other properties like high drug loading capacity, good permeation capabilities due to extreme small size, can cross blood brain barrier, nanogels are able to solubilize hydrophobic drugs and diagnostic agents in their core or networks of gel. Nanogel systems have better stability over the surfactant micelles and exhibit lower critical micelle concentrations, slower rates of dissociation and longer retention of loaded drugs and this type of delivery system usually does not produce any immunological responses.

T130: PELLETIZATION – A NEW HORIZON

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Pellets are the multiparticulate drug delivery system which prove to be promising and highly flexible system with various kinetics of drug release such as immediate release, sustained and controlled release which are easy to formulate. In order to overcome the physicochemical interaction such as drug-excipient or drug-drug interactions multiparticulate dosage forms can be implemented. The technology of pelletization as oral drug delivery system is gaining substantial attention in the present time. Pelletization is the process where the aggregates of granules or fine powders mixture of drugs and excipients. They form small spherical or semi-spherical free flowing solid units ranging from 0.5 mm to 1.5 mm. Pellets are commonly used as multiparticulate systems as it has technical as well as clinical advantages over single unit dosage forms. The present review focuses on advantages, disadvantages, mechanism of pellet formation, different methods of pellet preparation, characterization of pellets, and also the recent approaches for pelletization techniques.

T131: BREAST CANCER DRUG DELIVERY USING SOLID LIPID NANOPARTICLES

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The current drug delivery system is anticipated to be revolutionized by nanotechnology. Solid lipid nanoparticles are at the forefront of the fast-growing nanotechnology sector in the breast cancer drug delivery. Solid lipid nanoparticles are a new form of colloidal drug carrier system consisting of nanometer (50-1000 nm) spherical lipid particles dispersed in aqueous surfactant or co surfactant solution. Solid lipid nanoparticles is an alternative carrier system for traditional colloidal carriers such as polymeric nanoparticles, dendrimers, liposomes, polymer-drug / protein conjugates, mesoporous silica nanoparticles and carbon nanotubes. This review highlights and presents an overview of the types of solid lipid nanoparticles, drug delivery mechanisms, selection of common ingredients, and different ways of producing solid lipid nanoparticles. Prospects of solid lipid nanoparticles stabilization can be enhanced through freezing and spray drying. To characterize solid lipid nanoparticles, suitable analytical methods are required. This review also summarizes the study findings of the various researchers of the most common cell-line experiments and in vivo studies aimed at improving the effectiveness of solid lipid nanoparticles in breast cancer treatment. There is no type of solid lipid nanoparticles marketed for breast cancer treatment.

T132: TOPICAL GEL – A REVIEW

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Topical formulations provide both systemic and local effects that are generally applied on to the skin. Topical gel is one such formulation meant for topical use. They are defined as semisolid preparations where the drug is dispersed in the liquid medium. As it enhances the delivery of the drugs, they are used widely. Gels are 3D (3 dimensional) structures that are made of either natural or synthetic polymers which are interlinked by physical, chemical or ionic interactions. Gels are classified based on the nature of colloidal system, solvent system, rheological properties and physical nature. As topical gels have gained their advantages, it raised to the development of novel approaches like hydrogel, emulgel, organogel, etc. There are different methods of preparing gels like- cold method, chemical method, dispersion method, flocculation method and due to thermal changes. This review article deals with the information about the various aspects like classification, novel approaches, applications, mechanism of formation of gels, method of preparation and evaluation parameters.

T133: DRUG DELIVERY APPROACH BASED ON CHRONOMODULATION: A REVIEW

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Drug delivery systems are methods used to ensure medications are entering the body and reaching the region where they are needed. These systems taken into consideration numerous factors ranging from ease of delivery to drug efficacy. Circular rhythm regulates many body functions in humans, such as metabolism, actions, patterns and hormone production. Hypertension displays circadian rhythm in the form of two peaks, one around 7 pm in the evening and the other between 4 am to 8 am in the early morning. The conventional drug delivery systems immediately release drug and require it to be taken at peak. Conventional treatments are unable to set time points when the symptoms actually get worse. chronotherapeutic delivery system may offer greater benefits in order to achieve drug release at two time points. Chronotherapeutic drug delivery systems have been recognized as potentially beneficial for chrono-therapy (time optimized) for chronic diseases that show symptoms that are time-dependent. By tailoring the dosing schedule based on chrono-biological trend, therapy can be adjusted in the pulsincap process. pulsatile release after a fixed release period can be a successful solution to delivering the medication rapidly. This focus primarily on the role of circular cycle and diseases, the different distribution of drugs and the global chronotherapy market.

T134: STABILITY STUDIES OF PHARMACEUTICAL PRODUCTS

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Stability studies must be carried out according to the guidelines provided by ICH, WHO and other agencies in a scheduled manner. The pharmaceutical product's stability can be defined as the ability, within its physical, chemical, microbiological, toxicology, protective and informational requirements of a particular formulation in a specific container-closure system. It also guarantees that the performance, safety and efficacy are maintained throughout the shelf-life of any pharmaceutical product which are considered as pre-requisite for the acceptance and approval. In this review we have included the relevance of different methods used to test the stability of the pharmaceutical product, guidelines issued to test the stability of pharmaceuticals and other aspects of stability.

T135: A SNAPSHOT OF NANOEMULSION FOR TRANSDERMAL DRUG DELIVERY

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Nanoemulsions (NEs) are colloidal dispersions of two immiscible liquids, oil and water, in which one is dispersed in the other with the aid of a surfactant/co-surfactant mixture, either forming oil-in-water (o/w) or water-in-oil (w/o) nanodroplets systems, with droplets size of 20– 200 nm. This review gives a brief description about how oral nanoemulsions act as a tool to improve the bioavailability of poorly water-soluble drugs and gives clear-cut idea about all possible methods for the preparation of nanoemulsions and the advantages and disadvantages of each method are described. NEs are easy to prepare and upscale, and they show high variability in their components. They have proven

to be very viable, non-invasive, and cost-effective nanocarriers for the enhanced transdermal delivery of a wide range of active compounds that tend to metabolize heavily or suffer from undesirable side effects when taken orally. In addition, NE possess anti-microbial and anti-viral properties leading to preservative-free formulations. It also gives a brief idea about the mechanism of NE formation, characterization of NE, factors affecting formulation and ongoing clinical trials on nanoemulsions.

T136: PELLETIZATION TECHNIQUES: NOVEL APPROACH FOR DRUG DELIVERY

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Pelletization is novel drug delivery system which converts fine powder particles in to pellets. Pelletization has gained great interest in recent years due to various advantages with respect to conventional dosage form, such as dose uniformity, flexibility in dosage form, prevention of dust formation. Drugs with shorter half-life and lesser absorption rate can be formulated as sustain release pellets in order to enhance its absorption rate. Pellets are typically varied between 0.5-1.5 mm in size and these pellets are physicochemically and microbiologically stable because of their entrapment of drug into matrix. With the advent of controlled release technology, drug loaded pellets have been widely investigated for its control release property in gastrointestinal tract. This review will provide an insight into advantages and disadvantages, pellet formation mechanism, drug selection criteria, coating of pellets and investigation of various pelletization techniques namely: Extrusion spheronization, layering, Cryopelletization, Hot melt extrusion etc. The study also talks about parameters affecting pelletization, characterization of pellets like particle size, surface area, shape and sphericity, porosity, density, friability, flow property and dissolution of the pellets are explained with various applications of pellets.

T137: OSMOTIC DRUG DELIVERY SYSTEM AS A PART OF MODIFIED RELEASE DOSAGE FORM

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Typically, the oral drug delivery systems distribute the drugs without a specific pattern of release and then spontaneous plasma levels enter the intended process with less efficient control. A lot of research and progress had been carried out to address this challenge and included NDDS-the novel drug delivery system. It is a massive system dealing with complex patterns of release such as matrix, diffusion, floating osmotic liposome, nanoparticles, microsphere and so on. These days, both aged and groundbreaking disease processes using currently-developed frameworks for the prevention and which comprises NDDS that support patients. In NDDS, amidst all, the osmotic drug delivery system is currently trendy in the market due to its unique qualities against other delivery systems. A selection of old and new osmotic systems technology was included in this review article. The osmotic system is premised on osmosis and osmotic pressure, which allows the solvent to move via the semi-permeable membrane until there is an equilibrium betwixt both compartments, i.e. the internal and external compartments. It comprises mainly of three things-a semi-permeable membrane, a core, and a delivery orifice.

T138: FLOATING MICROBALLOON – A NOVEL FORMULATION FOR GASTROINTESTINAL DISORDER

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According to a survey, 7 million population are suffering with gastrointestinal disorder whereas in India 25.8% deaths has been reported. Many marketed formulations like tablets, capsules or effervescent granules have more cons than pros such as side effects, lower bioavailability, less efficacy. Therefor present world need a new formulation which can avoid all the above cons.One of the most effective formulation is floating microballoons, it has high floating efficacy which releases and delivers the drug at the site of action and hence side effects are minimized. The bioavailability of the microballoons are more in comparison to other formulations.The microballoons are hollow microspheres which incorporates drug and the drug release can be controlled at a desired rate. These floating microspheres which floats over the gastrointestinal fluid as the density is less than the density of the gastrointestinal fluid. Targeted drug delivery can be achieved, thus used for target specific drug delivery. Solicitations of microballoons are not only limited for treating of GIT disorders; it also plays a major role in treating many other complied diseases. At present this floating system is used to treat many gastrointestinal diseases such as Ulcers, GERD, Zollinger-Ellison diseases etc. Floating microballoons were prepared

by dissolving polymers in organic solvents at a suitable ratio and stirred to form a homogenous solution. Aqueous phase is prepared by dissolving drug and tween 80 in a beaker and stirred at 500rpm at 400C. The polymer solution is then poured into aqueous phase and stirred for 20 minutes. Later the microballoons were filtered and dried. The characterization of microballoons will be assessed by micromeritic properties, floating time, drug release and entrapment efficiency.This article will provide sufficient information related to use, method of preparation and evaluation of microballoons formulation.

T139: NANOSPONGES-THE TOPICAL DRUG DELIVERY BRISK ACCESSION ON REVISED OVERVIEW

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The drug delivery systems combine one or more innovative drug delivery methods with advanced technology. Nanotechnology developments have resulted to the emergence of many forms of pharmaceutical products like Nano emulsions, Nano micelles, Nano sponges and Nano niosomes. In order to reduce systemic toxicity, Nanosponge technology has been developed to allow controlled release of drugs over the period of time. Nanosponges consist of nanoporous particles capable of suspending or entrapping a broad range of drug substances, and then beig incorporated into a various dosage form. Later, as they effectively overcome the problems like increasing the solubility of water insoluble drugs, increasing bioavailability, reducing the drug toxicity, avoiding drug degradation and targeting the drug to a specific site, this promises controlled drug delivery for topical use. They can also be used as carrier as biocatalysts for vaccines, enzymes, proteins and antibodies. Nano sponges are below 1µm thereby decreases side effect and protect drug from degradation. This review study to expound the current standing of β-cyclodextrin based Nano sponges in drug delivery, applications in topical formulation and comparison of different marketed products of Nano sponges along with cyclodextrin in various drug delivery and offer high drug loading compared to other Nano carriers.

T140: NIOSOMAL DRUG DELIVERY SYSTEM: A REVIEW

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The field of Nano-chemistry research has shown a great progress in the developing of novel Nano carriers as potential drug delivery systems. Niosome is a class of molecular cluster formed by self-association of nonionic surfactants in an aqueous phase. The niosome may plays a major role in site targeting (or) site specific that may promote maximum therapeutic index and lower toxicity. Today, most research subjects are more interested in Nano particle drug delivery system such as liposomes, niosomes, transferosomes etc. Especially niosomes are mostly aimed by researchers because of its stability and be economic. They also release the drug in a controlled manner over a longer period of time. The most salient feature of a niosomes is its amphiphilic in nature and can encapsulate large number of drugs with an extensive range of solubility. The aim of this study is to illustrate the physiochemical properties, characterization, methods of preparation and more importantly benefits of niosomes in cancer therapy may perform in recent articles.

T141: DIOSMIN - HESPERIDIN COMBINATION - A NOVEL DRUGS FOR CARDIOTONIC ACTIVITY

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Heart is the vital organ and central part of circulatory system which involves pumping of oxygenated blood throughout the body. Cardiac vascular disease includes CHF, Coronary Heart Diseases, MI and Dilated cardiomyopathy. CDC (Centers for Disease Control and Prevention) has identified that leading cause for mortality rate in United States, UK, Australia and Canada is due to heart diseases. According to CDC, 6,10,000 peoples are dying in every year, whereas in India 50% deaths are due to cardiac arrest and other cardiovascular diseases. Cardiac glycosides and adrenergic drugs are currently have been using in the treatment of congestive heart failure, but these drugs have narrow therapeutic index and been reported to cause a severe oxidative stress in the myocardium. Present world is using herbal medicines when compare to synthetic drugs because of less toxicity. Diosmin - Hesperidin are flavanone glycosides majorly found in citrus fruits (Family Rutaceae).

Diosmin-Hesperidin are the two citric fruit derived flavonoids marketed as dietary supplements also as a combination famously known as micronized purified flavonoid fraction (Daflon) which act on venous tone, lymphatic vessels, micro-circulation and treats hemorrhoids. Numerous studies on Diosmin-Hesperidin have reported various pharmacological activities. Both Hesperidin and Diosmin (9:1) are used in the present study. The acute toxicity study was carried out for Hesperidin-Diosmin combination as per OECD guideline 423 to establish the LD50 of the formulation and In-vitro cardiotonic activity of Hesperidin-Diosmin combination was performed by using langendorff's apparatus and Heart failure is represented by using HRLS. The Hesperidin-Diosmin complex was developed. Acute toxicity study didn't show any signs of abnormalities when administered with 2000mg/kg body weight. Different concentration of Hesperidin-Diosmin (5mcg, 10mcg and 20mcg) was administered in failed heart. Failed heart was treated with Hesperidin-Diosmin, showed significant increase in the force of contraction, heart rate and cardiac output in dose dependent manner when compared with HRLS alone treated heart. The results of the present study demonstrate that the novel Hesperidin-Diosmin combination has the ability to recover cardiac function and showed potent cardiotonic activity. Therefore, the In-vitro study showed positive inotropic & chronotropic effect. 20mcg of Hesperidin-Diosmin combination treated heart showed more effective in recovering of failed heart than 5mcg and 10 µg.

T202: PYRIMIDINE DERIVATIVE TARGET CANCER THROUGH INHIBITION OF BRD4 EXPRESSION

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The series of novel pyrimidine derivatives were designed for its anti-cancer activity and designed compound were docked on BRD4 (Bromodomain) using drug discovery studio 3.5. Lys325 and leu243 in 4hy3; amino acids interaction was found to possess good binding similar to that of standard compound, based on best docking score the designed compound were synthesized, the synthesized compounds were confirmed by the spectral data like IR, 1H NMR, and Mass spectroscopy the anti-cancer activity will be carry out using EAC cell in mice. All the compound were screened for anti-cancer activity from which compound 2c were found to possess good anticancer activity. Based on the Binding affinity with receptor as compared to standard compound 2c possess good anti-cancer activity. Finally, it was concluded that compound 2c can act as potent anti- cancer agent.

T203: PROTECTIVE ROLE OF HESPERIDIN METHYL CHALCONE AGAINST CEREBRAL ISCHEMIA/REPERFUSION INDUCED RATS

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Oxidative stress, excitotoxicity and mitochondrial dysfunction play a crucial role in the pathogenesis of acute ischemic stroke or other neurodegenerative conditions. Several components of reactive oxygen species (ROS) that are generated after ischemic reperfusion injury play an important role in neuronal loss after cerebral ischemia. Hesperidin methyl chalcone (HMC) has been reported to exhibit antioxidant, anti-inflammatory and hypotensive property. It also has free radical scavenging activity and chelating activity which is significant for reducing the concentration of catalyzing transition metals in lipid peroxidation. In this study the effect of HMC on acute focal cerebral ischemia and long term cerebral hypoperfusion was investigated. The neurological activity was determined using behavioral tests before and after surgical procedures. Rats were anesthetized by administrating thiopental sodium (45 mg/kg) by i.p route. Focal cerebral ischemia and long term cerebral hypoperfusion was induced by BCCAO method. The drug HMC (30mg/kg, i.p) was administered for 7 days. Ischemia induced neuronal damage was assessed by cerebral infract area, biochemical estimations, histopathological examinations and behavioral studies. The observations suggested that the drug HMC posed Neuroprotective actions in cerebral ischemic injury by antioxidant mechanisms, and to be useful as adjunct in the treatment of stroke.

T204: AMELIORATION OF COGNITIVE DEFICIT BY HESPERIDIN METHYL CHALCONE IN ALUMINIUM CHLORIDE INDUCED ALZHEIMER'S DISEASE MODEL IN RATS

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Alzheimer's disease is a progressive neurodegerative disease

characterized by chronic memory loss. Risk factors include degradation of Acetyl choline and butyryl choline, Accumulation of neurofibrillary tangles, Amyloid precursor protein and neuronal cell death. Hesperidin is a bioflavonoid and having Neuroprotective effect mediated by improvement of neuronal growth factors and endogenous antioxidant defense functions, diminishing neuro-inflammatory and apoptotic pathways. The limited bioavailability of hesperidin and hesperidin is another significant factor which should be considered. The water-soluble flavonone hesperidin methyl chalcone (HMC) is selected because of its improved bioavailability and multi-targeted ability to treat Alzheimer's disease. Based on molecular docking studies, Hesperidin methyl chalcone having effect on Human tau proteins, Acetyl cholinesterase, butyryl cholinesterase and Beta secretase 1 (BACE1). Based on the results of behavioral studies like elevated plus maze, Morris water maze and Novel object recognition test HMC was found to be having good memory enhancing property and drug to treat Alzheimer's disease.

T205: TOXICOLOGICAL STUDIES ON SINDHUVALLATHY MEZHUGU - AN INDIAN SYSTEM OF MEDICINE

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The current study was aimed to evaluate the safety of the Sindhuvallathy Mezhugu after a single or 28 consecutive daily oral administrations. In assessing the safety of Sindhuvallathy Mezhugu, acute and sub-acute oral toxicity tests performed following OECD guidelines 423 and 407, respectively, with slight modifications. In acute oral toxicity test, Sindhuvallathy Mezhugu administered to female Sprague Dawley rats by oral gavage at a single dose of 300 and 2000 mg/kg body weight. Rats observed for toxic signs for 14 days. In sub-acute oral toxicity test, Sindhuvallathy Mezhugu administered to the rats by oral gavage at 500, 1000, and 1500 mg/kg body weight daily up to 28 days to male and female Spradgue Dawley rats. The control and high dose in satellite groups were also maintained and handled as the previous groups to determine the late onset of toxicity of Sindhuvallathy Mezhugu. At the end of each test, hematological and biochemical analysis of the collected blood were performed as well as gross and microscopic pathology. In acute oral toxicity, no treatment-related death or toxic signs were observed. It revealed that the Sindhuvallathy Mezhugu could be well tolerated up to the dose 2000 mg/kg body weight and could be classified as Category 5. The sub-acute test observations indicated that there are no treatment-related changes up to the high dose level compared to the control. Food consumption, body weight, organ weight, hematological parameters, biochemical parameters and histopathological examination (liver, kidney, heart, spleen and lung) revealed no abnormalities. Water intake was significantly higher in the Sindhuvallathy Mezhugu treated groups compared to the control. This study demonstrates tolerability of Sindhuvallathy Mezhugu administered daily for 28 days up to 1500 mg/kg dose.

