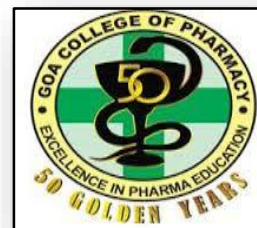




GOA – CENTER FOR EXCELLENCE IN INTELLECTUAL PROPERTY



**4th Annual International Conference
on**

Prosecution to Litigation: Part III

Asserting Exclusive Rights to IP

Nov. 11-12, 2019
Goa College of Pharmacy
Panaji, Goa - INDIA

G-CEIP

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**Goa – Center for Excellence in
Intellectual Property**

**Prosecution to Litigation: Part III
Asserting Exclusive Rights to IP
November 11-12, 2019**



**Umesh Banakar, PhD, Professor and Founder
Goa-Center for Excellence in Intellectual Property [G-CEIP]**

Message

Goa – Center for Excellence in Intellectual Property [G-CEIP]

Gaining Traction and Setting Tracks: CAMPAIGN 2020 AND BEYOND !!

At the outset, it is my distinct privilege to welcome you to the 4th Annual International Conference on Intellectual Property organized by the **Goa – Center for Excellence in Intellectual Property [G-CEIP]** in association with **Goa College of Pharmacy [GCP]**. Global experts in IP have gathered here to share their rich and extensive experience in IP matters.

G-CEIP completes four years, as of date !! Of the many “*first of its kind*” the Center has accomplished, such as, Research Showcase Presentation (RSP) – a platform for the scientists (IP generators); scientific and technical focus based courses in IP to enhance the knowledgebase of the IP generators; signing of a MOU with a U.S.A. based law firm specializing in IP services worldwide; among others, not to mention the mere establishment of this nonprofit Center itself in the country. The Center continues to strive to reach out and provide services to its stakeholders (IP generators) nationally through various formats such as institution based professional advancement programs, focus presentations at scientific discipline centered conferences, both inter- and intra-national. Such reach out programs and services have been well supported and equally well received by industry and academia. The Center has reached six states: Goa, Maharashtra, Karnataka, Haryana, Punjab, and Andhra Pradesh; and four global scientific forums: ISC, IPC, SPDS and FPQL. The Center has demonstrated sustained commitment to its vision and, slowly but surely, gaining traction within the scientific community.

The principal focus of G-CEIP continues to be ***Recognize and Protect Scientific Discovery with the Rights it Deserves !!*** In keeping with the objectives of the Center, it is time to penetrate and permeate nationally by reaching out to IP generators at grassroot levels in a comprehensive and systematic manner. **G-CEIP2019** will unveil the blueprint of **CAMPAIGN 2020 AND BEYOND !!** – a 5-year dedicated effort to enhance the knowledgebase and awareness of IP to the scientific communities across disciplines and across state boundaries in the entire country.

The central theme of **G-CEIP 2019 International Conference on Intellectual Property** is entitled:
Intellectual Property: Prosecution to Litigation - Part III: Asserting Exclusive Rights to IP

I, personally, welcome each and every one of you to take maximum advantage of this opportunity, not only to listen to these experts in IP, but also to interact one-on-one with them. I hope this program will be a professionally enriching and rewarding experience which will go a long way in your professional development.

Warm wishes,

Umesh Banakar, Ph.D.
Professor & President

RSP Abstracts

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TITLE: DEVELOPMENT OF LEVOCETIRIZINE ORAL DISPERSIBLE TABLETS
USING NOVEL GRANULATION TECHNIQUES

AUTHORS: Nafid Ansari*, Raymond Balajied, Marwein, BLR Madhavi and Divakar Goli



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ABSTRACT: This study was aimed at development of levocetirizine hydrochloride oral dispersible tablets which can disintegrate rapidly once placed in oral cavity. Levocetirizine competes with endogenous histamine for binding at peripheral H1-receptor sites on the cell surfaces. This prevents the negative symptoms associated with histamine release and allergic reaction. In addition, as histamine plays an important role in angiogenesis during an allergic inflammatory reaction, blocking the action of histamine may modulate the expression of proangiogenic factors and thus prevent angiogenesis. Resins like Indion 214 and Tulsion 335 were used to mask the taste of drug by forming a drug resin complex. The tablet was prepared with combination of superdisintegrants like Croscarmellose sodium, crospovidone and sodium starch glycolate at different concentrations. The blend was evaluated for angle of repose, bulk density, tapped density, compressibility index and Hausner's ratio. The granules were prepared by using melt granulation technique and steam granulation techniques. The tablets were evaluated for thickness, hardness, friability, weight variation, content uniformity test, taste, wetting time, water absorption, dissolution study and FTIR studies. The most satisfactory formulation showed minimum disintegration time of 30 sec and released maximum amount of drug in shortest duration of time in 25 min. It was found to be stable during stability studied conducted for 3 months as per ICH guidelines.