T206: STUDIES ON THE INFLUENCE OF NIFEDIPINE/AMANTADINE ON THE PHARMACOKINETICS AND PHARMACODYNAMICS OF SITAGLIPTIN IN RATS

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Diabetes mellitus (DM) is a condition of increased blood glucose levels in body. Sitagliptin, a novel therapeutic agent for treatment of type 2 DM is a selective inhibitor of enzyme dipeptidyl peptidase 4 which metabolises the incretin hormones in control of blood glucose levels. Nifedipine, a calcium channel blocker used for the treating patients with severe hypertension and Amantadine used to treat Parkinson's disease. Clinically Sitagliptin is given as an oral antidiabetic drug to treat DM. Nifedipine and Amantadine may be coprescribed along with Sitagliptin to treat hypertension and Parkinson's disease respectively. As such, no information is available regarding the interaction taking place between Sitagliptin / Nifedipine / Amantadine. Hence the present work has been undertaken to find out the interaction taking place between the above said drugs in rodent model, since such studies cannot be performed in humans. Methods: Studies were conducted in normal and alloxan induced diabetic rats with oral doses of 9 mg / kg B.W of Sitagliptin, 18 mg /kg B.W of Nifedipine and 2.7 mg /k g of Amantadine and their combinations with adequate washout periods in between the treatments. Blood samples were collected at regular time intervals in rats through retro orbital puncture. All the blood samples were analyzed for blood glucose by GOD / POD method in pharmacodynamic studies and for pharmacokinetic studies. The serum Sitagliptin concentrations were estimated by UV Spectrophotometry. The pharmacokinetic parameters such as AUC, AUMC, Vd, Ka, Ke, Cmax, Tmax of serum Sitagliptin calculated using Ramkin Software and serum insulin by chemiluminescence assay. Sitagliptin shows hypoglycemic

action in both normal and diabetic rats and the peak action was observed at 6 hr after administration. Nifedipine shows hyperglycemia which is peak at 2 hr, whereas Amantadine shows hypoglycemia which is peak at 4hr. The combination showed biphasic response in blood glucose levels. The same responses were observed even when administered along with Sitagliptin. The serum Sitagliptin concentrations were not altered by the co-administration of drugs and hence the other pharmacokinetic parameters of Sitagliptin were also not changed significantly. Serum insulin levels were inhibited by administration of Nifedipine and potentiated by Amantadine and initial reduction followed by surge observed with combination of Nifedipine and Amantadine. The similar responses were observed when co-administered with Sitagliptin. Thus, it could be concluded that the combination of Nifedipine and Amantadine should be taken with care for clinical benefits in diabetic patients. However, further studies should be carried out in non-rodent species and in clinical settings are warranted.

T207: MICRO-NUTRIENTS SUPPLEMENTED WITH ALLANTOIN ATTENUATE NEUROPATHIC PAIN BEHAVIOR VIA MODULATION OF OXIDATIVE STRESS

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Diabetic neuropathy is one of the major complications and available treatment neither affects the underlying pathology nor do they slow the progression of the disease. Therefore, the purpose of the study was to evaluate the combination of drugs to delay the progression of diabetes induced peripheral neuropathy in rat model. Diabetes was induced in male Wistar rats by administrating streptozotocin (STZ) (52mg/kg, i.p). Diabetic rats were treated with allantoin (100 mg/kg), allantoin (200 mg/kg), nutritional supplement, allantoin (100 mg/kg) +nutritional supplement and allantoin (200 mg/kg) +nutritional supplement for 6 weeks. At the end of the study, behavioral parameters, sciatic nerve conduction velocity, fasting serum glucose level and glycosylated hemoglobin (HbA1c) levels were measured. Further, antioxidant enzymes and MDA levels in sciatic nerve homogenate were estimated. Supplementation with combination of drugs ameliorated the diabetic induced peripheral neuropathy in rats. Administration of combination of drugs significantly reduced serum glucose level, glycosylated hemoglobin, significantly elevated the body weight, sciatic nerve conduction velocity, motor co-ordination, sensitivity to a mechanical stimulus, thermal and cold hyperalgesia and grip strength compared to diabetic control rats. Further, the treatment also increased sciatic nerve conduction velocity (NCV) and anti-oxidants levels with reduction in MDA levels. Treatment with combination of drugs may be a way to offset the early pathophysiologic damage of nerve resulting from hyperglycemia.

T208: COMPARATIVE STUDY ON EFFICACY OF GLYCOPYRRONIUM AND TIOTROPIUM IN THE TREATMENT OF COPD

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BACKGROUND: COPD is a general term that describes progressive respiratory disease like emphysema and chronic bronchitis. Chronic Bronchitis is characterized by excessive mucous production whereas emphysema is marked by permanent alveolar enlargement and destructive changes on the alveolar walls which result in airflow limitation. Two once-daily acting muscarinic antagonists (LAMA) are currently available for the treatment of Chronic Obstructive Pulmonary Disease-Tiotropium and Glycopyrronium. AIM: Aim of the study is to compare the efficacy of glycopyrronium and tiotropium in treatment of COPD. METHODS: In this prospective comparative study, patients with moderate to severe COPD were randomized 1:1 to glycopyrronium 50µg once daily and tiotropium 9 µg twice daily. The severities of infection of the subjects were assessed on the first day (before treatment). Then the patient was followed after 3months of treatment using St George respiratory questionnaire. Subjects with moderate to high risk of COPD and an age group of 40 to 75 years were enrolled in the study. Pregnant women, lactating mothers and psychiatric patients were excluded from the study. RESULTS AND DISCUSSION: A total of 96 patients were randomized with each group containing equal population 48 (50%). 60 males and 36 females were enrolled in the study. The efficacies of the two drugs were assessed using the St George respiratory questionnaire. On comparison, the results showed similar symptom score, activity score and impact scores. Both the drugs are having almost similar efficacy since the mean value does not show much difference. Both p-values are found to be significant since the p-value is less than 0.005. CONCLUSION: In patients with moderate-to-severe COPD, 12-week treatment with once daily glycopyrronium 50µg or

tiotropium 9µg twice daily provided similar efficacy and safety. The study concluded that the efficacy of glycopyrronium and tiotropium are equal.

T209: COMPARISON OF PAIN RESPONSE OF ETODOLAC AND COMPARISON OF PAIN RESPONSE OF ETODOLAC AND ACECLOFENAC IN LOW BACK PAIN

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Low back pain (LBP) is the most common musculoskeletal condition affecting the adult population. It is defined as located pain and discomfort below the costal margin and above the superior gluteal line, with or without related pain in the lower limb, being chronic if it persists for three months or more. The visual analogue scale is a simple frequently used method for the assessment of variations in intensity of pain. In clinical practice the percentage of pain relief assessed by VAS, is often considered as a measure of pain severity of treatment. To compare the pain response of Aceclofenac and Etodolac in low back pain. A prospective observational study, was conducted on 108 patients for duration of 6 months in 700 bedded tertiary care hospital, department of orthopedics. Patients were randomly arranged into 2 groups. Group 1 received Etodolac whereas the others received Aceclofenac. The comparison was done among both the groups to assess the pain severity, using VAS (Visual Analog Scale). All details were collected on a specially designed data entry form. Results showed that in the entire study population, Etodolac showed a significant reduction in the pain. Patients treated with Aceclofenac showed least significant reduction in the pain. In this study the patients in the Etodolac treatment group showed major reduction in the pain score i.e., average pain score before the study was 4.9630 and 2.0556 after the study. Aceclofenac treatment group showed only less reduction in the pain score compared to that of Etodolac, i.e., 5.3500 was the average pain score before the study and 4.5185 after the study. Our study was carried out to compare the pain response of Aceclofenac and Etodolac. Etodolac showed a significant reduction in the pain. Patients treated with Aceclofenac showed least significant reduction in the pain.

T226: FORMULATION AND EVALUATION OF A FUNGAL KERATINASE AND SCREENING FOR ITS ANTI-CANCER POTENTIAL

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Onychomycosis is a fungal infection of the nail caused by dermatophytes, which results in mycelial hyphae penetration of the skin under the nail bed and leads to infection. Current treatment regimens are limited owing to their prolonged and repetitive therapy and the need for bridging of newer biochemical entities with drug moiety is soaring. Keratinase coupled with a nano-formulation has clear advantages of targeted and sustained-release drug delivery systems. Fungal isolates, previously screened from soil samples obtained from a poultry feather waste area, were biochemically processed and subjected to enzyme production and precipitation after ensuring high keratinolytic activity. The acetone precipitated fraction contained enzyme was found to have an enzyme activity of 1.15 U/mL and was further validated by SDS-PAGE and gel electrophoresis. The prepared ketoconazole transethosome suspension was found to have the ability to encapsulate 88.5% of the drug. The transethosome particle size Z-average, zeta potential and PDI were calculated. Formulations prepared with the enzyme show synergistic anti-fungal activity with zones >30 mm. MTT assay was performed with Vero cell line and the cytotoxicity concentration was determined to be 317.18µg/ml. Inhibitory concentrations were determined to be 218.79µg/mL and 56.62µg/mL with MCF-7 and A549 cell lines respectively. These results suggest that keratinase shows anticancer activity against A549 cell line which is further substantiated by the positive test with immunoperoxidase staining.

T301: GAS CHROMATOGRAPHIC: ECOFRIENDLY NOVEL METHOD DEVELOPMENT AND STABILITY STUDIES FOR THE DETERMINATION OF PARGEVERINE HYDROCHLORIDE

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A simple novel ecofriendly, stability indicating Gas chromatographic (GC) method was developed for determination of Pargeverine hydrochloride. The gas chromatography united with flame ionization detector (GC-

FID), the novel method developed using column ZB-Drug-1 30.0m length, 0.25mm internal diameter and film thickness of 0.25um, using nitrogen as a carrier gas. The prominent peak for Pargeverine hydrochloride appeared at 7.7min at a pressure of 131.8 kPa, with a flow rate of 14.0mL/min. The total run time was 10min, the column and the detector temperature were maintained at 200°C and 210°C respectively. The drug was found to be a linear in the concentration range of 100-500 µg/mL and LOD, LOQ found to be 40.0 and 78.8 µg/ml. Pargeverine hydrochloride was subjected to forced degradation studies, following ICH guidelines under different stress conditions. The percentage degradation of Pargeverine hydrochloride was 50.97 and 2.4 when subjected to oxidizing agent and on exposure to UV light respectively. The forced degraded product gave prominent peaks at 5.5min. The developed novel gas chromatographic method was simple, rapid and ecofriendly and the method can be used for the determination of Pargeverine hydrochloride in pure and in pharmaceutical dosage forms. Method was validated for accuracy, precision and robustness respectively.

T302: ANALYTICAL METHOD VALIDATION OF RIZATRIPTAN BENZOATE IN FASTED STATE SIMULATED INTESTINAL FLUID USING UV SPECTROPHOTOMETRIC METHOD

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Rizatriptan benzoate, a new antimigraine drug is a selective subtype agonist of serotonin 5-hydroxytryptamine receptor. For rapid and prompt action, the drug is administered in the empty stomach. Therefore, the present study focuses on establishing a simple and sensitive UV spectrophotometric method for the estimation of rizatriptan benzoate in bulk and formulation in fasted state simulated intestinal fluid of PH 6.5. The validation of the proposed method was done as per International Conference of Harmonization (ICH Q2 R1) analytical validation guidelines. The method was validated for its linearity, accuracy, precision, specificity, robustness and ruggedness. The study was carried out in fasted state simulated intestinal fluid of pH 6.5 and λ max was found to be 280nm. The solution of pure drug was prepared in the concentration range of 10-60 µg/ml and the linear regression analysis showed good linear relationship with R2 value of 0.999. The limit of detection and limit of quantification were found to be 1.37 and 4.15 µg/ml, respectively. The specificity and precision showed a %RSD of less than 2%. Therefore, it can be concluded that the developed process is simple, sensitive, robust, relatively inexpensive and suitable for analysis of commercial sample of rizatriptan benzoate.

T303: STABILITY INDICATING RP-HPLC METHOD FOR SIMULTANEOUS DETERMINATION OF PYRIMETHAMINE AND SULFAMETHOXYPYRAZINE IN PHARMACEUTICAL FORMULATION: APPLICATION TO METHOD VALIDATION

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The present work takes into account the development of RP-HPLC for simultaneous method estimation and validation of pyrimethamine and sulfamethoxypyrazine in pharmaceutical formulation. The chromatographic separation was accomplished on C8 column by using acetonitrile and potassium dihydrogen phosphate as the mobile phase (60:40 v/v) having a flow rate of 0.8 mL/min. The eluent was detected at 254nm, simultaneously for both the drugs. The retention time for pyrimethamine and sulfamethoxypyrazine was found to be 3.33 min and 4.21 min respectively. According to the ICH guidelines the develop method was validated in terms of accuracy, precision, linearity, limit of detection, limit of quantitation, robustness and stress degradation studies. This validated method can be suggested for the routine simultaneous laboratory analysis of pyrimethamine and sulfamethoxypyrazine.

T304: ANALYTICAL METHOD DEVELOPMENT AND VALIDATION OF DIMETHOATE PESTICIDE USING RP-HPLC METHOD

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Organophosphates are group of pesticides which are developed at Germany in 1940s and soon became an important defense against agricultural pests. Dimethoate which is a commonly used group of pesticide is a broad-spectrum organophosphate compound having insecticidal activity. Most of the organophosperous insecticides are harmful to mammals including man i.e., they were not

selectively toxic to insects. The detailed literature survey shows that methods like HPLC, GC, and TLC methods were used for the detection of Dimethoate. In the proposed method HPLC LC-20AD equipped with PDA detector is used for the present research work. The separation was done by using Phenomenex Luna C18 column (250 mm X 4.60 mm 5µ). The run time was set for 10 min. Acetonitrile (ACN) and 0.1% orthophosphoric acid (50:50 v/v) at 1ml/min flow rate is used as mobile phase for analysis. The column temperature was set at 40˚C. The detection wavelength was set at 205nm and PHENEX PTFE 0.02µm syringe filter was used for filtration. The detection range was found to be 10 to 50µg/ml and the retention time of Dimethoate was found to be 3.0 minutes with correlation coefficient 0.9788, LOD and LOQ was found to be 0.274µg/ml and 0.831µg/ml respectively. The method was validated as per ICH guidelines.

T305: ENANTIOMERIC SEPARATION OF MECLIZINE HYDROCHLORIDE IN RABBIT PLASMA BY UFLC AND SEPARATION MECHANISMS BY DOCKING STUDIES: APPLICATION IN STEREOSELECTIVE PHARMACOKINETIC STUDY

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A novel Ultra- Fast Liquid Chromatographic (UFLC) method with photo diode array (PDA) detector was developed for enantiomeric separation of meclizine hydrochloride. A superior resolution was obtained between the enantiomers on Cellulose tris (4-methylphenylcarbamate) (150 x 4.6 mm x 5 µm) column using the mobile phase acetonitrile: 10 mM ammonium bicarbonate (95: 05, v/v). The obtained method validation results were in accordance with International Conference for Harmonization (ICH) guidelines. Enantioselective assay of meclizine hydrochloride in its marketed formulation was executed by this technique. Identification of the separated enantiomers was achieved by polarimetry. Docking studies between meclizine hydrochloride and the chiral stationary phase to predict the elution order of the enantiomers. This method was extended to enantioseparation of meclizine hydrochloride in rabbit plasma using cyclizine as an internal standard (IS). The developed and validated method was used to perform pharmacokinetic studies using Phoenix WinNonlin 8.1 software, to determine the stereo-specific disposition of meclizine hydrochloride in rabbit plasma. The results confirmed a significant difference in the stereo-specific disposition of meclizine hydrochloride enantiomers. No such prior study was accomplished for the drug. These outcomes could likewise be affirmed by performing studies on human subjects.

T306: Characterization of Impurities in Acarbose Hydrate by Using LC-MS/MS And NMR

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An accurate and lively LC-MS/MS and NMR analytical methods have been developed for recognition and characterization of key impurities in Acarbose. Acarbose is an anti-diabetic drug used to treat Diabetes mellitus Type II and in some country's prediabetes also. Three unknown impurities were detected in Acarbose hydrate bulk drug substance using RP-HPLC method at RT 17.65 min, 18.4 min and 25.85 min. These impurities were isolated by preparative HPLC and further characterized by using LC-MS/MS and NMR techniques. LC-MS/MS analysis was performed using C18 reverse phase column and with Methanol and Ammonium Format (80:20) as a mobile phase. The flow rate was maintained at 0.5mL/min with injection volume as 10 µL. The separations were achieved with binary gradient program and the column is maintained with ambient temperature. The MS conditions adopted for this analysis with scan range of m/z = 50 to 500 with dwell time 3 seconds. NMR was carried out using DMSO as solvent. Based on spectral data, the impurities have been characterized as IMP B, IMP D and IMP E.

T307: BIO-ANALYTICAL METHOD DEVELOPMENT AND VALIDATION FOR SIMULTANEOUS ESTIMATION OF NEBIVOLOL, METOPROLOL AND AMLODIPINE IN HUMAN PLASMA BY LC-MS/MS

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A selective, sensitive, rapid and precise LC-MS/MS method has been developed and validated for simultaneous

estimation of Nebivolol, Metoprolol and Amlodipine in human plasma by LC-MS/MS in human plasma. Bio-analytical method validation is used to establish the developed analytical method whether is it precise, accurate, rugged and robust and also is it suitable for the bio medical applications or not. The Nebivolol, Metoprolol and Amlodipine were extracted by Protein precipitation method. The stationary phase used as Zorbax-SB C18 (50 x 4.6mm i.d, 5µm) column and the mobile phase as Solvent A (cyanomethane) and Solvent B (10mM Ammonium acetate buffer, pH 6.0) with the ratio 80:20 v/v. The flow rate was found to be 0.5ml/min and the detection was performed by Triple quadrapole mass spectrometry LC-MS/MS using electron spray ionization (ESI) as positive and negative mode. The linearity of Nebivolol, Metoprolol was determined by using Amlodipine as Internal standard which is consistently accurate for plotting calibration curve and r2 value is within the limits. The precision and accuracy were found in acceptance limits. The method was developed and validated as per USFDA guidelines. The established method can be used for the quantification of Nebivolol, Metoprolol and Amlodipine in Human plasma for Bio-availability and Bio-equivalence studies, new drug development, Clinical pharmacokinetics, and biopharmaceutical sciences.

T308: DEVELOPMENT AND VALIDATION OF ANALYTICAL METHODS FOR SIMULTANEOUS ESTIMATION OF ACECLOFENAC AND PANTOPRAZOLE

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A new simple, specific, precise and accurate RP-HPLC method was developed and validated for simultaneous estimation of Aceclofenac (ACECLO) and Pantaprazole (PANTO) in bulk, and marketed pharmaceutical dosage form. A new RP-HPLC method was developed using RP C18 column (Phenomenex Luna 10µ, 250mm × 4.6mm) as stationary phase and acetonitrile: ammonium acetate buffer (50:50 v/v) as mobile phase. The flow rate of mobile was 1 ml/min. The analysis was performed at ambient temperature with UV detection at 282 nm. The retention time of ACECLO and PANTO was found to be 2.9 min and 4.1 min respectively. Both the drugs showed linear response between the concentration ranges from 10-100 µg/ml.

T309: STRUCTURAL ALTERATION APPROACH TO SOLVE THE STABILITY ISSUES IN ANTI RETRO VIRAL DRUG

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As per WHO, HIV-AIDS considered as second most dangerous disease which produces a high mortality rate. Hence combinational therapy is considered as a key tool to control the life loss and to extend the life span of patients. Abacavir sulfate, an anti-retroviral drug is used for the first-line treatment of HIV/AIDS as part of the Anti-Retroviral Therapy (ART). Abacavir sulfate (ABC) has been shown to pose a few pharmacokinetic problems regarding its side effects. Physicochemically, ABC faces the challenge of instability in acidic conditions, higher temperatures, and it also shows photo-instability. In order to enhance its physicochemical properties in terms of stability, semi-synthetic derivatives of ABC have been hypothesised the same have been achieved. These derivatives have shown pharmacokinetically enhanced performance, but involve complex synthetic routes. Schiff's base synthesis has been selected as a route of synthesis to improve the stability. This reaction route appears promising as the resulting imine is considered relatively stable than the parent compound. The synthetic compound has been analysed for its stability. As result of the study potential semi-synthetic moieties have been developed and its stability parameters have been studied. As a result, the compound under consideration has enhanced stability parameters.