KEY WORDS: Oral dispersible tablets, Resins, Super disintegrants, Levocetirizine hydrochloride

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TITLE: Fabrication and evaluation of Sesamin loaded Nanosponge Drug Delivery System

AUTHORS: Karambelkar A, Ding M, Bhandarkar A, Joshi AB, Gurav S.

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ABSTRACT:

In this study, ethyl cellulose based nanosponges of Sesamin indicum were fabricated and optimized using quasi-emulsion solvent diffusion technique. QbD approach was used to set the parameters of the batches i.e. drug: polymer ratio and emulsifier concentration, keeping amount of polymer, volume of external phase, stirring time and stirring rate constant. The optimized batch was then evaluated using techniques like FTIR, DSC, SEM, Particle size analysis, porosity studies and X-ray diffraction. The optimized formulation had a drug content of 81.43% and entrapment efficiency of 93%. SEM studies showed the nanosponges to be spherical with numerous pores and the average particle size around 436.40nm. The nanosponges could be formulated into various dosage forms.

KEYWORDS: Nanosponges, Quasi-emulsion solvent diffusion technique, QbD approach,

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TITLE: Formulation and evaluation of Shikakai paste as Denture cleanser

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ABSTRACT:

The objective of the current study was to prepare Shikakai paste and evaluate their effect on *Staphylococcus aureus* and *Escherichia coli* biofilm formed on dentures. Shikakai (*Acacia concinna*) has marked antibacterial activity against bacterial strains of gram positive and gram negative. Denture cleansers remove not only the biofilm, but also stains and other forms of food debris from dentures. The Shikakai paste was formulated by trituration method using varying concentrations of Shikakai powder. The formulated paste was then evaluated for different parameters such as pH, physical examination, foamability, moisture content, spreadability, abrasiveness, extrudability, cleaning ability, anti-microbial activity and stability studies. From the results of cleaning ability, it was found that the colour was removed completely without excessive brushing. The developed Shikakai denture cleanser exhibited fairly well anti *S. Aureus* and *E.Coli* activity as compared to the standard Cefixime medication. The results of the present research highlighted that the Shikakai has the potential to act as a denture cleanser.

KEYWORDS: Denture cleanser, Shikakai, *Staphylococcus aureus*, *Escherichia coli*.

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**TITLE: CELLULAR TRAFFICKING OF NANOCARRIERS IN ALVEOLAR
MACROPHAGES FOR EFFECTIVE MANAGEMENT OF PULMONARY
TUBERCULOSIS**

AUTHORS: VIPUL A. SANSARE^{1,2}, DEEPA U. WARRIER¹, UJWALA A. SHINDE¹



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ABSTRACT:

The aim of the present study was to design mannose anchored rifampicin nanostructured lipid carrier for active targeted drug delivery to alveolar macrophages. Targeting ligand, N-octadecyl-mannopyranosylamine was synthesized and characterized. Rifampicin loaded nanostructured lipid carriers were composed of stearic acid, oleic acid and targeting ligand and were prepared by melt homogenization ultrasonication. The N-octadecyl-mannopyranosylamine decorated rifampicin loaded nanostructured lipid carriers were further characterized for physical state of component, *In-vitro* release, *in-vitro* lung deposition, drug loading as well as drug antimicrobial activity on *Bacillus subtilis* strain. Moreover cytotoxicity and cell internalization ability were evaluated on alveolar macrophages RAW 264.7 cell lines by confocal laser scanning microscopy. The nanostructured lipid carriers exhibited good aerodynamic characteristics and sustained drug release profile with preserved antimicrobial activity. The studies on cell lines demonstrated non-cytotoxicity of nanocarriers. The mannose anchored nanocarriers were found to internalize efficiently in cell cytoplasm than unconjugated nanocarriers. The prepared alveolar macrophages targeted rifampicin loaded nanostructured lipid carrier exhibited suitable features for inhaled therapy and could be considered as a promising avenue for tuberculosis therapy by means of a dry powder inhaler device.

KEYWORDS: Tuberculosis, Rifampicin, Inhalable Nanostructured lipid carriers, Mannose conjugation, Macrophages targeting

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TITLE : PHOSPHOLIPID BASED NANOVESICULAR DELIVERY OF BOSWELLIC ACIDS FOR IMPROVED ANTIARTHRITIC ACTIVITY

AUTHORS : Rucheera Verekar¹ Poonam Usapkar¹, Shailendra Gurav¹, Arun Joshi¹, Anant Bhandarkar¹ Nilambari Gurav², Pradnya Jagtap³

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ABSTRACT:

Naturosomes (also known as herbosomes/phytosomes) are amphiphilic phospholipid complexes of drugs bearing active hydrogen and emerged as a promising approach to enhance the bioavailability of active constituents. Boswellic acids are pentacyclic triterpenic acids isolated from the oleo gum resin of Indian variety i.e. *Boswellia serrata* (Burseraceae) and used to treat rheumatoid arthritis and osteoarthritis. Present research investigation aims to develop, characterize and evaluate nanovesicular naturosomal delivery of *Boswellic acids* on biological ground.

Phyto-phospholipid complex of *Boswellic acids* were prepared by solvent evaporation technique using QbD approach. The prepared naturosomal formulations were evaluated for physicochemical (particle size and zeta potential analysis) and functional attributes. The FTIR, DSC, PXRD, Photomicroscopy, SEM and the TEM studies indicated the successful formation of vesicular drug-phospholipid complex. The apparent solubility, the *in-vitro* dissolution, and the *ex-vivo* permeability studies indicated a significant improvement in the aqueous solubility, the drug release, and the membrane permeation of the *Boswellic acids* from the naturosomes respectively. Boswellic acid naturosomes were formulated in topical gel formulations and subjected for skin irritation study, *ex-vivo* permeation in rat skin and *in-vivo* anti-arthritic efficacy by formalin induced paw oedema animal models.

Present study confirmed naturosomes as a promising strategy to improve the aqueous solubility and bioavailability of Boswellic acids.

KEYWORDS:

Naturosomes, *Boswellic acid*, Phyto-Phospholipid complex, Bioavailability, Anti-arthritic activity

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TITLE: Formulation and Evaluation of emulgel

**AUTHORS: Chodankar Diksha, Kudchadkar Sachi, Gude Rajashree,
Narvekar Rakshanda***

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ABSTRACT:

The present study focused on the formulation of Flurbiprofen emulgel which is used in the treatment of rheumatoid arthritis. Flurbiprofen is a NSAID belonging from BCS Class II used in the management of pain and inflammation. Oral administration of Flurbiprofen for long term produces gastrointestinal side effects. Formulating Flurbiprofen into emulgel prevents the gastrointestinal side effects of the drug.

The aim of the present study involves formulation and evaluation of Flurbiprofen emulgel. Emulgels were prepared using same ratio of drug and polymer and different ratios of emulsifier and oil base. Formulations were evaluated for different parameters. The drug content of the formulations were found to be in the range of 97.9 to 100.8%. The in-vitro release studies for all the formulations were carried out for a period of 8 hours.

The release kinetics data showed that the formulations follows first order kinetics with Non-Fickian diffusion controlled release. The in-vitro drug release from the formulated emulgel was found to be extended over longer period of time as compared to the marketed Flurbiprofen gel.

All the test results obtained were acceptable and were found to be stable in gel base.

Method development of Flurbiprofen was carried out using 0.1 N NaOH and Methanol:Water (50:50 v/v) ratio by using UV Spectrophotometric method. λ_{max} of the drug FLB was found to be 247nm in both the solvent systems. The method was validated using ICH guidelines.

KEYWORDS: Flurbiprofen, emulgel, anti-inflammatory.