T310: UV-SPECTROPHOTOMETRIC METHOD FOR ESTIMATION OF TICAGRELOR IN BULK AND TABLET DOSAGE FORM

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A simple, precise, accurate UV spectrophotometric method based on single point standardisation and double bracketing method has been developed and validated as ICH guidelines in bulk and tablet dosage form. Ticagrelor belongs to an oral antiplatelet agent, which inhibits the platelet activation and aggregation which is mediated by the P2Y12 ADP receptor. Ticagrelor showed its maximum absorbance at 256 nm in

methanol, obeyed Beers range between 6 µg/mL to 20 µg/mL with linear regression coefficient of 0.9908 and assay percentage value when calculated based on single point standardisation method and double bracketing method was found to be 99.8% and 100.2% respectively. The method was validated for linearity, precision, accuracy, LOD, LOQ and recovery studies as per ICH guidelines. The proposed method can be adopted for routine analysis of ticagrelor in bulk and tablet dosage form

T311: ANALYTICAL METHOD VALIDATION OF LAURIC ACID PRESENT IN PURE AND COMMERCIAL PREPARATIONS OF COCONUT OIL

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Lauric acid is the chief constituent of Cocos nucifera (coconut oil). The main objective of the study was to develop a simple, robust and derivatization free GC-FID method that is suitable for routine analysis of lauric acid in the pure and commercial coconut oil. The sample was dissolved in methanol and diluted. The solution was then injected in split mode to ZB-WAX plus column of length 30 m, internal diameter of 0.25 mm ID and film thickness of 0.5 µm. The retention time of lauric acid was found to be 6.42 min. The method showed possibility to detect the standard solutions of lauric acid with a linear determination in the range of 100-500 mcg/mL with correlation coefficient (r) 0.9996. The limit of detection and limit of quantitation were found to be 0.385 and 1.168 respectively. The method showed good accuracy and precision for both interlay and intraday with % RSD <2%. This method can be employed for the estimation of lauric acid in various commercial oils present in the market.

T312: COMPLEXOMETRIC ESTIMATION OF CALCIUM CONTENT FROM DIFFERENT MILK SAMPLES FROM NELAGADARANAHALLI AREA, BANGALORE

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Milk has been recognized as a staple of the human diet since the agricultural revolution, approximately 8000 BC. Cow's milk and other dairy foods are the major source of calcium in diet, providing more than 70% of the calcium available in the food supply. In an analysis of food sources of calcium, milk and milk products provides 83% of the calcium in the diets of young children, 77% of the calcium in adolescent females' diets, and between 65 and 72% of the calcium in adults' diets. Milk contains water, carbohydrates, fat, protein, vitamins and minerals. Calcium is one of most abundant amount presents in cow's milk. Beyond the role of milk as part of a nutrient dense diet that provides necessary nutrients for normal growth and development, research over the past 30 to 40 years has shown that milk and milk products can help reduce the risk of chronic disorders including osteoporosis, hypertension, excess body weight and body fat, and colorectal cancer. The aim of this study was to estimate the amount of calcium content in cow's milk which was fed with organic feed in the Nelagadaranahalli area, grazed cow's milk in same area, pasteurised packaged milk and toned milk available in the market. The technique used for estimating the amount of calcium ions is based on complexometric titration using disodium EDTA as titrant in presence of ammonia and ammonium chloride as buffer, using Mordant Black II as indicator. It was found that sample collected from organic fed cow's milk showed more amount of calcium content compared to other milk samples. Among the four samples pasteurised packaged milk showed least amount. Variation of calcium content in different samples may be due to source of feed, geographical condition/ location, environment, different breed etc. Many Papers have reported that amount of calcium content is low in pasteurised packaged milk, may be due to heating process. Hence, we conclude that organic fed cow's milk is better than packed milk.

T313: FIRST AND SECOND DERIVATIVE SPECTROPHOTOMETRIC METHODS FOR DETERMINATION OF PALIPERIDONE IN PHARMACEUTICAL FORMULATION

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Simple, fast and reliable derivative spectrophotometric methods were developed for determination of paliperidone in bulk and pharmaceutical dosage forms. The solutions of standard and the sample were prepared in methanol. The quantitative determination of the drug was carried out using the first derivative values measured at 248 nm and the second derivative values measured at 246 nm (n=6). Calibration graphs constructed at their wavelengths of determination

were linear in the concentration range of paliperidone using 2-10 µg/ml for first and second derivative spectrophotometric method. The calibration graphs constructed at their wavelength of determination were found to be linear for UV and derivative spectrophotometric methods. All the proposed methods have been extensively validated as per ICH guidelines. There was no significant difference between the performance of the proposed methods regarding the mean values and standard deviations. Developed spectrophotometric methods in this study are simple, accurate, precise, specific, sensitive, and reproducible and can be directly and easily applied to pharmaceutical dosage form.

T314: A SIMPLE ECOFRIENDLY TECHNIQUE TO SYNTHESIZE REDUCED GRAPHENE OXIDE USING AGROWASTE MATERIAL

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In the present study, a simple, eco-friendly and cost-effective method was employed to synthesize reduced graphene oxide using sugarcane bagasse as agrowaste material. Reduced graphene oxide was synthesized by thermochemical process by subjecting the sugarcane bagasse to get pyrolyzed under muffled atmosphere at varying temperatures and time followed by chemical exfoliation. In order to improve the properties of reduced graphene oxide, precarbonized sugarcane bagasse was activated using KOH in same muffled atmosphere and exfoliated similarly. The product was subjected to evaluation by UV spectroscopic analysis, XRD analysis and EDS to confirm the synthesis of graphene and existence of graphene as graphene oxide or reduced graphene oxide. The product was also characterized for surface morphology by scanning electron microscopy, particle size distribution and zeta potential using zeta sizer. The UV absorption peak at 271 nm attributing to π - π * transitions suggested that graphene exists as reduced graphene oxide. The 2θ values of 26.2º and 24.8º obtained from XRD analysis confirmed the presence of graphene and reduced graphene oxide respectively. The scanning electron microscopic images showed single layered reduced graphene oxide sheets for pyrolyzed sugarcane bagasse and nonporous sheets for KOH treated sample. The EDS spectra indicated the presence of carbon and oxygen in the ratio of 3:1 which confirmed that the product synthesized is reduced graphene oxide. The average particle size and zeta potential was found to be 23.8nm ± 0.146 and -32.9mV ± 0.55 respectively. However, the particle size analysis report with dual peaks and polydispersity index of 0.79 ± 0.006 suggests heterogeneity of the dispersion which necessitates the refinement of procedure with further functionalization using natural polymers to get homogenous dispersion. The aforementioned findings clearly indicate that the proposed method is simple, ecofriendly and has potential for commercial exploitation in large scale production and meets the demands of nano-filler for reduced graphene oxide-based drug loaded polymer nanocomposites especially in the treatment of cancer.

T315: DEVELOPMENT, OPTIMIZATION AND VALIDATION OF SIMPLE SPECTROPHOTOMETRIC METHOD FOR RAPID DETERMINATION OF ZINC (II) IONS

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A review of literature pertaining to determination of zinc (II) ions is aplenty with atomic absorption spectroscopy methods; however spectrophotometric methods reported are scant and mostly involve the use of pM indicators to form colored complexes which absorb well in the visible region. However, the stability of the colored complex is greatly affected by reaction conditions such as pH, temperature and volume of reagent. Hence, we have made an attempt to develop, optimize and validate an easy spectrophotometric method for determination of zinc (II) ions, using xylenol orange as a chromogenic complexing agent at pH 4.4 using acetate buffer. Zinc (II) ion instantly forms an intense red colored complex with xylenol orange with an absorption maximum (λmax) at 571nm. The influence of analytical parameters such as pH, volume of buffer and volume of reagent on the absorbance of zinc (II) – xylenol orange complex were studied by applying Response Surface I-optimal Quadratic model, which suggested 22 runs for the study and analysis of response suggested a pH of 4.4 and volume of 5mL for acetate buffer and as well as reagent. Further the method was validated for linearity, specificity, system suitability, precision, ruggedness, robustness and accuracy. The linearity of zinc standard solution showed a good correlation over a concentration range of 6-48 µg/ml with linear regression equation y = 0.0195x + 0.0888 and regression coefficient (R2) was 0.9951. Accuracy was obtained in the range of 99.00-99.33%. The limit of detection and the limit of quantification were found to be 0.1692 and 0.5128 µg/ml, respectively. The relative standard deviation (%RSD) was 0.1791% and 0.4672% for inter-day and intra-day precision, respectively. All the validation parameters complied with the

acceptance criteria. Therefore, the method may be applied for the rapid determination of zinc (II) ions in pharmaceuticals.

T316: SIMULTANEOUS LC- ESI-MS/MSPMT METHOD DEVELOPMENT AND VALIDATION OF CEFIXIME, ORNIDAZOLE AND DICLOXACILLIN IN HUMAN BLOOD PLASMA

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A simple, selective, rapid and precise LC-MS/MS method has been developed and validated for simultaneous estimation of Cefixime, Ornidazole and Dicloxacillin in human plasma. Bioanalysis is defined as the quantitative measurement of drug molecule in the biological matrix which includes plasma, serum, urine, saliva, etc. Bio-analytical method validation is used to establish the developed quantitative analytical method is precise, accurate, rugged and robust and is suitable for the bio medical applications and validate the same. The Cefixime, Ornidazole and Dicloxacilliin were extracted by Protein precipitation method. The stationary phase used as Zorbax C18 (50 x 4.6mm i.d, 5µm) column and the mobile phase as Solvent A (Methyl alcohol) and Solvent B (10mM Ammonium acetate buffer, pH 6.0) with the ratio 90:10 v/v. The flow rate was found to be 0.8ml/min and the detection was performed by Triple quadrapole mass spectrometry LC-MS/MS using electron spray ionization (ESI) as positive and negative mode. The linearity of Ornidazole was found to be within a range 4.0 to 80.0mcg/ml and Dicloxacillin was found to be 1.5 to 30.0mcg/ml using Cefixime as Internal standard which is consistently accurate for plotting calibration curve. The precision and accuracy were found in acceptance limits and the R2 of Ornidazole and Dicloxacillin were 0.9936 and 0.9994 respectively. The limit of detection (LOD) values for Ornidazole and Dicloxacillin were found to be 330 ng/ml and 123.5ng/ml respectively. The limit of quantification (LOQ) value were 1000ng/ml and 375ng/ml for Ornidazole and Dicloxacillin respectively. The method was developed and validated as per USFDA guidelines. The established method can be used for the quantification of Ornidazole and Dicloxacillin 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.

T317: SYNTHESIS AND QUANTIFICATION OF FEW IMPURITIES OF DICLOFENAC SODIUM BY HPLC METHOD

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Regulatory bodies like ICH and US-FDA emphasizes the importance of impurity profiling to ensure quality of the drug product. Commonly used NSAID Diclofenac sodium was considered for the study. Diclofenac sodium have five potential specified impurities (Imp-A, Imp-B, Imp-C, Imp-D, Imp-E) were identified with reference to British Pharmacopoeia (BP), Indian Pharmacopoeia (IP) and United States Pharmacopeia (USP). Diclofenac sodium specified impurity-B: 2-[(2,6-dichlorophenyl) amino] benzaldehyde was synthesized by reaction of 2,6-dichloaniline with o-bromobenzaldehyde in presence of N, N1-Dimethylethylenediamine, cuprous oxide, potassium carbonate and N-methyl morpholine followed by hydrolysis with dilute acid and crude product purified in the laboratory with significant yields. Based on the physical and spectral data with IR and Mass spectra, the structure of Impurity-B was characterized and used as reference standard. New, accurate and reliable RP-HPLC method have been developed and validated for the simultaneous determination of Diclofenac sodium with their potential Impurity-B. The chromatographic separation was achieved for Diclofenac sodium and its Impurity-B were eluted by using isocratic conditions on aphenomenex-RP-C18, 50mm X 4.6mm, 5µm column with mobile phase consisting of Acetonitrile: phosphate buffer pH5 in the ratio of 80:20 at a flow rate of 1 ml/min. with UV detection at 275nm. The developed new method was validated as per ICH guidelines.

T401: EVALUATION OF ANTIGENOTOXICITY OF CUCURBITA PEPO (PUMPKIN) LEAVES: *IN VITRO* AND *IN VIVO*

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Genotoxicity is a word in genetics defined as the destructive effect on a cell's genetic material (DNA, RNA) affecting its integrity. Nowadays most of the therapeutics that prescribed for cancer treatment shows genotoxicity as their natural property (e.g., Nitrosoureas, Cisplatin, 5-Fluorouracil, Ionizing radiation etc.). The present study of antigenotoxic

potential of Cucurbita pepo leaf extracts both in-vitro and in-vivo opens a greater window for the safety of anticancer drugs. The study included micronucleus assay, chromosomal aberration test, peripheral blood nucleus test, sperm abnormality test, Allium cepa assay, and In-vitro antioxidant activity to give a clear idea about activity of Cucurbita pepo leaf extract. Cyclophosphamide (CP) a potent alkylating agent was used as positive control to produce genotoxicity and Cucurbita pepo leaf extract was assumed to protect it. Doses of Cucurbita pepo leaf extract used were 50,100, 200 µg/ml for Allium cepa assay and 50,100,200 mg/kg for micronuclei assay, chromosomal aberration test, peripheral blood nucleus test and sperm abnormality test. Swiss albino mice were used for in-vivo studies and they were divided into 5 groups of 6 animals each. Onion roots were used for Allium cepa assay. The ethanolic extract of Cucurbita pepo leaf was able to show antigenotoxic activity in CP induced genotoxicity in mammalian bone marrow erythrocytes micronucleus assay (MNA), Chromosomal aberration (CA) test, peripheral blood nucleus test, sperm abnormality test and Allium cepa assay dose dependently. It showed maximum antigenotoxic activity when given at a dose 200 mg/kg in micronucleus assay, chromosomal aberration test, peripheral blood nucleus test and sperm abnormality test whereas 200 µg/ml in Allium cepa assay. The leaf extract also has good antioxidant activity with IC50 value ~ 30 µg/ml in DPPH scavenging activity and the total phenolic content of ethanol extract of Cucurbita pepo leaf reveled 16.29 mg GAE/g and flavonoid content of ethanol extract of Cucurbita pepo leaf reveled 25.43 mg QE/g of dried plant material. Cucurbita pepo leaf extract possess good antigenotoxic and antioxidant activity and it can be used as a combination therapy with potent and novel anticancer molecules.

T402: CARDIOPROTECTIVE EFFECT OF *CUCURBITA PEPO* SEED OIL IN ISOPROTERENOL INDUCED MYOCARDIAL DAMAGE IN RATS

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In the present study, the research work deals with the evaluation of the cardioprotective effect of Cucurbita pepo seed oil in isoproterenol induced myocardial damage in rats. Cold pressed extract of Cucurbita pepo seeds was administered orally at two different doses of 200mg/kg and 400mg/kg for 14 days in acute model and 30 days in chronic model in rats that were then induced with isoproterenol on 15th and 16th (acute model), and 31st and 32nd days (chronic model) at 24 hours interval. Multiple parameters such as the serum markers like SGOT, SGPT, lactate dehydrogenase, CK-MB were measured along with in vivo antioxidant parameters such superoxide dismutase, lipid peroxidation and reduced glutathione. The cardiac markers compared with Enalapril Maleate at 10 mg/kg b.w. p.o. as standard. The study reveals that both 200mg/kg and 400mg/kg of Cucurbita pepo seed oil shows significant improvement in lowering of the cardiac marker enzymes. The extracts have shown improvement the HDL levels and reduction in the levels of the other lipoproteins as well as cholesterol and triglycerides. It's clear from detailed study that the C. pepo seed oil influences the cardiac marker enzymes levels and the lipid profile in isoproterenol induced rats. It was found that there was no dose dependent activity and exhibited similar effects at both the low dose and the high dose of the extract.

T404: DESIGN AND CHARACTERISATION OF ETHOSOMES LOADED WITH SPONDIAS PINNATA EXTRACT WITH ANTIMICROBIAL ACTIVITY

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The aim of this study is to formulate and evaluate ethosoames loaded with Spondias pinnata extract. Ethosomes loaded with Spondias pinnata extract formulation were fabricated by using quality by design (QbD) approach. Ethosomes were prepared by cold method according and evaluated for vesicle size, zeta potential, entrapment efficiency, optical microscopy, scanning electron microscopy, and transmission electron microscopy. In vitro drug permeation study of optimized formulation was performed through goat skin membrane and compare with pure drug solution. The optimized ethosome had an acceptable vesicle size of 141.1 nm and entrapment efficiency 71.24% within 95% CI. Microscopic images showed presence of uniform spherical vesicles. Antimicrobial screening of the extract can be performed by Cup plate diffusion method using nutrient agar. At the end optimized formulation shows 91% of In vitro drug release proved sustained release of the ethosome.

T405: CURCUMIN LOADED SILVER NANOPARTICLES CONTAINING SCAFFOLDS FOR WOUND HEALING APPLICATIONS

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Wound healing occurs in four phases: haemostasis, inflammatory, proliferative and Maturation phase. It is a complex and systematic process coordinated by combination of biological and molecular events in extracellular matrix. Wounds can be Characterized as injuries to the body that outcome in disturbance of the congruity of the body structure. Turmeric (Curcuma longa) is a ginger family flowering plant, Zingiberaceae, whose roots may enhance the wound healing process. Turmeric can help prevent (and possibly even treat) cancer. It contains Curcumin which is a lipophilic polyphenol substance with a turmeric powder content of 2–5%, which may help reduce inflammation and, in effect, may speed up the progress of the stages of wound healing. Silver acts as a healing agent with antibacterial property. Most commonly used practices such as skin grafts and wound dressings are in combination with the anti-bacterial nanoparticles. The latest advancement in the formulation for wound healing is biological scaffolds. Chitosan is a natural polymer with good biocompatibility and biodegradability many experiments have been done to obtain chitosan scaffolds which include designing scaffolds such a way that it mimics the 3D extracellular matrix structure, also transferring of signaling factors to control and effect the cell response that induces the wound healing. The in vitro and in vivo therapeutic effects were evaluated to test potential effects of chitosan scaffolds with low side effects. In vivo experiment on animal proved chitosan as a good wound dressing material. In this study, Chitosan scaffolds showed an increased effect of wound healing, change in the wound area and formation of new blood vessels. This study gives the recent information about wound healing scaffolds, state of the art techniques and the recent projects undergoing pre-clinical phase and clinical phase in wound healing.