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TITLE: A NOVEL SYSTEM FOR THE TREATMENT OF
ONYCHOMYCOSIS THROUGH TRANSUNGAL ROUTE



AUTHORS: Preetesh S, Suman V, Krati N, Rajashree Gude

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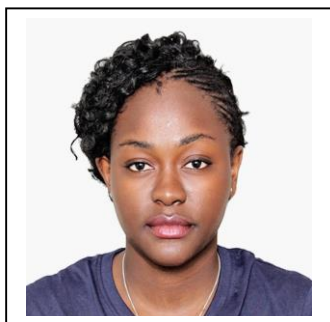
ABSTRACT: Onychomycosis is a chronic fungal infection that affects the nail plate and the nail bed caused by dermatophytes and it is the most difficult to manage and eradicate and tends to recur. Itraconazole is drug of choice for onychomycosis treatment with broad spectrum of activity and highly lipophilic molecule that gets accumulated in nails. The present aim of the study was to develop a novel formulation of itraconazole which can be delivered through transungal route. Itraconazole liposomes were prepared by thin film hydration method and optimised by using Central composite design. Influence of drug: lipid and lipid: cholesterol ratio on entrapment efficiency and drug release was studied. The optimized formulation was analysed for parameters such as particle size, polydispersity index and zeta potential which were found to be 277nm, 0.265 and -30.6mv respectively. Entrapment efficiency and drug release of the formulation was found to be 96% $\pm$ 1.2 and 78% $\pm$ 0.2 respectively. Lyophilized liposomes of itraconazole incorporated in to a nail lacquer base was studied for physical parameters, drug content, *in vitro* drug release, antifungal activity and invitro transungal permeation study. The amount of drug permeated from itraconazole nail lacquer was 33.51 μ g/cm²/hr which was found to be higher than the minimum inhibitory concentration responsible for its antifungal activity. The Formulation was found stable for a period of 3 months at 25°C and 60% RH. It was concluded that Itraconazole loaded liposomes in nail lacquer base can be a promising delivery system for the treatment of Onychomycosis.

KEYWORDS: Onychomycosis, Thin film hydration technique, Central Composite Design

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**TITLE: PREPARATION, EVALUATION AND OPTIMIZATION OF NANOPARTICLES
OF ANTICANCER DRUG DOCETAXEL**



**AUTHORS: YODJEU PABO; Dr PRAKASH RAO;
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ABSTRACT:

The current research based on formulation of nanoparticles of Docetaxel had for objectives to develop and optimize the nanoparticles and also to extend the release period of drug in stomach and reduce the dose frequency, the stability studies of the formulation was also performed. The prepared nanoparticles were evaluated for entrapment efficiency, drug release capacity at 1H, 5H AND 10H, particle size, and it was found that the nanoparticles formulation of Docetaxel formulated by polymer dispersion method has a maximum entrapment efficiency of 87.15% (w/w), drug release capacity at 1H of 39.24; at 5H of 67.66; at 10H of 92.03, particle size of 127.2 nm out of all the four formulations (F1-F4).

The DSC Studies melting peak appeared at 168.243C for Docetaxel. There was no change in melting point of binary mixture of Docetaxel, pectin and Docetaxel tri hydrate Nanoparticles which indicate that there is no interaction between drug and polymers. The in-vitro release of docetaxel tri-hydrate from the prepared nanoparticles formulation was studied in Phosphate buffer pH 6.8 for 10 hours. As the concentration of polymer increased, the drug release also decreased proportionally. The highest release of the drug took from the formulation F1.

Docetaxel binds to microtubules reversibly with high affinity and has a maximum stoichiometry of 1 mole docetaxel per mole tubulin in microtubules. Docetaxel is administered via a one-hour infusion every three weeks over ten or more cycles.

Nanoparticles of Docetaxel have been successfully formulated as it was observed Optimizations of polymeric nanoparticles are mainly made based on particle size, drug content, entrapment efficiency.

KEYWORDS: Docetaxel, Pectin, Polymer dispersion method.

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**DEVELOPMENT AND CHARACTERIZATION OF MICROSPHERES FOR THE
TREATMENT OF ULCERATIVE COLITIS**



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ABSTRACT: The objective of the study was to develop Microspheres of prednisolone sodium Phosphate for the better treatment of ulcerative colitis, with reduced side effects, controlled release and patient compliance. The prednisolone Microsphere formulation were prepared by ion gelation method by incorporation of polymer like chitoson and sodium Tripolyphosphate. The compatibility was studied by FTIR which has no evidence of any physical or chemical interaction with drug and polymers. The prednisolone microspheres were evaluated in terms of particle size, surface morphology, DSC, Drug Entrapment Efficiency and In-vitro drug release. The drug released studies were performed in stimulated gastric fluid (pH7.4) for 10h at 37°C±1°C with 100rpm. The optimized formulation (F9) provides sustained release of drug of drug up to 82.18% in 10h. The optimized formula showed no significant changes on stability studies when stored at 40°C/75% RH for three month according to ICH guidelines. The r^2 values of zero order of all the formulation have shown higher values which indicates the drug release is directly proportional to time which means release of Prednisolone Phosphate sodium follows zero order. But n values range from 0.764 to 0.926 which indicate non-Fickian diffusion mechanism. The data obtained in the study suggested that microspheres of prednisolone sodium Phosphate can be successfully designed controlled drug delivery.

KEYWORDS: Prednisolone sodium phosphate, Chitoson sodium Tripolyphosphate, Ion gelation, Microspheres

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**TITLE: FORMULATION AND EVALUATION OF NANOSUSPENSION OF
ROSUVASTATIN BY QBD APPROACH**



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ABSTRACT: Nanosuspension is new carrier-free colloidal drug delivery system with nano-sized particles below 1000 nm with reduction of drug particles into submicron range leading to a significant increase in dissolution rate & therefore enhances the solubility. Rosuvastatin is lipid lowering agent, which has low solubility and low bioavailability of 20 % with oral administration. Rosuvastatin nanosuspension was made by Emulsification Solvent Diffusion technique in the presence of PVP K-30 as stabilizer, Poloxamer-188 and SLS as surfactant with the QbD approach. A 2² factorial design was employed to study the effect of independent variables and dependent variables. Amount of SLS (X1) & amount of PVP K-30 (X2) were taken as QTPP's and CQA's were total drug content (Y1) PDI (Y2). Prepared nanosuspension was evaluated for its Particle size, Zeta potential, SEM, TEM, and in-vitro drug release study. The Particle size & the Zeta potential of the optimized formulation were found to be 215 nm and -35.2 mV. The rate of dissolution of optimized formulation was enhanced by 89 % in 60 minutes.

KEYWORDS: Nanosuspension, Rosuvastatin, Particle size, Quality by Design.

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TITLE: Formulation And Evaluation Of Bilayer Tablets Of Atorvastatin Calcium And Aspirin

AUTHOR : Neha Londhe , Vinodh S. Mannur, Dylan A. Furtado, Vinayak S. Mastiholimath



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ABSTRACT: Aspirin and statin group active agents in combination is reported to decrease mortality rates of cardiovascular diseased patients. Atorvastatin Calcium (ATV) and Aspirin (ASP) can be used in combination for the mitigation of Myocardial Infarction (MI). Formulation and evaluation of bilayer tablets containing ATV as the immediate release layer and ASP as the sustained release layer was the objective of this work. ATV immediate release layers were formulated using sodium carboxymethylcellulose, sodium starch glycolate, croscarmellose sodium and crospovidone as superdisintegrants. ASP sustained release layers were formulated using polymers viz., ethylcellulose and different grades of HPMC (K4M, K15M, K100M). The optimized formulations of both ASP and ATV were compressed into tablets using a Rimek tablet press by direct compression method. The immediate release ATV layer containing 8% crospovidone and ASP sustained release layer containing 30% HPMC K100M, which extended the release for 12h, were selected as the optimized formulations. Atorvastatin Calcium was formulated as the immediate release layer using super disintegrants amongst which tablets containing crospovidone showed 97% drug release within 40 min. After precompression studies of the optimized formulations, bilayer tablets were prepared by double compression of the ATV powder blend over the ASP powder blend. The prepared tablets were then evaluated for hardness, thickness, weight variation, friability, content uniformity and *in vitro* disintegration time. All the physical parameters were within acceptable limits of the pharmacopeial specifications. The results of the present study indicated the potential to use crospovidone as a superdisintegrant for the immediate release of atorvastatin calcium and HPMC K100M as a matrix polymer to retard the release of aspirin in the preparation of the bilayer tablet.

KEYWORDS: Atorvastatin Calcium, Aspirin, Bilayer Tablets, Immediate Release, Sustained Release.