T406: ANTI CATARACTOGENIC ACTIVITY OF *MITRAGYNA PARVIFOLIA* (ROXB.) ROOT EXTRACTS AGAINST GLUCOSE INDUCED OPACITY IN GOAT LENS

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Mitragyna parvifolia (Roxb.) Korth. is a medium to large size tree belonging to the family Rubiaceae, popularly known as Kaim and is found growing throughout the drier parts of India, Pakistan and Srilanka. *M. parvifolia* is a substitute for the Ayurvedic drug Kadamba for which the accepted source is *Neolamarckia cadamba* and is used in the treatment of eye diseases, wounds, cough and edema. The aim of the present study was to evaluate the anti-cataract activity of *Mitragyna parvifolia* root extracts against glucose induced opacity in isolated goat lens model. The roots of Mitragyna parvifolia was collected from Tamil Nadu in 2018. The plant material was identified and authenticated by Dr. V. Chelladurai, Taxonomist. Botanical identification was carried out by using various floras. Alcohol and aqueous root extracts were prepared by Soxhlet and maceration technique respectively. The goat eyes were procured from nearby slaughter house immediately after slaughter and stored in normal saline. The lenses were removed by extra capsular extraction and incubated in artificial aqueous humor solution. Glucose (55mM) was used to induce cataract and the lenses of different groups were incubated for 72 hrs. Antibiotics like Penicillin (32 mg %) and Streptomycin (250 mg %) were added to all the group of lenses to prevent any microbial contamination during incubation. After the incubation period, the degree of opacity of the lenses was evaluated by placing them on a graph paper and counting the number of squares visible through the lenses macroscopically. Various antioxidant levels like MDA, reduced glutathione, catalase and SOD were estimated in the lenses. Induction of cataract by glucose showed a significant decrease in catalase, reduced glutathione and increased MDA level. The lenses treated with aqueous and ethanol extracts, ascorbic acid 20 µg/ml (standard) restored the level of reduced glutathione and catalase whereas reduced the increased level of MDA. Alcohol extract at 1000 µg/ml dose level showed better anti-cataract activity than aqueous extract substantiating the traditional use of the plant in the treatment of eye diseases.

T407: COMPARATIVE ANTI INFLAMMATORY ACTIVITY STUDIES ON BETALAINS OF *BETA VULGARIS* AND HAIRY ROOT CULTURE OF *BETA VULGARIS*

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The main objective of the present study was the production of betalains from hairy root culture of *Beta vulgaris* and comparative evaluation of its anti-inflammatory potential. Hairy roots were initiated using different strains of Agrobacterium Rhizogens such as A.2/83, A.20/83 and LMG 150; LMG 150 was found to initiate large number of hairy roots. Hairy roots were further grown on MS media and betalains was extracted with acidified water and its content was estimated spectrophotometrically. In -vitro anti-inflammatory activity of betalains from beetroot and hairy roots was evaluated by membrane stabilization and inhibition of denaturation of albumin methods. Betalains of hairy roots possess significant anti-inflammatory activity in a dose dependent manner, whereas exhibited extremely significant anti-inflammatory activity (1000 µg/ml) when compared with betalains of Beta vulgaris.

T408: PHARMACOGNOSTICAL AND PHYTOCHEMICAL STUDIES ON CLERODENDRUM PHLOMIDIS LINN. F. LEAVES

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Clerodendrum phlomidis Linn.f.is commonly known as Agnimantha and it belongs to the family Verbenaceae. Owing to its multifarious biological activity, the plant has gained importance in the treatment of many diseases such as asthma, rheumatism, dysentery, tooth ache, leprosy and other inflammatory diseases and is of great demand in the fast-growing herbal market. The aim of the present study is to perform the Pharmacognostical and phytochemical studies on the leaves of *Clerodendrum phlomidis*. The plant specimens were collected from Srivaikundam region of Thoothukudi district, Tamil Nadu. The paraffin embedded leaf specimens were sectioned with the help of Rotary Microtome. Preliminary phytochemical analysis was done as per Harborne and Wagner. The powder microscopy of leaf powder showed the presence of abundant fibers, non-glandular trichomes and cyclocytic stomata. The phytochemical analysis showed the presence of flavonoids, tannins, sterols, carbohydrates and proteins in both aqueous and ethanol extracts. The information derived from the present study helps in the botanical identification of *Clerodendrum phlomidis* and also be used as a valuable information to ensure the quality of the drug as adulteration is becoming common these days. The study will help in the better understanding of the use of this plant leaf for biological activities and for dissemination of knowledge for the researchers who undertake this plant part for further study.

T409: PROTECTIVE EFFECT OF *SARGASSUM WIGHTII GREVILLE* AGINST STREPTOZOTOCIN INDUCED DIABETIC ENCEPHALOPATHY IN WISTAR RATS

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Diabetes is known to be a chronic metabolic disorder with devastating consequences to nervous system. Diabetic encephalopathy is recognized as one of the major complications of both type 1 and 2 diabetes mellitus. Accumulation of intracellular glucose is known to cause neuronal damage which leads to impaired cognitive functions and associated structural as well as neurochemical abnormalities. *Sargassum wightii* Greville (*S. wightii*) being already reported for its hypoglycemic potential is evaluated for its beneficial effect in diabetic encephalopathy. Wistar rats weighing between 220-250 g were used in the present study. They were divided into six groups each group consisting of six animals. A single dose streptozotocin 65 mg/kg (i.p) was used to induce diabetes and associated encephalopathy. Group I served as normal control. Group II served as disease control. Group III and IV received Glimepiride (0.5 mg/ kg, p.o) and Donepezil (3 mg/kg, p.o) respectively. They served as standard groups. Group IV and V received ethanol extract of *S. wightii* (ESW) 100 and 200 mg/kg orally. Learning and memory was evaluated by Morris water maze test, single trial passive avoidance test. At the end of 30th day, animals were sacrificed and brain tissue was subjected to biochemical analysis and histopathological study. Increased intracellular glucose is known to be toxic to the neurons due to its accelerated oxidation. This leads to accumulation of reactive oxygen species which are the main cause for oxidative stress. In the present study, disease group showed significant cognitive deficits with a poor performance in behavioral studies. There was also a significant increase in hippocampal MDA, nitrite, AGE, AChE activity and a decrease in GSH, SOD in disease group animals which is correlated to oxidative stress and associated

cognitive deficits. Elevated level of Aβ protein and Tau protein indicated the neuronal damage in hippocampus by streptozotocin. Treatment with ESW 100 and 200 mg/kg significantly reduced oxidative stress which was manifested by a reduction in MDA, nitrite, AGE and AChE activity. Protective antioxidants such GSH and SOD were restored by the treatment with ESW 100 and 200 mg/kg. From Congo red staining technique, it was observed that ESW prevented the accumulation of Aβ protein indicating their protective effect in diabetic encephalopathy. Thus, it may be suggested that ESW offered significant protection against diabetic encephalopathy induced by streptozotocin in Wistar rats. Antihyperglycemic and antioxidant potential of *S. wightii* are postulated to responsible in attenuating diabetes associated cognitive deficits.

T410: EVALUATION OF ACUTE AND SUB-ACUTE ORAL DOSE TOXICITY STUDIES OF LIQUORICE AND CATECHU ON EXPERIMENTAL ANIMALS

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The currently available locally acting formulations to treat recurrent aphthous stomatitis (RAS) are either less efficacious or they are not comfortable for the use in the patients. A single administration of LC was given orally at the highest dose level of 2000 mg/kg body weight in the acute toxicity study. Signs of toxicity were observed every hour for the first 6 h and every day for 7 days. In the repeat oral toxicity study, LC was administered to rats at doses of 250, 500, 750 and 1000mg/kg body weight for 28 days. Mortalities, clinical signs, body weight changes, biochemical and haematological parameters were monitored during the study period. There were no mortalities or clinical signs observed in rats in the acute toxicity study. The observable increase in the level of alkaline phosphatase (ALP) in the group administered 1000 mg/kg body weight of LC may be as a result of congestion or obstruction of biliary tract, which may occur within the liver. ALP activity on the other hand is related to the functioning of hepatocytes and an increase in its activity may be due to its increased synthesis in the presence of increased pressure. The increased level of lactate dehydrogenase (LDH) observed in the present investigation apparently indicated the toxic effect of LC in rat. There were no significant changes in total protein in rats treated with LC, which suggested that there was no sign of impaired renal function. The near–normal levels of total cholesterol observed in groups treated with LC may be attributed to the presence of hypolipidemic agents in the herbal drug. Similarly, the drug had no adverse effect on the concentration of creatinine and urea. This is suggestive of no kidney damage specifically by renal filtration mechanism. Increase in platelets observed in rats treated with 1000 mg/kg body weight may be attributed to enhanced production and secretion of thrombopoietin the primary regulator of platelet production by LC indicating that it has hemostatic property. NOAEL from this preclinical study was found to be 500mg/kg.

T411: *IN VITRO* ANTIOXIDANT AND ANTICOAGULANT ACTIVITY OF RED MARINE ALGAE SPECIES *HYPNEA FLAGELLIFORMIS*

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An antioxidant is a mineral, vitamin or other nutrients that might protect and repair cells in your body against that damage that is caused by free radicals and Disorders like blood coagulation can lead to an increased risk of bleeding (hemorrhage) or clotting (thrombosis). We aimed to evaluate the possible invitro antioxidant and anticoagulant effect of marine algae extracts of *Hypnea flagelliformis.* The algae were collected from different locations of Mandapam area, Tamilnadu. The algae extracted with ethanol solvent the antioxidant assay DPPH photometric, Superoxide radical scavenging activity and anticoagulant assay the APTT, PT, TT assay were performed with standard kit. the concentration for antioxidant is 125,250,500,1000mcg/ml and for anticoagulant from 2mg/ml to 20mg/ml the result was tabulated and the1000mcg/ml possess maximum antioxidant activity and the anticoagulant as APTT value for 20mg/ml is 158sec, PT values is 36sec and TT values is 68sec respectively.

T412: EXPLORATION OF HEPATOPROTECTIVE ACTIVITY OF POLYHERBAL FORMULATION AGAINST ACETAMINOPHEN INDUCED LIVER INJURY IN RATS

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Oxidative stress plays a crucial role in the development of

several liver diseases. Many natural polyphenols can attenuate oxidative stress and liver injury. The present study was undertaken to explore in-vivo hepatoprotective effects of polyherbal formulation against acetaminophen induced hepatotoxicity in rats. A phytochemical profiling of an ethanolic extract of Madhuca longifolia leaves, Polyalthia longifolia leaves and Delonix regia flower has been prepared by soxhlet extraction process which revealed many phytoconstituents belonging to flavonoids, phenolic acids, tannins etc. The ethanolic extracts of three plants were mixed in equal proportion, to obtain the best formulation in order to increase the acceptability and adoptability of herbal medicine. Hepatoprotective activity potential of polyherbal formulation (PHF) were tested at doses of 200 and 400 mg/kg on wister albino rats. The PHF and silymarin treated animal groups showed significant decrease in activities of different biochemical parameters like Serum glutamate oxaloacetic transaminase (SGOT), serum glutamate-pyruvate transaminase (SGPT), alkaline phosphatase (ALP), which were elevated by acetaminophen (2 g/kg p.o) intoxication. The levels of total bilirubin were also restored to normal by PHF and silymarin treatment. Additionally, Histology of the liver sections reveals the normal liver architecture with well brought out central vein. Pre-treatment with PHF and silymarin also caused marked decrease in inflammatory cells. The present study demonstrates that PHF possesses significant hepatoprotective activity in a dose dependent manner against acetaminophen induced hepatic injury in rats and this may be attributed due to the antioxidant principles which are presented in polyherbal formulation.

T413: ANTI-ASTHMATIC ACTIVITY OF A POLYHERBAL FORMULATION ON OVALBUMIN INDUCED ASTHMA IN RATS

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The purpose of this study was to see how well a polyherbal formulation worked in a rat model of ovalbumin-induced asthma. The polyherbal formulation and allopathic standard anti-asthmatic medications were administered orally for sixty days. Number of leukocytes, intact mast cells, levels of protein, MDA, NO, MPO activity was estimated for the evaluation of anti-asthmatic effects. Histopathological examination of lungs was carried out. Polyherbal formulation treatment alleviated ovalbumin induced oxidative changes in lungs. Furthermore, lung injury was attenuated by Polyherbal formulation as suggested by lower MPO activity, significant ($p<0.001$) decrease in levels of protein, MDA, NO when compared to ova sensitized control. Number of intact mast cells was increased significantly ($p<0.001$) in Polyherbal formulation treated group when compared to ova sensitized control. Treatment with Polyherbal formulation at a dose of 100mg/kg, 200mg/kg body weight for 60 days after ova treatment significantly ($p<0.001$) ameliorated the indices of asthma induced by ovalbumin. The present research work suggests that the polyherbal formulation may have anti-asthmatic potential and may be used for the management of asthma clinically.

T414: ANTIUROLITHIATIC ACTIVITY OF POLYHERBAL FORMULATION INETHYLENE GLYCOLINDUCED LITHIATIC RATS

Moumita Mukherjee, Anbu Jayaraman, Jyothi Lakshmi, Vaishnavi Balraj, Soumal Chakraborty, Avinash Kumar

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This study was aimed to evaluate the effectiveness of ethanolic Polyherbal formulation (EPHF) containing plant parts of *Pergularia daemia, Trigonella foenum graecum*, *Cynodon dactylon, Nigella sativa* and *Terminalia chebula* on albino rats against the development of kidney stones. The activity of EPHF was studied in animals by using ethylene glycol (5% v/v, 2ml/rat/7days) urolithiatic model using Cystone as Standard drug. Experimental induction of hyperoxaluria results in the rapid formation of calcium oxalate crystals in the renal tubules of experimental animals. The investigation was done based on estimation of stone-forming constituents' oxalate, calcium, and phosphate, in kidney and urine The Parameters are used including urinary volume, urine pH, urine analysis, and serum analysis to assess the activity. The results indicated that the administration of EPHF to rats with ethylene glycol induced lithiasis significantly reduced and prevented the growth of urinary stones. In the present study, treatment results with EPHE (200mg/kg, p.o) significantly lowered the increased levels of oxalate, calcium, and phosphate in urine and also significantly reduced their retention in the kidney. The presented data indicate that administration of EPHE decrease urolithiasis and also prevented the formation of urinary stones in rats.

T415: EVALUATION OF ANTI-ULCER ACTIVITY OF POLYHERBAL PREPARATION IN RATS

Avinash Kumar, Anbu Jayaraman, Vaishnavi, Moumita Mukherjee, Soumali Chakraborty and Jyothi Lakshmi

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The present study was carried out to evaluate the anti-ulcer activity of 80% ethanol extract of polyherbal (EEPH) in rats. The effect of EEPH on gastric ulcer in rats in the pylorus ligation-induced model was studied using single dosing (100, 200mg/kg) and repeated dosing (100 mg/kg for 7 and 14 days) approaches. Ranitidine (50 mg/kg) was used as the standard drug. The outcome measures were volume and pH of gastric fluid, total acidity, ulcer score, the 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. EEPH significantly ($P<0.001$) reduced gastric ulcer index by 48.44% and 58.24%, respectively, in pylorus ligation-induced model at the 100 mg/kg dose, which is comparable to the standard drugs. Seven- and fourteen-days pre-treatment with EEPH 100 exhibited significant ($P<0.001$) ulcer inhibition by 48.44% and 58.24%. EEPH possesses both dose-dependent and time-dependent anti-ulcer effects. The oral median lethal dose (LD50) is estimated to be higher than 2000 mg/kg for the extract, and secondary metabolites such as flavonoids, tannins, and saponins were present. The findings of this study confirmed that EEPH has an anti-ulcer pharmacologic activity. Further investigations on the isolation of specific phytochemicals and elucidating mechanisms of action are needed.

T416: ANTICANCER ACTIVITY OF EXTRACT OF CITRUS FRUIT PEELS ON MICE

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One of the largest causes of mortality worldwide is cancer. Increasing interest and research on herbal medicine have revealed its importance in treating many diseases including cancer. In the present study anticancer activity of the ethanolic extract of citrus fruit peels (EECFP) was evaluated on DAL bearing mice. After inoculation of DAL cells into mice, treatment with EECFP (200 and 400 mg/kg) and standard drug 5-Fluorouracil (20 mg/kg) were continued for 9 days. Evaluation of the effect of drug response was done by the study of tumor growth response including increase in life span, study of hematological parameters, biochemical estimations, antioxidant assay of liver tissue and in vitro cytotoxicity. Experimental results revealed that EECFP possesses significant anticancer activity which may be due to its cytotoxicity and antioxidant properties. Further research is going on to find out the active principles of EECFP responsible for its anti-cancer activity.

T417: A STUDY ON AQUEOUS LEAF EXTRACT OF *BRASSICA OLARACEA* (ALEB) AGAINST EXPERIMENTALLY INDUCED ALZHEIMER'S DISEASE IN MICE

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In the present study the aqueous leaf extract of *Brassica olaracea* (ALEB) was evaluated for its effect against experimentally induced Alzheimer's disease in mice. The cognitive enhancing activity of ALEB on scopolamine induced memory impairment in mice was investigated by using behavioral parameters viz, Morris water maze, Passive shock avoidance paradigm and estimation of biochemical parameter was carried in terms of AChE activity. Two doses (500mg/kg) and (1000mg /kg b.w p.o) of ALEB were subjected for the study against experimentally induced Alzheimer's disease by scopolamine (0.4mg/kg, i.p) in young mice. Piracetam (400 mg/kg i.p) was served as standard in both the models. The long-term administration of both the lower (500mg/kg) and higher dose (1000mg/kg) of ALEB produced significant reduction of ELT and increase of TSTQ in MWM. And significance increase in SDL in PSAP model on both 19th and 27th day when compared with control and induced groups. ALEB at higher dose significantly reduce the activity of AchE in the brain indicates the improvement in learning and retention of memory in young mice. The present study concluded that ALEB was found to be effective against amnesia induced by scopolamine.

T418: EFFICACY OF POLYHERBAL FORMULATION IN EXPERIMENTALLY INDUCED ULCERATIVE COLITIS IN RATS

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Herbal formulation from an ancient authentic literature was evaluated for its effectiveness against ulcerative colitis. Ulcerative colitis is a type of inflammatory bowel disease with an unknown aetiology and a poorly understood pathogenesis. In this study the herbal formulation consisting viz., *Morinda citrifolia* L (Rubiaceae), *Artemisia annua* L (Asteraceae) *Glycyrrhiza glabra* L (Fabaceae) and *Ocimum basilicum* L (Lamiaceae) in variable amounts was evaluated on indomethacin-induced ulcerative colitis in rats. Mesalamine was used as standard drug in the study. Quantification of serum LDH, tissue MPO & GSH levels, and the histopathological features of inflammatory cells and recovered cells were used to establish the efficacy of the formulation. Formulation treatment showed appreciable increase in the GSH level. The tissue MPO activity and serum LDH levels were significantly decreased during the treatment. The ulcer scores of weight analysis were comparable with the scores of mesalamine treated group. Histopathological studies reveal decrease in oedema and reduced inflammation followed by the treatment. This analysis reveals that the aqueous extract of polyherbal formulation is effective as mesalamine in the treatment of ulcerative colitis. The results obtained established the efficacy of this polyherbal formulation against ulcerative colitis following subchronic administration.

T419: PHYTOCHEMICAL SCREENING OF *PHLEBODIUM DECUMANUM* AND *BOVIDIA OFFICINALIS* FOR ANTI-PSORIASIS EFFECT

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Psoriasis is a chronic inflammatory skin disorder that affects about 2–3 percent of the world's population and among them plaque psoriasis is a typical current form of psoriasis. The present study was aimed for the phytochemical screening of *Phlebodium decumanum* and *Bovidia officinalis* and their synergistic efficacy for the treatment of psoriasis. Two different dose levels (200 mg /kg b.w and 400 mg/kg. b.w.) were used for both the methanol extracts (based on acute toxicity study) and the result was compared with standard Rentino A (0.05%). Psoriasis severity index (PSI) according to the phenotypic (redness, erythema, and scales) changes and histological features (epidermal thickness) were evaluated for 28 days. Results revealed progressive reduction ($P<0.05$) in the severity of psoriatic lesions (redness, erythema, and scales from histopathology study) from the 7th day to the 28th days and decreased epidermal thickness in animals treated with combined extracts at a dose of 400 mg/kg b.w. Finally, the result concluded that the significant anti psoriasis activity of combined methanol extract of *Phlebodium decumanum* and *Bovidia officinalis*.