Formulation and evaluation of oral in situ gel for anti ulcer drug

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Abstract

The objective of the present research work formulation and evaluation of in situ gel for Rabeprazole sodium, used as anti-ulcer agent which lowers the release of gastric acid and prevent from ulceration. The in situ gel formulation were prepared by sample mixing based ionic cross-linking system by incorporation of various polymers like, sodium alginate, calcium chloride and sodium citrate in different proportions. The same was evaluated for clarity, drug content, in vitro drug release. FT-IR studies revealed that there was no interaction between the drug and polymers used in the study. The optimized formulation provides sustained release of drug up to 92.48% in 10 hours. Optimization was done by using design expert software. The optimized formula showed no significant changes on stability studies when stored at 40°C/75%RH for three month according to ICH guidelines. The drug release mechanism from optimized formulation was found to be diffusional. Thus the release of the drug from the dosage form was found to be time independent. It also showed almost linear regression in Higuchi's plot which conforms that diffusion is one of the mechanism for drug release and n value of peppas plot was found to be 0.946-0.981. So it indicates the drug release followed Fickian diffusion controlled mechanism.

Keywords : oral in-situ gel, Rabeprazole sodium, sodium alginate, calcium chloride.

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**TITLE: OSMOTIC DRUG DELIVERY OF ANTIVIRAL DRUG ZIDOVUDINE USING
SWELLABLE CORE TECHNOLOGY**



**AUTHORS: First author : Miss Ayesha Naik
Second author : Master Aprant Karbotkar
Third author : Dr. Ajeet Godbole**

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ABSTRACT:

The objective of the study was to develop sustained release osmotic tablets of zidovudine by using swellable core technology (SCT) for the sustained release oral drug delivery system providing enhanced efficacy, reduced side effects and improved patient compliance. SCT formulation uses osmotic pressure and polymer swelling to deliver drugs to the GIT. Tablets were formulated into homogeneous core (single layer), tablet-in-tablet (TNT), and bilayer by using direct compression method. The SCT formulations consisted of a core tablet containing the drug (zidovudine) and a water-swallowable component coated using EUDRAGIT S-100. All the formulations were evaluated for pre and post compression parameters, FTIR studies revealed that the drug and the polymers are compatible and there are no interactions with the excipients. *In vitro* dissolution studies showed that all formulations showed release ranging from 57.93% to 97.5%. The F8 showed better *in-vitro* drug release of 97.5% and obeys "Koesmeyer-peppas" model and hence the best formulation was based on experimental data. It can be concluded that osmotic tablets of zidovudine can be successfully formulated by using swellable core technology.

KEYWORDS: Swellable-core technology, Zidovudine, Osmotic tablets, Homogeneous.

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**TITLE: DEVELOPMENT AND EVALUATION
OF SUBLINGUAL TABLETS CONTAINING SUMATRIPTAN
SUCCINATE AS A MODEL ANTIMIGRAINE DRUG**

AUTHORS: First author: Master Veyal Quadros
Second author: Miss Prasanna Naik
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ABSTRACT: The main objective of the research work was to prepare a drug loaded sublingual tablet which can bring in a quicker release of the drug from the dosage form in the treatment of migraine. Sumatriptan succinate is a selective 5-HT_{1B/1D} receptor agonist effective in the treatment of acute migraine. Sublingual tablets provide fast intended release. The tablets were prepared by direct compression method. The superdisintegrant used was sodium starch glycolate along with lubricant lactose monohydrate. All formulations were evaluated for pre compression and post compression studies and the results obtained were found to be satisfactory. The formulation containing 80% of lactose and 6% of SSG disintegrated faster and showed high *in vitro* drug release and can be adjudged as the best formulation.

KEYWORDS: _sublingual tablet, Sumatriptan succinate, Sodium starch glycolate , lactose

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TITLE: Stability indicating RP-HPLC method development and validation for estimation of steroidal drug Methylprednisolone in tablet dosage form



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ABSTRACT: A stability indicating RP-HPLC method for estimation of methylprednisolone was developed and validated for routine analysis of methylprednisolone in tablet dosage form using C18 column (250mm×4.6mm×5µm) with mobile phase consisting of Acetonitrile: Water: methanol in the ratio 40:40:20 at the flow rate of 1ml/min and injection volume was 10µl. The detection was carried out using UV detector set at 254nm. The developed method was validated as per ICH guideline. All validation parameters were found to be within acceptable limit. The drug was successfully analyzed with no interference from its excipients. For assessment of the stability, pure drug and sample was subjected to various stressed conditions; acidic, basic, photolytic, oxidative and heat. Degradation product did not interfered with the analyte peak. The method was found to be simple, economic, precise, accurate, and faster than in use method and can be used for routine analysis of methylprednisolone.

KEYWORDS: Analytical method, Methylprednisolone, RP-HPLC, Stability indicating Method, Validation.

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TITLE: VALIDATED UV-SPECTROPHOTOMETRIC METHOD FOR ESTIMATION OF AGOMELATINE IN BULK AND PHARMACEUTICAL DOSAGE FORMS



AUTHORS: TUSHAR POWALKAR^{*1}, V. S. MASTI HOLIMATH¹, V. S. MANNUR¹, RAJPUT PRATIMA NEMU¹

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ABSTRACT: In the present research attempt has been to develop and validate new UV-Spectrophotometric method for estimation of Agomelatin in bulk and its pharmaceutical dosage forms. UV-Spectrophotometric method was developed by utilizing solvent system composed of methanol: phosphate buffer (50:50 v/v). Agomelatin showed maximum absorbance wavelength at 229 nm. The method was optimized and validated in terms of specificity, selectivity, linearity, precision, robustness, ruggedness, accuracy and solutions stability as per ICH guidelines. Agomelatin showed linear response between the concentration ranges of 0.5-4 µg/mL. Newly developed method was found to be specific, selective linear, precise, robust, rugged and reproducible for estimation of Agomelatin with %RSD values less than 2%. The newly developed method was successfully applied for estimation of Agomelatin in its pharmaceutical dosage form. Hence newly developed and validated UV-Spectrophotometric method can be used for estimation of Agomelatin in bulk drug combination.

KEYWORDS: __ Agomelatin, Spectrophotometric, Stability, Robust, Estimation.

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TITLE: DEVELOPMENT AND VALIDATION OF SPECTROPHOTOMETRIC METHOD FOR DETERMINATION OF GENTAMICIN AND CURCUMIN IN BULK POWDER

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ABSTRACT: Gentamicin is a class of broad spectrum fluoroquinolone antibiotic used as antibacterial agent and its antibacterial effect found to enhance in the presence of Curcumin. In the present research work an attempt has been to develop new analytical method for determination of Gentamicin and Curcumin in its bulk powder. UV-Visible spectrophotometric method was developed by using water as solvent. Gentamicin and Curcumin showed maximum absorbance wavelength at 207 nm and 421 nm respectively. The method was optimized and validated in terms of specificity, selectivity, linear range, precision, ruggedness, reproducibility and solutions stability as per ICH guidelines. Gentamicin and Curcumin showed linear response between the concentration ranges of 2-10 µg/mL for Gentamicin and 4-24 µg/mL for Curcumin. Method was found to be precise, rugged and reproducible with %RSD values less than 2%. Hence newly developed, optimized and validated UV-Spectrophotometric method was found to be simple, selective, specific, linear, precise, rugged, reproducible and economical and can be used for simultaneous determination of Gentamicin and Curcumin in bulk drug combination.

KEYWORDS: Antibacterial, Gentamycin, Curcumin, Spectrophotometric, Stability.

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**TITLE: DEVELOPMENT AND VALIDATION OF RP-HPLC METHOD FOR
SIMULTANEOUS ESTIMATION OF ACECLOFENAC AND PANTOPRAZOLE
IN BULK AND TABLET DOSAGE FORMS**



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ABSTRACT:

In present research work an attempt has been made to develop and validate new reverse phase-high performance liquid chromatographic method for simultaneous estimation of Aceclofenac and Pantoprazole in bulk and tablets dosage form. The reverse phase chromatographic elution using HPLC was carried out in isocratic mode on C-18 column (Phenomenex Luna 10 μ m, 250 mm X 4.6 mm) as stationary phase utilizing a mobile phase composed of acetonitrile: ammonium acetate buffer (50:50 v/v) with a flow rate of 1.0 ml/min. The analysis was performed at ambient temperature and detection of separated components was carried out using UV detector at 282 nm. The retention time of Aceclofenac and Pantoprazole was found to be 2.9 min and 4.1 min respectively. The newly developed RP-HPLC method was validated in terms of linearity and range, system suitability, specificity, precision, sensitivity, robustness, ruggedness and accuracy as per ICH guidelines. The linearity was observed between the concentration ranges from 10-100 μ g/ml with correlation coefficient 0.9998 for both the drugs. The precision assays values were found to be less than 2% for both the drugs. The mean percentage recovery values for Aceclofenac and Pantoprazole was found to be 99.33-99.50 % and 99.43-100.67 respectively. Based on the results obtained the proposed method can be regarded as simple, specific, precise, sensitive, robust, rugged and accurate and can be used for routine quality control analysis of Aceclofenac and Pantoprazole in bulk and tablets dosage forms.