T420: TARGETED ISOLATION OF BIOACTIVE MOIETIES OF ANTIOXIDANT ACTIVITY OF *JUSTICIA BEDDOMEI*

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The aim of the present study was focus to phytochemical evaluation by Supercritical Fluid Extraction's and antioxidant activity. *Justicia beddomei* leaves are collected and authenticated by the taxonomist. The collected plant materials are subjected to Supercritical Fluids: A fluid at supercritical condition, also referred to as a dense gas, is a fluid above its critical temperature (TC) and critical pressure (PC) to a certain extent: to be supercritical, the reduced temperature Tr (i.e., T/TC) must not exceed 1.2 or 1.3, whereas the reduced pressure Pr (i.e. P/PC) may be as high as allowed by technological limits. Obtained extract was subjected to column chromatography and isolated bio compounds are screened for antioxidant activity. Antioxidant activities of *Justicia beddomei* by DPPH and SOD method. In the DPPH radical scavenging method; the assay was carried out in 96 well microtiter plate. Estimation of super oxide dismutase (SOD) by nitro blue tetrazoline (NBT) method; SOD in the serum was estimated using methods reported in the literature.3. In vitro antioxidant activity; Healthy Swiss albino mice were divided into 5groups (n=6). The of isolated fractions Justicia beddomei contain mainly flavonoids. The Rf factor ~ 4.1 closely resembles specifically they may be flavone or flavanone. The extract and isolated fractions showed excellent antioxidant activities at the concentration of 200 µ g/ml. These finding indicates that the extracts and isolated fractions has significant antioxidant activity. On these pre-clinical evidences, the related products may provide a novel approach to the

chemoprevention and treatment of cancer.

T421: ANTI-OBESITY ACTIVITY OF ETHANOLIC EXTRACT OF HERBAL DRUG ON HIGH FAT DIET-INDUCED OBESE RATS

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Obesity is a medical condition in which excess body fat gets accumulated such that it produces an adverse effect on health. It is considered as a very common global health problem which is linked to various cardiovascular and cerebrovascular diseases. Obesity is associated with morbidity and mortality. Obesity is usually determined by body mass index which is closely related to both body fat percentage and total body fat composition. In children healthy weight varies with age and sex. Obesity in children and adolescents is defined not by an absolute number but in relation to normal group such that obesity is a BMI greater than 95%. The synthetic drug orlistat for treating obesity has already been introduced into the market but it has various side effects so to overcome these side effects the use of herbal medicines became the subject of interest for the management of obesity due to its natural origin, cost effectiveness and minimal side effects. The present study was designed to study the anti-obesity effect of ethanolic extract of *Terminalia paniculata* bark on high fat diet induced obese rats.

T501: A SURVEY ON USE OF GENERIC AND BRANDED DRUGS AMONG SELECTED AREAS OF KALABURAGI CITY

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A generic drug is a chemically equivalent, lower-cost version of a branded name drugs costing 30-80% less. Generic drugs are the ways to reduce the pharmaco-economic burden of patient without compromising the quality of drugs. A survey was carried out for a period of six months to evaluate the knowledge and use of generic medicines among different populations (pharmacists, non-science and science background students). The aim of the study was to carryout survey on knowledge and use of Generic and branded medicines among the selected areas of Kalaburgi city. We have enrolled 772 population, out of 255 pharmacists 34 % said that they keep generic medicines and 52.94% feel that branded drugs have simpler regimen than generic drugs. However, 34.90% only promoting the sale of generic drugs. In the non- science background students, out of 257 students 70.8%students have idea about generic medicines but only 51.7% feel that generic drugs are safe. However, only 59 % students believe that medicines prescribed by doctor are very expensive. In the science background students, out of 260students, 72.3% students are conscious about the generic medicines and its effectiveness and 96.9% feel that there is a price difference between generic and branded medicines. Hence, Pharmacists play a major role in promoting generic medicines. Hence more awareness and knowledge are required regarding government laws and initiatives for the population to promote sale of generic medicines.

T502: A STUDY TO ASSESS THE MANAGEMENT OF HYPERTENSION FOR PRE AND POST-OPERATIVE CARE HYPERTENSIVE CANCER PATIENTS

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The aim of this study was to determine the prescribing pattern of antihypertensive medication in cancer patients undergoing surgery, to assess the control of hypertension postoperatively and to assess the cardiovascular complications post operatively if any in patients who had been admitted in a tertiary care hospital, South Bangalore, India. A prospective observational study was carried out for 6 months in 152 patients of above 40yrs of age who were on antihypertensive medication and undergoing cancer surgery. Patients pre and post-operative blood pressure readings were recorded (3 readings at 6hr time interval) and patients pre and post-operative antihypertensive medication were recorded. The data was analyzed. Calcium channel blockers (31.74%) and angiotensin receptor blockers (49.20%) were mostly prescribed monotherapy agents. ARB+diuretics (42.16%) were mostly prescribed combination therapy agents followed by ARB+CCB (18.07%), CCB+beta blocker (14.45%),CCB+alpha blocker (10.84%), ARB+beta blocker (9.63%). Amlodipine+atenolol was found to be significant in controlling of B.P in hypertensive cancer patients with Prob>F= 0.013, and other drugs were found to be not

significant. Management of hypertension preoperatively is important to prevent peri and postoperative cardiovascular complications. It was found that patient taking combination antihypertensive agents like calcium channel blocker and alpha blocker or angiotensin receptor blocker and diuretics were more effective in controlling their hypertension. Calcium channel blockers and angiotensin receptor blockers were commonly prescribed monotherapy agents. Amlodipine + atenolol was found to be most prescribed agent and effective in blood pressure control in hypertensive cancer patients.

T503: ANTIPYRETIC EFFECT OF ORAL VERSUS RECTAL PARACETAMOL IN FEBRILE CHILDREN

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To compare the antipyretic effect and safety profile of oral and rectal Paracetamol in febrile children. The prospective observational study was conducted in 76 children in tertiary care teaching hospital in Bangalore. Subjects were divided in two groups, Group O (oral) and R (Rectal) based on the route of administration of Paracetamol. Group O was given oral Paracetamol at a dose of 15 mg/kg and group R was given rectal Paracetamol at a dose of 15 mg/kg. Required data was collected in specially modified case report form. Baseline axillary temperature and temperature after 1, 2 and 3 hours of drug administration was recorded using digital thermometer. The Adverse Drug Reactions (ADRs) associated with oral and rectal Paracetamol were monitored. The suspected ADRs were assessed for causality using WHO scale and severity using Hartwig's and Siegel scale during study. The collected data was compared using 2 sample t-Test and followed by one-way ANOVA and appropriate post-hoc test. It was observed that the antipyretic effectiveness of equal doses of oral and rectal Paracetamol (15mg/kg) is non-significant in terms of mean change in temperature in comparison to the baseline values in between patients of both the groups after 1 hour ($P = 0.364$), 2 hours ($P = 0.900$) and 3 hours ($P = 0.757$) which is more than 0.05. The difference in the antipyretic effect of oral and rectal Paracetamol is still unclear. The results of the study concludes that both the oral and rectal Paracetamol have similar effectiveness in reducing temperature in febrile children. Rectal route can be preferred in case of unconscious patient, patient with complaints of vomiting and any condition which precludes the administration of oral Paracetamol.

T504: ASSESSMENT OF KNOWLEDGE, ATTITUDE AND PRACTICE OF SELF-MEDICATION AMONG COLLEGE STUDENTS IN BANGALORE (EAST).

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To assess the incidence of bacteremia in febrile neutropenic (FN) patients and to assess the pattern of bacteremia in FN cancer patients. To assess the prescription pattern of empirical antibiotic therapy in FN cancer patients, specific antibiotic therapy in FN cancer patients with bacteremia and to assess the sensitivity and resistance pattern of antibiotics in cancer patients with FN and bacteremia. To correlate between the febrile neutropenia and the risk factors. A prospective Observational study was conducted in Sri Shankara Cancer Hospital and Research center, Bengaluru-04, India. Study was conducted for 6 months in In-patients who were diagnosed to have FN. The incidence and pattern of bacteremia in the FN cancer patients were assessed. The prescription pattern of empirical and specific antibiotics therapy was assessed. The susceptibility pattern of antibiotics to isolated pathogens in FN cancer patients was studied by using descriptive analysis and relation of FN development with other factors was analysed by logistic regression. A total of 70 patients were observed in which 51% were males and 48% were females and the mean age of the study population was 50.54yrs. Out of 70 patients, 8 patients had positive blood cultures and out of which, Gram-positive Micro-organisms were found in 4(5.71%) and Gram-negative Micro-organisms in 2(2.85%) and polymicrobial cultures in 2(1.14%) patients. Out of 91 antibiotic prescriptions screened, it was found that 89.01% of antibiotics were prescribed as empirical therapy and 10.98% antibiotics were prescribed for specific therapy (Micro-organism culture positive patients) in FN patients. Meropenem 45.71% and Cefoperazone 44.28% were prescribed most commonly in this study group as empirical therapy. Cefoperazone 4.28% was found to be utilized more frequently than other antibiotics for culture proven cases. There was no correlation found between febrile neutropenia and other risk factors such as age, gender, eGFR, catheter usage, use of immuno-suppressants, anthracycline use in this study population. FN is the complication of cytotoxic chemotherapy. Prompt administration of empiric broad-spectrum antibiotic is lifesaving. Bacteremia in neutropenic patients following chemotherapy for cancer is associated with high mortality, unless appropriate empiric antibiotic therapy is rapidly administered. Although many antibiotic regimens have been evaluated as monotherapy or in combination for FN, superiority of many particular regimen has not been established. Antibiotics prescription depends greatly on the prevalence of pathogens causing infection and their antibiotic

susceptibility, which may change overtime.

T505: UTILIZATION STUDY OF ANTIBIOTICS IN FEBRILE NEUTROPENIC CANCER PATIENTS WITH BACTEREMIA

Chandanashree KS, Dr. Janet Jacob

To assess the incidence of bacteremia in febrile neutropenic (FN) patients and to assess the pattern of bacteremia in FN cancer patients. To assess the prescription pattern of empirical antibiotic therapy in FN cancer patients, specific antibiotic therapy in FN cancer patients with bacteremia and to assess the sensitivity and resistance pattern of antibiotics in cancer patients with FN and bacteremia. To correlate between the febrile neutropenia and the risk factors. A prospective Observational study was conducted in Sri Shankara Cancer Hospital and Research center, Bengaluru-04, India. Study was conducted for 6 months in In-patients who were diagnosed to have FN. The incidence and pattern of bacteremia in the FN cancer patients were assessed. The prescription pattern of empirical and specific antibiotics therapy was assessed. The susceptibility pattern of antibiotics to isolated pathogens in FN cancer patients was studied by using descriptive analysis and relation of FN development with other factors was analysed by logistic regression. A total of 70 patients were observed in which 51% were males and 48% were females and the mean age of the study population was 50.54yrs. Out of 70 patients, 8 patients had positive blood cultures and out of which, Gram-positive Micro-organisms were found in 4(5.71%) and Gram-negative Micro-organisms in 2(2.85%) and polymicrobial cultures in 2(1.14%) patients. Out of 91 antibiotic prescriptions screened, it was found that 89.01% of antibiotics were prescribed as empirical therapy and 10.98% antibiotics were prescribed for specific therapy (Micro-organism culture positive patients) in FN patients. Meropenem 45.71% and Cefoperazone 44.28% were prescribed most commonly in this study group as empirical therapy. Cefoperazone 4.28% was found to be utilized more frequently than other antibiotics for culture proven cases. There was no correlation found between febrile neutropenia and other risk factors such as age, gender, eGFR, catheter usage, use of immuno-suppressants, and anthracycline use in this study population. FN is the complication of cytotoxic chemotherapy. Prompt administration of empiric broad-spectrum antibiotic is lifesaving. Bacteremia in neutropenic patients following chemotherapy for cancer is associated with high mortality, unless appropriate empiric antibiotic therapy is rapidly administered. Although many antibiotic regimens have been evaluated as monotherapy or in combination for FN, superiority of many particular regimen has not been established. Antibiotics prescription depends greatly on the prevalence of pathogens causing infection and their antibiotic susceptibility, which may change overtime.

T506: DRUG UTILIZATION EVALUATION OF OLANZAPINE AND ASSESSMENT OF ADVERSE DRUG REACTIONS ASSOCIATED IN PSYCHOTIC PATIENTS OF TERTIARY CARE HOSPITAL

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To assess the drug utilization pattern of pattern of olanzapine in psychotic patients in tertiary care hospital. To monitor and assess the adverse drug reactions associated with olanzapine. 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 prescribing pattern of olanzapine therapy were assessed among the included patients and those patients were monitored for any adverse drug reactions associated with olanzapine using case record forms. Results: A total of 68 patients were enrolled into the study of which 51%were females and 49% were males. Majority of the patients belong to the age group of 28-37years 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. The most commonly seen interactions are lorazepam-olanzapine. These drug interactions increase the risk of side effects associated with the drugs. Major adverse effects found are weight gain in 24 patients (35%) sedation in 20 patients (29%) constipation in 8 patients (11%) was found. 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. Major drug interaction associated with olanzapine was lorazepam characterised with excessive sedation and hypotension. Weight Gain is major adverse reaction associated with olanzapine followed by sedation and constipation

T507: ASSESSMENT OF KNOWLEDGE AND INTEREST OF COMMUNITY PHARMACISTS FOR TB SUSPECT REFERRAL PROGRAMME AND DOTS PROVISIONS IN BENGALURU

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To assess the knowledge and interest of the community pharmacists about their role in TB suspect referral Programme and DOTS provisions in Bengaluru. A descriptive observational study was carried out in 180 pharmacies in different areas of Bangalore out of which 150 pharmacists had participated in the study. The retail pharmacy details were collected and they were made to fill KAP questionnaire. Each question under the knowledge and attitude was scored to assess their KAP level regarding Tuberculosis and their willingness to participate in the TB suspect referral programme. The interested pharmacist details were forwarded to RNTCP wing. The unwilling pharmacist were further educated regarding the Programme. A total of 150 pharmacist participated in the study from different areas of Bangalore. Assessment of extent of Knowledge, Attitude and Practice about Tuberculosis and TB suspect referral programme showed that a majority of them had a poor Knowledge score. A very few pharmacists had accepted for storing RNTCP drugs. The remaining pharmacist had given the few reasons like lack of time, lack of storage space, lack og qualified pharmacist. The Pharmacist Knowledge, Attitude, Practice about Tuberculosis and TB suspect referral programme are the important determinants to assess the pharmacist. A combined effect from members of District Tuberculosis Centre can make the attainment of the coverage of the areas in Bangalore.

T508: ASSESSMENT OF SELF-MEDICATION PATTERN IN ELDERLY

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L to analyze the prevalence and pattern of self-medication and the various socio-demographic factors that influence self-medication in elderly patients and also assess the impact of education intervention on self-medication knowledge, attitude in elderly patients. A community based cross sectional study was conducted on Bangalore area such as Bellandur, Carmelaram, Kaikondrahalli and Naganahalli over the period of 6months in 320 subjects. The demographic, clinical and social data were collected into specially designed case report form. The assessment of self-medication was carried out using modified structured questionnaire11 on the day zero and 30. The patient education intervention was carried out on the day zero. The patient education intervention about self-medication was carried out verbally as well as by providing patient education information leaflets. Whenever they practiced self-medication, they were asked to mark in the calendar and the data was analyzed. The data on assessment of self-medication in elderly were collected from 320 study participants, a significant correlation was observed for elderly aged above 65 years aged above. Moderate correlation for economic status, education and occupation. Significant correlation was observed with medical history of the patient. Fever 66.25%, headache 54.68%, cough and cold 38.43%, were the most common illness where self-medication being used. Anti-pyretic 58.5%, anti- histamine 34.68%, anti-diabetic 19.68% were most commonly used self-medicating drugs. Pharmacist 79.30%, self-decision 30.93% and care takers 25% were the most common source for information about self-medication. Time saving 68.75%, no need to visit doctor for minor illness61.25 %, previous use of medication 55.93% and economic 53.43% were the major reason for self-medication. The results indicate that self-medication is widespread among elderly and 100% of elderly from the study population practiced self-medication without consulting the physician. The various factors like reason, indication and source associated with self-medication were analyzed during the study. A significant association between knowledge and attitude among the study population was drawn from the pre and post studies. The intervention will require better patient education of the public and health professionals to avoid the irrational use of drugs.

T509: A COMPARATIVE STUDY OF INSULIN PEN DEVICES AND DISPOSABLE PLASTIC SYRINGES – SIMPLICITY, CONVENIENCE, SAFETY AND COST DIFFERENCES

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The aim of the study was to evaluate the simplicity, safety, convenience and cost effectiveness of the administration of insulin using the pen device versus the conventional vial/syringe in patients with diabetes. To assess the simplicity, convenience, safety of the administration of Insulin using the pen versus the conventional vial/syringe device. To assess the difference in the total healthcare cost between insulin pen and insulin syringe. This prospective observational study was carried out on 100 Type 1 and Type 11 Diabetic patients who attended both inpatient and outpatient departments from MVJ Medical College Hoskote. An investigator interviewed patients with diabetics using an insulin pen or conventional vial/syringe. A total 100 questionnaire were filled over a period of 6 month. Answers were entered into the statistical package for social science (SPSS) software and Excel spreadsheet. Wilcoxon signed rank test were used in order to analyse the results. The mean simplicity, convenience and safety scores among syringe users was 10, 8 and 9 respectively, compared to pen users was 6, 3 and 6 respectively. The difference in these means of scores were statistically significant ($P<0.0001$). While comparing the mean of cost scores among syringe users was 2 and pen users was 3 ($P<0.0001$). All patients felt the use of pen devices was costlier compared to vial/syringe, with pen users spending on their insulin therapy on an average of Rs 1610 per month while Syringe users spent Rs 560 per month. In this study, more patients have reported the use of insulin pen devices compared to conventional vial/syringe, to be simpler, safer and convenient. Better glycaemic control was associated with pen users' group also less painful, less hypoglycaemic episodes and no bruises at site of administration. However, the monthly expenditure on the treatment in pen users' group was 3 times higher than conventional syringe/vial users.

T510: A STUDY ON KNOWLEDGE, ATTITUDE AND DIETARY PRACTICES AMONG ADOLESCENT SCHOOL GIRLS ON IRON DEFICIENCY ANEMIA FROM RURAL AREAS

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The knowledge, attitude and dietary practices among adolescent school girls on iron deficiency anaemia from rural areas was assessed. Education on the dietary requirements for preventing the iron deficiency anemia in adolescent school girls was provided and the impact of dietary education in improving knowledge, attitude and practice towards iron deficiency anaemia among adolescent school girls was assessed. Methodology: A Cluster randomised control trial was conducted among 272 adolescent school girls from rural schools of Bangalore. The study population was divided into control and intervention group. Pharmacist assisted interventional education was provided verbally to the Intervention group and Patient Information Leaflets (PIL) were provided to the Control group. The changes in KAP towards iron deficiency anaemia were being assessed by comparing the Pre-test and Post- Test responses among the Control as well as interventional group using statistical analysis. Results: After education the mean scores of knowledges, attitude and practice had a significant increase in the interventional group compared to control group. There was a statistically significant improvement in knowledge ($p< 0.05$), attitude ($p<0.05$), and practice ($p< 0.05$) scores and no significant difference in these scores in the control group. Conclusion: Educational intervention was provided to the intervention group. It was observed that there was an improvement in the knowledge, attitude and practice towards IDA in intervention group compared to the control group. Nutrition education programcan help improve young person's eating habits and could significantly improve knowledge, attitude and practise among children.

T511: STUDY ON PRESCRIBING PATTERN OF ANTIBIOTICS IN SURGICAL PROPHYLAXIS

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Surgical Site Infection (SSI) is a frequent cause of morbidity and mortality and adds significantly to the cost of care.

Surgical antimicrobial prophylaxis refers to a brief course of antibiotics given just before surgery. Inappropriate antimicrobial use increases the incidence of drug resistance, toxicity, super-infections and healthcare costs. To study the usage pattern of prophylactic antimicrobials in surgical patients and to assess the appropriateness concerning the selection, dose, timing and re-dosing of prophylactic antibiotics. A prospective cross-sectional study was conducted over a 6-month period in a tertiary care teaching hospital. 110 patients have been enrolled in our research and information regarding the demographic data, type of surgery and antibiotic therapy (selection of antibiotic, dose, timing, re-dosing) were documented. Of the total 110 patients who received antimicrobial prophylaxis, third-generation cephalosporins were the commonly used pre-operative antibiotic through the intravenous route. Ceftriaxone (89.8%) was the commonly prescribed antibiotic in general surgery and orthopedics whereas cefotaxime (84.3%) was the drug of choice in the OBG department. The antimicrobials were administered in the appropriate doses one hour prior to surgery. No intra-operative re-dosing was given. From the study, the selection of prophylactic antibiotic shows considerable variations. The main concern is the excessive use of third-generation cephalosporins in a majority of the surgical cases which need to be addressed. Thus, practitioners must prescribe an antibiotic based on their hospital antibiotic policy or standard guidelines.

T512: IMPACT OF PATIENT COUNSELLING ON IMPROVING KNOWLEDGE ATTITUDE AND PRACTICE (KAP) IN ASTHMA PATIENTS

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According to the World Health Organization, asthma is the worldwide problem with an estimated 300 million affected individuals. In India, an estimated 57, 000 deaths were attributed to asthma in 2004 and it was seen as one of the leading causes of morbidity and mortality in rural India. Workplace conditions, such as exposure to fumes, gases or dust, are responsible for 11% of asthma cases worldwide. About 70% of asthmatics also have allergies. Occupational asthma contributes significantly to the global burden of asthma, since the condition accounts for approximately 15% of asthma amongst adults. Patient education is an important aspect in the Indian setup since most of the patients are illiterate and having low socioeconomic status. With this background, it is aimed to educate the patients about the disease, risk factors, medication management and preventive measures thereby improving their Knowledge, Attitude, Practice (KAP) towards Asthma. To assess the impact of pharmacist assisted patient counselling in improving Knowledge, Attitude, Practice of Asthma Patients. To assess knowledge, attitude, practice of asthma patients, to provide educational/patient counselling interventions to study population to assess the impact of pharmacist assisted patient counselling to improve knowledge, attitude and practice of asthma patients. A total of 196 patients were included in the study. After providing patient counselling, it was observed that there was a significant improvement in certain domains of KAP from the baseline scores. Patients were educated and counselled about the causative factors and awareness provided in concern with the treatment aids for Asthma. After counselling, there was a statistically significant improvement in the KAP scores which showed a p value of <0.0001*. Pharmacist assisted patient counselling had a significant impact in improving KAP in Asthma 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.

T513: A STUDY ON EPIDEMIOLOGY AND RISK FACTORS ASSOCIATED WITH HYPERTENSION IN A TERTIARY CARE HOSPITAL

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Hypertension is identified as one of the most significant risk factors for cardiovascular disease. Increasing awareness about the disease, timely diagnosis and appropriate management strategy are considered as critical health initiatives to reduce cardiovascular morbidity and mortality. Epidemiological studies are important as they provide the scientific foundation for such an approach by identifying the distribution and determinants of high blood pressure in general population. The objectives of this study were to identify epidemiological aspects of hypertension and to analyze the risk factors associated with hypertension. A cross sectional, observational and analytical study was conducted on patients admitted to in-patient departments of Sagar hospitals, Bengaluru for a period of 6 months. The demographic details, medical and medication history, diagnosis, co-morbidities, laboratory data were collected. Out of 160 patients included in this study, 128 (80%) were

suffering from hypertension. There was a positive association of hypertension with smoking, alcohol intake, diabetes, socioeconomic status, dietary habits, family size, salt intake and physical activity. This study identified a significant (≤ 0.05) association between hypertension and risk factors such as alcohol intake, smoking and diabetes. Our study identified a high prevalence of hypertension in the study population. Targeted interventions are required to modify and reduce the impact of risk factors of hypertension on general population.

T514: MILD LEFT PARA-CENTRAL BULGE OF INTERVERTEBRAL DISC-C4/5 AND C5/6 WITH MILD NARROWING OF LEFT INTERVERTEBRAL FORAMEN INDUCING SEVERE NECK PAIN AND IPSILATERAL SYMPTOMS: A CASE REPORT

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Cervical disc bulge or other cervical spine diseases often results into neck and arm pain in patients formulating an etiology of direct impingement of nerve roots and associated inflammatory process. The clinical presentation also corresponds with the ipsilateral symptoms associated with the cervical disorder as depicted in the patient. A 33 years old Indian male is diagnosed with Para-central bulge at the level of C4/5 and C5/C6-Intervertebral disc presented to the physical therapy with neck pain radiating into left sided upper and lower extremity pain. Results from magnetic resonance image (MRI) scan show the alignment and the morphology of the vertebrae to be normal. Also, the CSF displays normal intensity in all sequences. A magnetic resonance imaging revealed mild Para central bulge of C4/5 and C5/6-Intervertebral disc with mild narrowing of the left intervertebral foramen. The patient reported to physical therapy for cervical pain and radiculopathy. After evaluation he was asked to continue with regular home exercise programme like cervical lateral flexion stretch, unilateral wall stretch which resulted to reduce the cervical pain and shows improvement in its subsequent symptoms.

T515: EFFECT OF ANTIBIOTIC STEWARDSHIP IN PERI-OPERATIVE SETTING IN A SECONDARY CARE HOSPITAL

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Antimicrobial resistance as a result of over use and misuse is of rising concern globally. Common practices observed in prophylactic antibiotic use in various clinical settings are observed to be increasing the risk of resistance, super infections with resistant pathogens, toxicity and unnecessary financial burden. Antimicrobial stewardship program is an effective strategy to constrain the excessive use of antibiotics if executed properly. The study examined the prescribing pattern of prophylactic antibiotic in surgery (Appendectomy, Hernioplasty, Hemorrhoidectomy, and Hysterectomy) and assessed the effect of AMS by analysing the data obtained before and after intervention to the clinician. The interventional study was undertaken in the in-patient department of General surgery and Gynaecology in a teaching hospital for a period of 6 months. Prophylactic antibiotic use was assessed for selection of antibiotics, time of administration and duration with the help of the national antimicrobial treatment guidelines and hospital antibiotic policy. The results obtained after the AMS meet was compared with the pre-intervention data to find out the effect of antimicrobial stewardship. A total of 154 surgical cases were collected during pre-intervention and post-intervention period. Majority of patients underwent hernioplasty accounting for 35.06% and the most prescribed antibiotic for prophylaxis was Ceftriaxone (96.10%). The intervention reduced the total number of antibiotics used prophylactically($X2 = -3.921$, p-value <0.001) and duration of antibiotics use ($Z= -4.442$, p-value <0.001) which was statistically highly significant. There was improvement in the timing of antibiotic administration from 80.51% to 100% between the two periods. Although no surgical site infections were reported during both periods, the results indicated that the surgical antibiotic prophylaxis compliance can be improved significantly through antimicrobial stewardship program. Thus, the study proved that AMS programme is an effective solution for reducing irrational antibiotic usage.

T516: CASE REPORT-STEVEN JOHNSON SYNDROME SECONDARY TO DOTS THERAPY

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A 50 year male patient was suffering from left temporal lobe tuberculoma since three months and was on medication. He was given first line ATT and phenytoin a seizure medication for his condition.one month later he had complaints of hyperpigmented scaling of skin along with erosion, severe itching all over the hand, which was progressive in nature and which was started after initiation of ATT. His absolute eosinophil count was 1357 cells/cumm3. Identification of the offending drug was difficult as the patient was talking more than one drug. Our Patient had undergone rechallenge test which includes the addition of suspected drug and increasing the dose until an adverse reaction is seen. After rechallenge test pyrazinamide, isoniazid and phenytoin were found to cause adverse drug reaction. Hence was diagnosed with steven Johnson syndrome secondary to DOTS therapy. So, the offending drug was removed from his drug regimen and was modified. Phenytoin was replaced with leviteracetam. levofloxacin (500mg)was added to the treatment chart and dose was increased for ethambutol (800mg), rifampin (500mg), streptomycin (750mg IM). Cetrizine (10mg) and topical corticosteroid clobetasol propionate was given to reduce itching and also alprazolam (0.25mg) following which the lesions subsided. The treatment was continued post discharge. He was further treated by providing supportive care and getting feedback on the adverse reactions.

T517: EFFECT OF ANTIBIOTIC STEWARDSHIP IN PERI-OPERATIVE SETTING IN A SECONDARY CARE HOSPITAL

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To study the prescription pattern of psychotropic drugs in different psychiatric disorder. The prospective observational study was conducted in 100 psychiatric in-patients at a tertiary care hospital in Bangalore. Study was conducted on gaining approval from the institutional human ethical committee. All patients who meet the study criteria were enrolled in to the study after taking the informed consent from the patients or their legal representatives. The demographic, clinical and medications data were documented into a specially designed case report form. All the data was analysed using descriptive statistics. In 100 study subjects 194 different psychotropic drugs were prescribed. Among 194 psychotropic drugs 74 were sedatives and hypnotics, 70 were antipsychotics, 36 were antidepressants and 14 were mood stabilizer. The burden of Psychiatric illness leads to public health problem. Psychotropic substances are commonly used in patients with various prescription habits of prescriber.

The study found that schizophrenia was the most common illness in psychiatric patients. Male patients were more prone to psychiatric disorders than female. Most of the study populations were non-alcoholic and non-smokers. Sedatives and hypnotics of benzodiazepine class were found to be the most commonly used drugs followed by antipsychotics, antidepressants and mood stabilizers in the studied population.

T518: INDIVIDUALIZING ANTIPLATELET REGIMENS – CLOPIDOGREL PHARMACOGENETICS READY FOR PRIME-TIME?

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In patients with coronary artery disease undergoing percutaneous coronary intervention, dual antiplatelet therapy consisting of aspirin and a P2Y12 inhibitor (eg:- clopidogrel, prasugrel, ticagrelor) is necessary to curb recurrent thrombotic events like stent thrombosis. Despite proven benefits of dual antiplatelet therapy, adverse ischemic events including stent thrombosis do occur and continue to daunt clinicians. Clopidogrel is a thienopyridene class oral P2Y12 inhibitor antiplatelet drug. It is a prodrug which gets transformed into its active metabolite by hepatic cytochrome p450 enzymes. It has been found that antiplatelet response to clopidogrel shows marked individual variation in the level of platelet inhibition achieved. Part of this variation can be explained by genetic polymorphisms such as CYP2C19*2 and CYP2C19*3 loss of function alleles. In patients without these loss of function alleles, clopidogrel has shown synonymous efficacy to that of ticagrelor and prasugrel which are currently more favored antiplatelet agents but carry a higher risk of bleeding. Determining an individual's

responsiveness to clopidogrel is now possible by performing CYP2C19 genotyping. Emerging evidence suggests a possible role of genotype guided strategy in patients undergoing coronary stenting with a view on optimizing response to P2Y12 inhibitors during and after the procedure. Hence, we aim to emphasize the need for tailoring antiplatelet regimens in order to achieve better clinical outcomes with fewer adverse effects

T519: IMPACT OF PATIENT COUNSELING IN KNOWLEDGE, ATTITUDE AND PRACTICE AMONG ASTHMATIC PATIENTS

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Respiratory diseases are common and significant cause of illness and death around the world. Approximately one in seven individuals are affected by some chronic lung disease, most commonly Asthma and COPD. Asthma is a chronic disease characterized by recurrent attacks of breathlessness and wheezing. The "Global Asthma 2018" report suggests that asthma kills around 1000 people every day and affects 339 million people. In order to facilitate effective management patient knowledge, attitude, and practice (KAP) must be evaluated. To assess KAP in asthma patients using pre and post counseling. A prospective interventional study was conducted on 75 patients for duration of 6 months in 700 bedded tertiary care hospital, department of pulmonology. Patients diagnosed with asthma were enrolled for the study. Patients' demographic details were collected including their past medical and medication history. Evaluation was done using KAP questionnaire. All details were collected on a specially designed data entry form. Results showed that knowledge, attitude, and practice of patients with asthma improved after [M1] post counseling with a significant p value of (0.000). The study also shows the significance of total improvement in post counseling with a value of (58%) than pre counseling total (42%). The result of the present study revealed that (73.33%) of asthmatic patients showed improvement in knowledge, attitude and practice after providing pre and post counseling. Our study was carried out to assess the impact of knowledge, attitude, and practice for improving the quality of life of patients with asthmatic condition. The study results prove that the quality of life was improved drastically after post counseling.

T520: ASSESSMENT OF SLC22A1 (1022C>T) GENOTYPE FREQUENCIES IN SOUTH INDIAN POPULATIONS AND STRUCTURAL PHARMACOGENETICS OF NON-SYNONYMOUS POLYMORPHISM IN HUMAN ORGANIC CATIONIC TRANSPORTER – 1

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Organic cation transporters (OCTs) belong to a superfamily of influx transporters encoded by the solute lipid carrier (SLC) genes. Human OCT1 exhibits broad tissue distribution in the body and is predominantly expressed in the hepatocytes and the renal tubules. hOCT1 plays a significant role in the intestinal uptake of several xenobiotics including therapeutic agents. Since the gene coding for hOCT1 is highly polymorphic and majority of the reported non-synonymous polymorphisms have been associated with functional changes of hOCT1 thereby causing significant alterations in substrate pharmacokinetics. Thus, this study is done to assess the effect 1022C>T non- synonymous polymorphism in hOCT1. Methodology: High resolution crystal structure of Human Organic Cationic Transporter 1 (hOATP1) was modelled using I-TASSER. The mutant variant was modelled using Rotamer Explorer Tool (Molecular Operating Environment, CCG LLC) and the energy was minimized using YASARA Server. The active site of the target protein was predicted using Prank Web. The three-dimensional structure of the ligand molecule was retrieved using Zinc small molecule database. Docking experiments were carried out using Auto dock Suit 4.2 and the complexes were visualised using Pymol (Schrodinger LLC). Results and Discussion: It was observed that the binding energies and inhibitory constants of the docked OCT1 substrates significantly differ between wild type (Pro341) and mutant (Leu341) variant with binding energies -3.8 ± 1.2 and -2.4 ± 4.8 respectively (P Value 0.037, 1.37 [0.46-3.91]). The number of hydrogen bonds were also found to be less in the mutant variant suggesting a possible significant alteration in the protein conformation and the ligand transporting ability. Conclusion: The influx transport of hOCT1 substrates via the Human OCT1 has decreased due to the non-synonymous polymorphism (Pro41Leu). Therefore, patients receiving drugs with Pro341Leu variation are more prone to develop therapeutic failure at normal doses.

T521: STUDY OF POSSIBLE DRUG-DRUG INTERACTIONS IN MEDICINE DEPARTMENT OF A TERTIARY CARE HOSPITAL

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An interaction is said to occur when the effects of one drug are altered by the co-administration of another drug, herbal medicine, food, drink or other environmental chemical agents. This study was designed to analyse the possible drug-drug interactions in medicine department of a tertiary care hospital. A prospective study was conducted on inpatients admitted to the medicine department of a tertiary care hospital for a period of 6 months (May 2018-October 2018). The demographics of the patient, diagnosis and drugs prescribed were noted from patient case sheet and presence of possible drug-drug interactions were detected using databases – drugs.com, Medscape.com, Micromedex. Out of 60 cases collected, 36(60%) and 24(40%) were men and women respectively, where interactions were seen in 47% of male patients and 50% of female patients. A total of 682 drugs were prescribed at an average of 11 drugs per prescription. A total of 665 possible interactions were reported. Major interactions were 36 (5%) and moderate interactions were 550 (83%). Aspirin had the highest number of interactions with involvement in 65 types of moderate and 6 types major interactions. As per the study, among the top 5 drug combinations involved in drug-drug interactions, Aspirin+ Insulin combination was found to have the highest prevalence (36%). The study observed increased number of possible interactions with increase in number of drugs/prescription. Conclusion: This study reported a total of 665 interactions. Aspirin was involved in most of the drug interactions. Aspirin and Enoxaparin was the most frequent interacting drugs.

T522: IMPACT OF PATIENT COUNSELLING IN THE IMPROVEMENT OF QUALITY OF LIFE OF HAEMODIALYSIS PATIENTS

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Hemodialysis is the most frequent treatment method for CKD. There are number of restrictions and modifications accompany this treatment, which have a detrimental impact on the quality of patient's life and affect individuals' physical and psychological well-being. To assess the quality of life of hemodialysis patients using SF36V2 questionnaire. To reassess the QOL in patients after patient education and see if there is any improvement. To study the statistical significance of observed results. This is a prospective observational study of 50 chronic kidney disease (CKD) patients by using SF36V2 questionnaires. Patients were counselled and educated. Assessment of impact of patient counselling was carried out after 3 months interval using same questionnaire. ESRD is a chronic disease-causing high level of disability in different domains of patient's life, leading to impaired QOL. SF36V2 questionnaire administered for the scoring of QOL of hemodialysis patient, which consist of 36 questions. This confirms previous observations in CKD and dialysis patients, with significantly low quality of life. Education initiatives in the form of counselling can help in improving the patient's QOL. The study emphasizes the impact of periodic counselling at regular intervals rather than single counselling session to Improve QOL in hemodialysis patients.

T523: THE RELATIONSHIP BETWEEN IRON DEFICIENCY ANAEMIA AND ANTENATAL DEPRESSION AMONG PREGNANT WOMEN

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Antenatal depression is a contributing factor in causing post-partum depression, preterm birth and developmental delays among infants. Though there are several factors that could lead to antenatal depression, iron deficiency anaemia is an emerging aetiology. Iron deficiency in the oligodentrocytes of brain causes altered myelination of neuronal cells along with dysregulation of neurotransmitters. The primary objective of this study is to determine the relationship between iron deficiency anaemia and antenatal depression among pregnant women. A cross- sectional study was conducted among the second trimester pregnant women who attended the obstetrics department for antenatal care. A total of 210 participants were categorised into iron deficient (N=140) and iron sufficient (N=70) groups based on the haematological results. The risk of depression was assessed using a validated Edinburgh depression scale. The distribution of depression was significantly varied between the groups. Edinburgh Depression Scale score was

significantly higher in the Iron Deficiency Anaemia group in comparison with the Non- Iron Deficiency Anaemia group (12.78± 3.40 vs. 8.82± 3.12; p value= 0.005; 95% CI 2.94 to 4.87). The strength of association between haemoglobin with EDS scores was found to be moderately increased with a decrease in the haemoglobin level. The odds of developing antenatal depression was 12 times higher in the iron deficient group, p <0.001.

T524: ASSESSMENT OF ADVERSE DRUG REACTIONS OF CHEMOTHERAPEUTIC AGENTS AND RADIOTHERAPY IN ONCOLOGY DEPARTMENT OF A QUATERNARY CARE HOSPITAL

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Cancer chemotherapeutic agents and radiotherapy have a high propensity to cause ADRs and DDI, as they are toxic to rapidly dividing cells in the body. Nevertheless, an early detection of these ADRs and DDI may help in minimizing the damage by either modifying the dose or changing the offending agent. The present study was designed to explore the adverse drug reaction among the patient treated with chemotherapeutic agents and radiotherapy in oncology department of quaternary hospital in Bangalore. Total 102 patient has been enrolled where assessment was done on59 female and 43 male patients. In inclusion criteria age selected 2 years to 85 years old patient for all type of cancer with all type of chemotherapeutic agents. The patient who undergoes radiotherapy also included for the study. Patient with chronic disease and clinical trial patient has excluded for the study. The criteria like Rawlins and Thompson method for predictability, Hartwig's method for severity and Naranjo's method for the probability adopted for the study. ADR reports indirectly from patient case file and directly by questioning the patient analysed. The result showed total 32 ADR reports with 56.25 % in female and 43.5% in male. Classification of ADRs based on WHO and HARTWIGS SHOWED the possible ADR with 52.94%. Additionally, assessment reports also showed 21.56% severe ADRs. Naranjos scale (causality assessment) and Rawlins and Thompson method of assessment also showed 52.94 % probable incidence of ADR. The study reveals 31.37% of anemia and 19.60% of febrile neutropenia. In indirect method majority of patients were female and patients belonging to the age groups 41-70 years (7 in each decades) had a higher incidence of ADRs. Breast carcinoma was the commonest. In direct method, majority of patients were male and patients belonging to the age group31-40 years had a higher incidence of ADRs. Most of the ADRs were "possible" "moderate" and "predictable", Anemia nausea, vomiting and pain were the commonest ADRs reported. Combination Cisplatin + Dox and docetaxol were the common drugs causing the ADRs. This knowledge can also prevent the occurrence of similar such reactions in the future. There is a great need to set up an effective ADRs monitoring and reporting system in all hospitals and also create awareness among health care professionals regarding the importance of this system. Our study was one of its kinds in providing a baseline data regarding the safety profile of cancer drugs in a teaching hospital in south India.

T525: ASSESSMENT OF SELF-CARE PRACTICES AMONG TYPE 2 DIABETIC PATIENTS IN A SECONDARY CARE TEACHING HOSPITAL

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Diabetes is one of the major health problems worldwide that can be effectively managed by good self-care activities like medication adherence, exercise, monitoring of blood glucose, foot care and diet. The study assessed the self-care activities of diabetic patients using summary of diabetes self-care activities scale (SDSCA) and the variables (Age, gender, educational level, socioeconomic status (SES)) associated with it. A cross-sectional descriptive study was undertaken in 400 Type 2 diabetic patients. Self-care practices of the patients were evaluated by using SDSCA and correlation with variables were determined statistically. Among 400 diabetic patients about 215 (53.75%) had an average score of self-care. Self-care was poor in 184 (46%) subjects, and only 1 subject (0.25%) scored good. Blood sugar monitoring was the highest (100%) followed by medication adherence (92.75%) whereas inadequate levels of self-care were reported in foot care (1.5%), and physical activity (31.5%) domains. A significant positive correlation was found between self-care practices and socio-demographic variables such as age (r=0.298, p=0.000), income (r=0.490, p=0.000) occupation (r=0.433, p=0.000), education (r=0.582, p=0.000), and Socio-Economic status (r=0.599, p=0.000). The study revealed higher level of adherence to self-care activities in terms of blood sugar monitoring and medication

taking behavior in the current setting, but self-care in other domains such as foot care is critically low. Age, education and Socio-Economic status seems to affect the selfcare practice by the patients.

T526: ASSESSMENT OF MEDICATION ADHERENCE BARRIERS IN COPD PATIENTS IN A SECONDARY CARE HOSPITAL

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COPD is characterised by persistent airway obstruction in which better clinical outcome can be attained by appropriate management of the disease. Adherence to COPD medication is poorly understood due to chronic nature of the disease. It is crucial to identify the barriers of adherence to build up and execute policies and interventions to upgrade medication adherence. To identify the predisposing barriers of medication adherence and to find the association between medication adherence and variables. A descriptive analytical study was conducted and data was collected from COPD outpatients. The Morisky Medication Adherence Scale was used to measure adherence and self-assessed questionnaire was employed to identify the predictors of poor adherence. Chi square test was carried out to find the relationship between medication adherence and variables such as age, gender, literacy, socioeconomic class, polypharmacy, medication delivery device and climate.

A total of 403 patients were involved in the study where 68% reported lower adherence. The most common adherence barriers found were forgetfulness (88%), intentional stoppage of medicines when symptoms improve (83%) and negligence towards medication (82%).A significant association was found between gender, literacy, socioeconomic class, polypharmacy, medication delivery device and climate. Adherence to medication regimen in COPD patients is poor, even though it is a preventable and a treatable disease. Well-structured education, training and counselling is required to overcome medication adherence particularly among illiterate and low socioeconomic class patients. The combined interventions such as video clip demonstrations of inhaler technique should be given.

T527: STRUCTURAL PHARMACOGENETICS OF HUMAN ORGANIC CATIONIC TRANSPORTER - 1WITH 1222A<G NON-SYNONYMOUS GENETIC POLYMORPHISM

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Background and objective: Organic cation transporters (OCTs) belong to a superfamily of influx transporters encoded by the solute lipid carrier (SLC) genes. Human OCT1 exhibits broad tissue distribution in the body and is predominantly expressed in the hepatocytes and the renal tubules. hOCT1 plays a significant role in the intestinal uptake of several xenobiotics including therapeutic agents. Since the gene coding for hOCT1 is highly polymorphic and majority of the reported non-synonymous polymorphisms have been associated with functional changes of hOCT1 thereby causing significant alterations in substrate pharmacokinetics. Thus, this study is done to assess the effect 1022C>T non-synonymous polymorphism in hOCT1. Methodology: High resolution crystal structure of Human Organic Cationic Transporter 1 (hOATP1) was modelled using I-TASSER. The mutant variant was modelled using Rotamer Explorer Tool (Molecular Operating Environment, CCG LLC) and the energy was minimized using YASARA Server. The active site of the target protein was predicted using Prank Web. The three-dimensional structure of the ligand molecule was retrieved using Zinc small molecule database. Docking experiments were carried out using Auto dock Suit 4.2 and the complexes were visualised using Pymol (Schrodinger LLC). It was observed that the binding energies and inhibitory constants of the docked OCT1 substrates significantly differ between wild type (Met408) and mutant (Val408) variant with binding energies -4.11 ± 1.1and -2.68 ± 2.62 respectively (P Value 0.027,1.49 [0.35-4.53]). The number of hydrogen bonds were also found to be less in the mutant variant suggesting a possible significant alteration in the protein conformation and the ligand transporting ability. Conclusion: The influx transport of hOCT1 substrates via the Human OCT1 has decreased due to the non-synonymous polymorphism (Met408Val). Therefore, patients receiving drugs with Met408Val variation are more prone to develop therapeutic failure at normal doses.

T528: STRUCTURAL PHARMACOGENETICS OF HUMAN ORGANIC ANIONIC TRANSPORTING POLYPEPTIDE WITH 521T<C NON-SYNONYMOUS GENETIC POLYMORPHISM

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Organic Anion Transporting Polypeptides (OATPs) are multi-specific influx transporters encoded by the genes of the SLCO family. It expressed in numerous epithelia throughout the body. OATPs mediate the gastrointestinal and hepatocellular uptake of a broad range of endogenous substrates and numerous xenobiotics in addition, OATPs are also expressed in the kidney where they are involved in active tubular secretion. The gene coding for OATP1 is highly polymorphic, and numerous promoter and coding region SNPs have been reported to influence the pharmacokinetics of drugs that are substrates of OATP1B1. Hence this study is done to assess the effect 521T>C non-synonymous polymorphism in hOATP1. High resolution crystal structure of Human Organic Anionic Transporting Polypeptide1 (hOATP1) was modelled using I-TASSER. The mutant variant was modelled using Rotamer Explorer Tool (Molecular Operating Environment, CCG LLC) and the energy was minimized using YASARA Server. The active site of the target protein was predicted using Prank Web. The three-dimensional structure of the ligand molecule was retrieved using Zinc small molecule database. Docking experiments were carried out using Auto dock Suit4.2 and the complexes were visualised using Pymol (Schrodinger LLC). It was observed that the binding energies and inhibitory constants of the docked OATP1 substrates significantly differ between wild type (Val174) and mutant (Ala174) variant with binding energies -3.85 ± 1.4 and –2.05 ± 3.76 respectively (P Value 0.041, 1.80[0.71-4.11]). The number of hydrogen bonds were also found to be less in the mutant variant suggesting a possible significant alteration in the protein conformation and the ligand transporting ability. Conclusion: The influx transport of hOATP1 substrates via the Human OATP1 has decreased due to the non-synonymous polymorphism (Val174Ala). Therefore, patients receiving drugs with Val174Ala variation are more prone to develop therapeutic failure at normal doses.

T529: EFFECT OF 2677G>T (ALA893SER) ANTI-NEOPLASTIC AGENT TRANSPORT VIA THE HUMAN P-GLYCOPROTEIN

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Non-synonymous polymorphisms in the human MDR1 gene tend to decrease the transporter activity of the P-glycoprotein, a major efflux transporter of endogenous substrates and xenobiotics predominantly cytotoxic agents. Hence this study was determined to assess the effect of 2677G>T genetic polymorphism of human MDR1 gene on the structure of P-glycoprotein. Methodology: High resolution crystal structure of human P-glycoprotein was retrieved from RCSB PDB (PDB Identifier: 6C0V). Mutant variant was modelled using Rotamer Explorer tool (Molecular Operating Environment, CCG LLC) and energy minimized using YASARA Server. Active site of target proteins was predicted using PRANK WEB server. Docking experiments were carried out using Autodock Suite 4.2 and complexes were visualized using Pymol (Schrodinger LLC). Three-dimensional structure of ligand molecules was retrieved from ZINC small molecule database. Results and Discussion: It was observed that the binding energies and inhibitory constants of docked anti-neoplastic agents significantly differed between wild type (Ala893) and wild type Ser893 mutant variant with binding energies 3.9±1.2 and 1.9±1.5 respectively (P Value 0.002, 1.7 [0.2 – 4.5]). Number of hydrogen bonds were also found to be less in the mutant variant suggesting a possible significant alteration in the protein confirmation and ligand transporting ability. Conclusion: Efflux transport of anti-neoplastic agents via the human P-gp is decreased by nonsynonymous Ala 893Ser variant. Therefore, patients receiving cytotoxic agents with Ala893Ser variation are more prone to end organ toxicity including neuronal toxicity due to accumulation of cytotoxic agents.

T530: A STUDY ON ANTIMICROBIAL USAGE IN RENAL AND HEPATIC FAILURE PATIENTS AT A TERITIARY CARE HOSPITAL

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Both the kidney and liver play an important role in our body by performing various necessary functions. The liver helps the body to fight against diseases and infections. It is the

organ which helps in digestion of food and for the regulation of blood sugar level as well. Kidneys also play a much important role in waste elimination. It is the organ which keeps the body out of waste and provides a safe and clean working environment to all other body organs. The term "antibiotic" includes a variety of chemical compounds that exhibit great differences among them in terms of mechanism of action and physicochemical, pharmacokinetic, and pharmacodynamic characteristics. The uniqueness of each class makes independent study essential to provide accurate characterization of antibiotic behavior. From a clinical perspective, optimization of antibiotic use is particularly important for critically ill patients in whom early and appropriate antibiotic prescription has been shown to reduce mortality. Especially for antimicrobials known for a tight therapeutic range, therapeutic drug monitoring is strongly suggested to guide dosing adjustment in complex clinical settings such as septic patients with acute kidney injury undergoing renal replacement therapy, also Antibiotics used by general practitioners frequently appear in adverse-event reports of drug-induced hepatotoxicity. Most cases are idiosyncratic (the adverse reaction cannot be predicted from the drug's pharmacological profile or from preclinical toxicology tests) and occur via an immunological reaction or in response to the presence of hepatotoxic metabolites. Patients at risk are mainly those with previous experience of hepatotoxic or nephrotoxic reactions to antibiotics, the aged or those with impaired hepatic or renal function in the absence of close monitoring, making it important to carefully balance potential risks with expected benefits in tertiary care. Keeping this on the background a present study on 'A study on antimicrobials usage in renal and hepatic failure at a tertiary care hospital' is initiated. Therefore, an observational hospital-based study was done for the utilization pattern of antimicrobials among patients with Renal/Liver failure. In order to study about the various factors that influences the choice of antimicrobials, as well as to study the incidence of various common infections with liver and renal failure patients and to report the various drug related problems.

T531: HUMANISTIC OUTCOME ASSESSMENT OF TYPE 2 – A PROSPECTIVE STUDY

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Understanding and measuring the patient's perception on type 2 DM treatments and health outcomes are the important elements for developing type 2 DM treatment strategic choices which helps clinicians to make appropriate decisions and benefit the patients. In India very less studies were conducted to understand the HRQoL status of type 2 DM patients. In this context, we conducted a study on type 2 DM patients (n=) using the translated and validated DSC-r (Tamil Version) Scale to measure the patient's perception on type 2 DM treatment options. Internal consistency and content validity were analyzed and the Cronbach's Alpha = 0.9745, Standard Alpha= 0.9771, Guttmann's Lambda 6 (Squared Multiple Correlation) Reliability = 1 and Inter Item Correlation Average R= 0.5715 and these results showed that the translated Tamil Language DSC-r version had acceptable reliability and validity. Selected type 2 DM patients were categorized based on their oral hypoglycemic regimens such as, Metformin with Glibenclamide (M+GB), Metformin with Glipizide (M+ GP) and Metformin (M). DSC-r, (Tamil Version) 34 items self-administering questionnaire was used to measure the type 2 DM patients HRQoL status on major 8 type 2 DM symptom domains such as, cardiology, neurology, ophthalmology, psychology, hypoglycemia and hyperglycemia and etc. The DSC-r Mean Dimensional Score (MDS) were identified and it was found to be 1.97896 for M +GP treated group, 2.06448 for M+GB treated group and 1.96597 for M treated group. M+GB treated group was shown to have a higher MDS score indicating more symptoms or complications in these patients. M + GP and M + GB. Humanistic outcome analysis results showed that all the three anti-diabetic regimens produced only the partial health level status (Avg Utility Value = 0.600) and the QALY average was 0.600/Year.

T533: DEVELOPMENT AND VALIDATION OF METHODOLOGY TO STUDY THE GENETIC POLYMORPHISM OF OCT1 (RS622342) GENE IN SOUTH INDIAN POPULATION– A PILOT STUDY

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OCT1 (rs622342) gene encodes for OCT1 influx transporter involved in the uptake of drugs in liver. Genetic polymorphism of OCT1 (rs622342) gene has been significantly associated with the variation in pharmacokinetics and pharmacodynamics of substrate drugs. Under the light of this information, it is necessary to establish the methodology to investigate the polymorphism of OCT1 which could help in determining its influence on pharmacokinetic and pharmacodynamic parameters of substrate drugs. The objective of this study is to develop and

validate the Reverse Transcriptase-PCR and gel electrophoresis method for identifying OCT1 rs622342 genetic polymorphism in study population. A prospective open label study was conducted among 10 South Indian healthy male volunteers. The DNA was isolated from whole blood of healthy volunteers by phenol chloroform method after designing the primers. The restriction enzyme was developed by using restriction mapper and used to find the genetic polymorphism of OCT1 (rs622342) gene by gel electrophoresis. Results: All the 10 samples showed fragmentation after the addition of restriction enzyme (PsiI) which indicates the validation of methodology and lack of OCT1 rs622342 genetic polymorphism in the samples. Conclusion: The study methodology could be carried for further larger population to determine the prevalence of OCT1 (rs622342) genetic polymorphism as stated in the literatures and assist in conducting studies to carry out the effect of OCT1 genetic polymorphism in relation to pharmacokinetics and pharmacodynamics of substrate drugs.

T534: PREVALENCE AND RISK FACTORS OF OCCUPATION INDUCED ASTHMA AMONG TRAFFIC POLICE IN BANGALORE CITY

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The aim of this study was to evaluate the cumulative effect of traffic related pollutants on subjects which mainly included traffic police. This evaluation is important to cater to the statistic that occupational asthma is the most common form of lung disease in the world which places the population with high exposure at great risk. We qualify the effect of exposure to pollutants like carbon monoxide, particulate diesel and other gaseous pollutant which can cause interminable harm that demonstrate as migraine, hazy vision, trouble in focus and confusion. They may also be carcinogenic with higher rates of malignancy. The predominance of respiratory complications among the policemen in highly polluted areas is higher than their counterparts. A careful assessment of history and quantification of severity markers and peak expiratory flow rate helps us identify patients who may require intensive immediate care or even hospitalization. The main objective of this work is to analyze the present health status of these policemen who work in extreme work conditions to ensure the safety of the public. It was also observed that the number of studies on assessing the health problems among traffic police in India is less. Hence, asthma mortality can be controlled by better understanding of the disease and reliability on prophylaxis rather than treatment. This research aims to assess the health problems among traffic police and provide a self-instructional module to create awareness about health problems with its prevention amongst all traffic police officers in Bangalore City.

T535: A STUDY ON PREVALENCE OF RISK FACTORS FOR OSTEOPOROSIS IN POSTMENOPAUSAL WOMEN AND THE IMPORTANCE OF OSTEOPOROSIS SELF-ASSESSMENT TOOL (OST) IN IDENTIFYING OSTEOPOROTIC RISK

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Osteoporosis is a highly prevalent health issue among postmenopausal women, which can be prevented if identified in the early stages. The use of Osteoporosis Self - assessment Tool (OST) will help in identifying the risk of osteoporosis and hence will allow the patients to seek the best treatment if required. In this study we have assessed the prevalence of risk factors for osteoporosis in 400 Postmenopausal women and have measured the osteoporotic risk by using OST in K. C. General Hospital, Bengaluru, for a period of 6 months. About 52% of the population was belonging to the late stage as per the postmenopausal classification. Average BMI of the population was found to be in borderline of normal that is 19.5 which indicates the risk for Osteoporosis. Attaining early menopause 243 (60.75%) and history of fall 223(55.75%) was the most common risk factors found in the population. 78 patients were identified with high risk using OST. The correlation between OST and risk factors revealed that OST is positively significant with progression of menopausal stage. Patient education regarding the use and interpretation of OST will help to identify risk of osteoporosis; this should be implemented within gynecological care units of all primary health care centers for the better outcome.

T536: ASSESSMENT OF KNOWLEDGE, ATTITUDE AND PRACTICE OF EPILEPTIC PATIENTS TOWARDS THE DISEASE AND ITS MANAGEMENT IN TERTIARY CARE TEACHING HOSPITAL – AN INTERVENTIONAL STUDY

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Epilepsy is one of the most common neurological disorder that affect more than 50 million people worldwide of all ages, especially, childhood, adolescence and elderly having a prevalence rate of 2.8-19.5per 1,000. Objectives: To assess the knowledge, attitude and practices (KAP) of epileptic patients towards their disease. Methodology: Prospective interventional study conducted over a period of 6 months after receiving the institutional ethical committee approval. Study patient were randomized into test and control groups. At baseline, and follow up visits the patients of both the groups were administered with knowledge, attitude and practice (KAP) Questionnaire. Test group patients received patient education. Results obtained were assessed to determine the influence of education on patient's knowledge, attitude and practice. Pharmacist mediated education influence of demographic characters on KAP was also assessed. Significance of change in KAP from baseline to final follow was assessed using paired t- test. Significantly to the education provided (Significant $p< 0.05$). Results: A total 72 patients were included and completed all the follow ups. There were more male patients compared to female patients (5:2). A significant ($P<0.05$) improvement in KAP score was observed in the test group patient compared to the control group. It was observed that illiterates responded significantly to the education provided (Significant $p< 0.05$).

T537: FOOD SAFETY AWARENESS, PRACTICES AND KNOWLEDGE LEVELS AMONG AILING GERIATRICS – A SYSTEMATIC REVIEW

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Food safety plays an essential role in geriatric population as there can be progressive decline in the physiological functions. There is a growing need for interventions to assure the health of the frail and senior geriatric population and to create an awareness to ensure meeting the healthcare and nutritional needs of the disabled elderly. Increasing deployment of cold food chain in these decades, dried salted fish exports are all a clinical bane to geriatric health as a source for cryptic infections. Deficient care, counsel and advice trigger the chances for additional infections. Elderly nutrition is often neglected and this abuse leads to a host of illness factors. Therapeutic diets ought to be inducted in any kind of bodily ailments among the elderly. A review was conducted with representative samples drawn from different senior age groups, sects, groups, community to evidence the functional limitations beyond the age of sixty years. As morbidity increased with age and with coupling social factors associated, the magnitude of malnutrition hovering upon the elderly in India is underreported. Impaired memory, social isolation, declining income, health problems and loss of spouse or friends, all do affect appetite and resulting in poor nutritional status. Predesigned, pre tested tool-based studies were reviewed. Healthy food concepts and friendly cooking practices are a true foundation for good health. Senior citizens need additional vitamins and or minerals. Nutrient-rich foods should maintain food intake balance against physical activity. The promotion of low cost, prevention-based initiatives viz., health, nutrition and physical education could significantly enhance the possibility of maintaining good nutritional status for the elderly patients.

T538: GIVE AND TAKE MEDICINE PRACTICE –SAFE OR UNSAFE

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Medicines are the key of many diseases provided that they have to be taken appropriately according to physician's guidance. The physician will prescribe the medication depending upon diseased condition and patient factors. But, due to some reasons such as financial problem, emergency condition, lack of knowledge and availability of other patient's medicine with same condition the transfer of medicines from one person to other is happening among the general population without notifying to the health care provider. Taking someone's medications may lead to serious health problems and development of drug resistance because the person might not know or understand the typical effects of medicine, its interaction with food and other drugs, potential of drugs i.e. dose and frequency, in which condition it is contraindicated, allergy, liver and kidney function, steps to be taken as precaution, conditions like pregnancy, pediatric or geriatric where dose may vary from normal adult dose regarding which most of the people are not aware. So an online survey was conducted to check the knowledge of the people regarding harmful effects of medicine transfer. From

this survey, it is observed that majority of the people (78% out of 238 people) are involved in medicine transfer. This indicates that there is a lack of knowledge regarding harmful effects of medicine transfer among general population. So there is a need to create awareness among general population and to develop drug disposal as well as drug repository program effectively to prevent these problems.

T539: RX-TO-OTC SWITCHES: FUTURE OPPORTUNITIES AND CHALLENGES

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Rx-to-OTC medications are those medicines which had been the prescription medicines but later transferred to the non-prescription drugs (OTC). Earlier the use of over the counter (OTC) drugs was focused only on minor afflictions like cough and cold, aches/pain, hyperacidity, etc. Now Rx-to-OTC switch process has expanded the category of OTC drugs to a wide range. The Rx-to-OTC switch drugs in present have been used for a number of indications like muscle pain and sprains, smoking cessation, diarrhea, heartburn, yeast infection, allergies, overactive bladder, sleeplessness, etc. About 40% of all OTC drugs used today in the US were once sold as prescription only medicines. When the medication is effective and has a high safety margin, it is possible to 'switch' the same drug to over the counter (OTC) status. The safety and efficacy data should be submitted to NDA together with post marketing data and additional clinical trials for Rx-to-OTC switch process. Certain changes in packaging and labeling are also made during approval of the Rx-to-OTC switch drug. The factors that support the Rx-to-OTC switch process includes consumer awareness, attempts of pharmaceutical companies to expand their market, self-medication act growth, high consultation fees, etc. The Rx-to-OTC switch process stimulates production of more OTC drugs for a number of ailments and supports the growth of pharmaceutical industries. This solves the unemployment problem faced by today's population. The availability of Rx-to-OTC switch drug candidates in market helps to meet the consumers' self-medication needs and demand. The challenges faced due to Rx-to-OTC switch process are misuse and abuse of OTC drugs, imbalance relationship between patients, doctors and pharmacists, pharmaceutical counterfeiting, etc. A number of analytical strategies has been adopted for counterfeit screening of Rx-to-OTC drugs.

T540: FASTING TECHNIQUES – CHANGING THE WAY YOU LOOK AT THERAPY

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Currently various complications like Diabetes, Cardio-vascular diseases, Cancer, Neurological disorders etc. have become treatable, almost completely due to the advances in science, but the drugs used for the treatment may cause some severe side effects like hypoglycaemia, kidney complications, diarrhoea, anaemia, weight gain, weight loss, rashes, loss of appetite, dyskinesia, insomnia, hypotension, confusion, hallucinations, compulsive behaviour, neurological complications etc. Some treatments cause defects in whole organ systems including damage to immune system, lungs, heart, nerve endings and reproductive organs. There are many treatment approaches using non-pharmacological techniques for treating diseases, without synthetic drugs. One such technique is fasting, a process where starvation conditions are imitated voluntarily. Fasting is extremely beneficial to health and has very good therapeutic efficacy. Some major fasting techniques.

T541: RHEUMATOID ARTHRITIS ASSOCIATED CARDIOVASCULAR DISEASES AND LUNG DISEASES: RECENT AVAILABLE TREATMENTS

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Rheumatoid arthritis (RA) is a chronic inflammatory autoimmune disease attacks the synovial lining of diarthrodial joints and causes formation of pannus tissue. The mediators for the pathogenesis of RA are IL-1, IL-6, TNFα, IL-1β. The uncontrolled release of these mediators is responsible for causing other severe diseases. The uncontrolled RA with chronic inflammation may cause Cardiovascular diseases, Interstitial lung disease, Renal dysfunction etc.. As there is no cure for RA, the treatment goals are to reduce the pain and stop/slow further damage. Initiation of treatment particularly by combination of Disease modifying antirheumatic drugs (DMARDs) concurrent with short duration of corticosteroid is expected to prevent progressive course and even change the natural course of RA. The recent available treatment can slow the progression of

rheumatoid arthritis and save the joints and other tissues from permanent damage. The present review is on different diseases caused by RA and their available treatments with complications.

T542: AN EVOLVING DIETARY ROLE IN ACNE PATHOGENESIS

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Acne vulgaris is a very common pilosebaceous inflammatory disease occurring primarily on the face and also rare on the upper arms, trunk, and back, which is caused by Propionibacterium, Staphylococcus, Corynebacterium, and other species. Pathophysiology of acne comprises of irregular keratinocyte proliferation, differentiation, increased sebum output, bacterial antigens and cytokines induced inflammatory response. Additionally, excess intake of dairy products, hyperglycemic meat, dietary, obesity, eating disorders, genetics medicine, aggressive skin care products, mechanical, hormonal, air pollution, modern lifestyle, stress and oxidative stress can also result in acne. One of the most important food groups causing acne are hyperglycemic carbohydrates, saturated fats like trans-fats and deficient - polyunsaturated fatty acids (PUFAs). The acne vulgaris is thus encouraged by diet-induced metabolomic alterations. Acne is a multifactorial skin disease which requires proper understanding of interrelationships between the various novel factors that could contribute to the pathology of acne in order to indicate the gaps and to overcome. Patients must regulate total calorie intake and limit refined carbohydrates, dairy, supplements of milk protein, saturated fats, and trans fats. Paleolithic diet supplemented with vegetables and fish are promising dietary supplements that support acne vulgaris nutritional therapy. Acne is a multifactorial skin disease that needs a proper understanding of the interrelationships between the different novel factors that may lead to acne pathology to identify the differences and resolve them and to encounter the unmet needs.

T543: THE PROMISE AND PITFALLS OF DIGITAL MEDICATION

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A digital pill is a pharmaceutical dosage form that contains an ingestible sensor inside of a pill. The sensor being transmitting medical data after it is consumed. The technology that makes up the pill, as well as the data transmitted by the pill's sensor, are considered as a part of digital medicine. The purpose of sensor is to determine whether the person is taking their medication or not. Digital medication combines an array of advanced technologies, including a biosensor patch, and some form of mobile online interface. A 1mm intelligible sensor, coated with digestible dietary minerals of copper and magnesium, is embedded into an oral, solid dosage formulation of a medication such as tablets or a capsule. The patch is approximately 10mm long, made of waterproof foam surface, and typically applied to the torso.

T544: POST-APPROVAL CHANGE MANAGEMENT PROTOCOLS: CURRENT STATUS AND WAY FORWARD

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Post-approval changes (PACs) to the registered quality (or CMC, i.e. Chemistry, Manufacturing & Control) information of authorised medicinal products, are introduced routinely worldwide to react to increasing supply demand, enhance the robustness and efficiency of the manufacturing process; improve quality control techniques; respond to changes in regulatory requirements; and upgrade to state-of-the-art facilities. Currently, the management of post-approval changes on a global scale is complex, unpredictable and time consuming. A Post Approval Change Management Protocol (PACMP) describes specific changes that a company would like to implement following marketing authorization and how these would be prepared and verified. A PACMP applies to all types of products and incorporates a science and risk-based approach to evaluate impact of changes on product quality in a proactive manner. The aim is to establish a simple, clear and more flexible legal framework for the handling variations or post approval changes of medicinal products, while ensuring a high level of protection of public health. The objective is to provide information on different post-approval changes in India, US and implementation of post approval change management protocol in Europe. The opportunities to continue to harmonize the requirements can positively impact patient access to life saving medications, and the effort required by the Agencies and sponsor when managing post-approval changes.

T545: XENOTRANSPLANTATION: THE FUTURE BULLET FOR MALADY

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Due to the shortage of organ donors around the globe most of the people are losing their life waiting for deceased organs this led to the emergence of xenotransplantation. The term xenotransplantation (xeno = alien; transplantation = relocate) consist of donor and acceptor which involves transfer of live cells, tissues, or organs from animal source into a human. Xenotransplantation benefits human life through multiple ways by Organ xenotransplants tissue xenotransplants, cellular xenotransplants. The research has shown that swine is the most acceptable animal in the process of organ, cells and tissue transplantations in humans and although it is said to be the most acceptable animal, there exists a chance of transmission of porcine retrovirus (PERV) for which numerous scrutinising methods are available and mentioned in various regulatory authorities' guidance. Considering the patient and public health which may get affected due to the potential risk linked with xenotransplantation, to prevent such problem regulatory framework was enforced to assist the ongoing clinical trial. The current regulatory study highlights the distinct focus on Xenotransplantation by overseeing the regulatory comparison between USA and New Zealand and projects the concern taken by these countries to safeguard the public health.

T546: CONSISTENCY REQUIREMENTS IN THE MONOGRAPH ON INDIAN ESSENTIAL MEDICINE IMPURITY PROFILING

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As per WHO, HIV-AIDS considered as second most dangerous disease which produces a high mortality rate. Hence combinational therapy is considered as a key tool to control the life loss and to extend the life span of patients. Abacavir sulfate, an anti-retroviral drug is used for the first-line treatment of HIV/AIDS as part of the Anti-Retroviral Therapy (ART). Abacavir sulfate (ABC) has been shown to pose a few pharmacokinetic problems regarding its side effects. Physicochemically, ABC faces the challenge of instability in acidic conditions, higher temperatures, and it also shows photo-instability. In order to enhance its physicochemical properties in terms of stability, semi-synthetic derivatives of ABC have been hypothesised the same have been achieved. These derivatives have shown pharmacokinetically enhanced performance, but involve complex synthetic routes. Schiff's base synthesis has been selected as a route of synthesis to improve the stability. This reaction route appears promising as the resulting imine is considered relatively stable than the parent compound. The synthetic compound has been analysed for its stability. As result of the study potential semi-synthetic moieties have been developed and its stability parameters have been studied. As a result, the compound under consideration has enhanced stability parameters.

T547: CLOSING THE LOOP ON DIABETES MANAGEMENT - ARTIFICIAL PANCREAS A CLOSE REALITY?

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Type 1 diabetes mellitus is characterized by autoimmune destruction of insulin-producing pancreatic β cells which usually presents with a classic trio of symptoms - polydipsia, polyphagia and polyuria; alongside of overt hyperglycemia, necessitating exogenous insulin replacement. Since the discovery of insulin, pharmacological and clinical developments have endeavored to replicate its endogenous pharmacokinetics and pharmacodynamics. At present, the most accessible mode of insulin replacement remains subcutaneous multiple daily injections or continuous subcutaneous insulin infusion via a pump. Despite developments in both these treatment modalities, post prandial hyperglycemia and late hypoglycemia remain the issue. Technological advances have made it possible to develop closed loop insulin delivery systems which operate as an artificial pancreas by making automated insulin dose adjustments which consists of an insulin pump, a Continuous Glucose Monitor (CGM) and a glucose control algorithm. Glucose control algorithms are a set of programmed rules which allow the glucose controller to perform the role of a normal pancreas and make automated insulin adjustments based on real-time CGM data. Studies have shown that closed-loop systems are superior to conventional insulin pump therapy at improving the glycemic control, whilst reducing the risk of hypoglycemia. Hence, we aim to highlight the importance and various aspects of this novel drug delivery system Hospital.

T548: TAILORING BREAST CANCER TREATMENT: ENTER PERSONALIZED MEDICINE

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Breast cancer is the fifth cause of cancer death among women worldwide and represents a global health concern due to the lack of effective therapeutic regimens that could be applied to all disease groups. Personalized medicine for breast cancer enables categorizing cancer subtypes and assigning the best treatment regimen based on patient characteristics, medical history and response to therapy. It enables clinicians in selecting appropriate drugs and doses to decrease adverse effects and increase efficacy. Based on molecular stratification, breast cancer is categorized into five distinct molecular classes hormone receptor positive luminal A and luminal B, human epidermal growth factor receptor-2 (HER2-positive), basal-like and normal-like, and Claudin-low type, with targeted therapy being aromatase inhibitors, HER2 and kinase inhibitors, PARP1 inhibitors. Each subtype has a different response to chemotherapy. Conclusion: The advents of modern diagnostics and therapeutics have provided significant advances compared with traditional medicine. With the increasing understanding of the molecular biology of signaling pathways the future of breast cancer therapy looks promising. Hence, we aim to outline the various targeted therapies for breast cancer based on molecular classification, thereby personalizing the treatment.

T550: COMPARATIVE STUDY ON EFFICACY OF GLYCOPYRRONIUM AND TIOTROPIUM IN THE TREATMENT OF COPD

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COPD is a general term that describes progressive respiratory disease like emphysema and chronic bronchitis. Chronic Bronchitis is characterized by excessive mucous production whereas emphysema is marked by permanent alveolar enlargement and destructive changes on the alveolar walls which result in airflow limitation. Two once-daily acting muscarinic antagonists (LAMA) are currently available for the treatment of Chronic Obstructive Pulmonary Disease-Tiotropium and Glycopyrronium. Aim: Aim of the study is to compare the efficacy of glycopyrronium and tiotropium in treatment of COPD. Methods: In this prospective comparative study, patients with moderate to severe COPD were randomized 1:1 to glycopyrronium 50µg once daily and tiotropium 9 µg twice daily. The severities of infection of the subjects were assessed on the first day (before treatment). Then the patient was followed after 3months of treatment using St George respiratory questionnaire. Subjects with moderate to high risk of COPD and an age group of 40 to 75 years were enrolled in the study. Pregnant women, lactating mothers and psychiatric patients were excluded from the study. Results And Discussion: A total of 96 patients were randomized with each group containing equal population 48 (50%). 60 males and 36 females were enrolled in the study. The efficacies of the two drugs were assessed using the St George respiratory questionnaire. On comparison, the results showed similar symptom score, activity score and impact scores. Both the drugs are having almost similar efficacy since the mean value does not show much difference. Both p-values are found to be significant since the p-value is less than 0.005. Conclusion: In patients with moderate-to-severe COPD, 12-week treatment with once daily glycopyrronium 50µg or tiotropium 9µg twice daily provided similar efficacy and safety. The study concluded that the efficacy of glycopyrronium and tiotropium are equal.

T551: COMPARISON OF PAIN RESPONSE OF ETODOLAC AND ACECLOFENAC IN LOW BACK PAIN

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Low back pain (LBP) is the most common musculoskeletal condition affecting the adult population. It is defined as located pain and discomfort below the costal margin and above the superior gluteal line, with or without related pain in the lower limb, being chronic if it persists for three months or more. The visual analogue scale is a simple frequently used method for the assessment of variations in intensity of pain. In clinical practice the percentage of pain relief assessed by VAS, is often considered as a measure of pain severity of treatment. To compare the pain response of Aceclofenac and Etodolac in low back pain. A prospective observational study, was conducted on 108 patients for duration of 6 months in 700 bedded tertiary care hospital, department of orthopedics. Patients were randomly arranged into 2 groups. Group 1 received Etodolac whereas the others received Aceclofenac. The comparison was done among both the groups to assess the pain severity, using VAS (Visual Analog Scale). All details were collected on a specially designed data

entry form. Results showed that in the entire study population, Etodolac showed a significant reduction in the pain. Patients treated with Aceclofenac showed least significant reduction in the pain. In this study the patients in the Etodolac treatment group showed major reduction in the pain score i.e., average pain score before the study was 4.9630 and 2.0556 after the study. Aceclofenac treatment group showed only less reduction in the pain score compared to that of Etodolac, i.e., 5.3500 was the average pain score before the study and 4.5185 after the study. Our study was carried out to compare the pain response of Aceclofenac and Etodolac. Etodolac showed a significant reduction in the pain. Patients treated with Aceclofenac showed least significant reduction in the pain.

T552: ASSESSMENT OF MEDICATION ADHERENCE IN SCHIZOPHRENIA VS TYPE II DIABETES MELLITUS PATIENTS: A COMPARATIVE STUDY

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As complexity and duration of therapy increases in chronic illnesses, non-adherence stands as a major threat. The mental health problems and its therapy are most challenging and complicated among all health problems approximately affecting 450 million persons worldwide. The medication adherence of psychiatry patients is highly important area which requires more care due to lifelong medication. AIM To assess the level of Medication Adherence in Schizophrenia patients and Type II DM patients and compare both the groups. Prospective, observational, naturalistic control study conducted in department of Psychiatry and General Medicine. A total of 100 patients who met with the inclusion and exclusion criteria were enrolled in the study where they were randomized into 2 groups each having 50. (Schizophrenia group and Diabetes Mellitus group). The level of Medication Adherence was measured using the scores obtained from Morisky's Medication Adherence Scale-8 item questionnaire (MMAS 8) and were tabulated. From the sample of 50 schizophrenic patients, 34 subjects (68%) had a low rate, 13 subjects (26%) had a medium rate and 3 subjects (6%) had a high of adherence. From the sample of 50 diabetic patients, 10 subjects (20%) had a low rate, 12 subjects (24%) had a medium rate and 28 subjects (56%) had a high of adherence. The comparison of adherence of Schizophrenia and Diabetes proved that there is a significant difference in both populations and the psychiatric patients showed a lower rate of adherence (Chi square =33.292 P=0.0001). As proved in our study there is high level of medication non-adherence for psychiatric illness and so full benefits of medication cannot be achieved. We need to adopt interventions which improve the conventional management of psychiatric illnesses.

T553: SURVEILLANCE AND ASSESSMENT OF MEDICATION ERRORS IN INTENSIVE CARE UNIT AT SECONDARY CARE HOSPITAL: A PROSPECTIVE STUDY

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Any preventable event that may cause harm to a patient is known as medication error. Errors happen due to the lack of knowledge, poor performance and psychological lapses. In 2013 study, the Harvard University estimated that India records a whopping 52 lakhs injuries each year (out of the 430 lakhs globally) due to medical errors and adverse events (5th may, 2016). In this pharmacist has a major role along with physicians, nurses, and administrators to examine and improve health-care system in order to ensure the patient safety. All medical records of the intensive care unit patients, above 14 years of age, with co-morbid / non-co-morbid conditions and occupation, caste and gender were checked for medication errors for a period of 06 months at Government headquarters hospital, Udhagamandalam. Among 200 patients, 212 errors were found after the assessment of the patient profile forms and their medication charts. From our study, out of the total 200 patients, prescription errors were found to be more in number in comparison with other errors like administration error, documentation error and transcription error.