KEY WORDS: Aceclofenac, Pantoprazole, HPLC, Simultaneous Estimation, ICH guidelines.

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**TITLE: Green Approach for the Synthesis of Pharmaceutically
Important Heterocycles**

AUTHOR: Dr. Sonia B. Parsekar



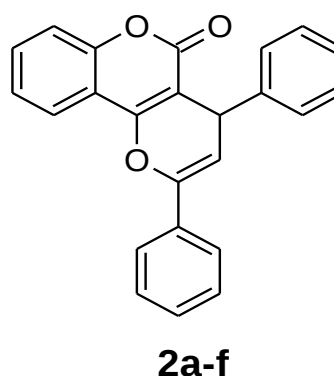
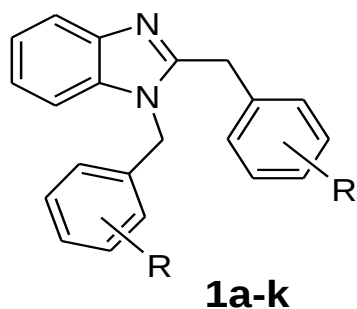
**COLLEGE ADDRESS: Dhempe College of Arts and Science,
Miramar-Panaji, Goa - 403 001.**

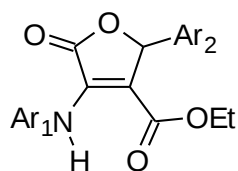
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ABSTRACT:

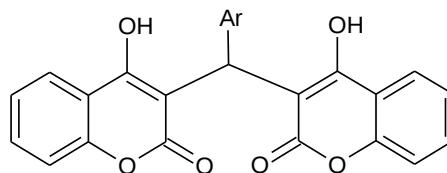
Chemistry has changed for ever the way we live during the twentieth century. The greatest perceived benefits to the general public, have come from the pharmaceutical industry with development of various drugs. But in doing so it has simultaneously created lot of pollution, caused environmental damage and has put life on earth in danger. The challenge for the pharmaceutical industry in the twenty-first century is to continue to provide the benefits we have come to rely on in an economically viable manner, but without the adverse environmental side effects. Hence, the role of todays chemist is to develop processes and design products, which can either eliminate or minimize the generation and use of toxic products, thereby reducing the environmental damage and this can be achieved by using the concept of Green chemistry. Green chemistry is considered as a revolution which addresses various issues related to synthesis of chemical compounds i.e. prevention/minimization of waste, atom economy, the use of less lethal chemicals and safer solvents, energy efficiency and use of green catalysts.

Many of the reported procedures for the synthesis of heterocycles are associated with certain drawbacks such as, use of costly metal catalysts, multistep strategies, longer reaction time, use of highly volatile organic solvents, tedious work-up procedures, difficulties in the isolation of the product, generation of toxic waste and creates environmental issues. We have developed greener methods for the synthesis of biologically important heterocycles such as 2-Aryl-1-arylmethyl-1H-benzimidazoles (**1a-k**), pyranocoumarins (**2a-f**), 3,4,5-substituted furan-2(5H)-ones (**3a-h**) and biscoumarins (**4a-q**) by utilization of principles of green chemistry.





3a-h



4a-q

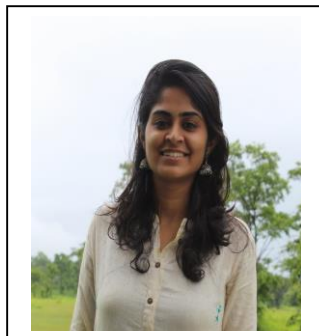
KEYWORDS: 1. Pharmaceutical; 2. Green Chemistry; 3. Heterocycles; 4. Benzimidazoles; 5. Pyranocoumarins; 6. Biscoumarins.

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**TITLE: DOCKING, SYNTHESIS AND IN VITRO
ANTICONVULSANT ACTIVITY OF SUBSTITUTED
1-(4-METHOXY-1-PHENYL/ METHYL-2-THIOXO-1,2-
DIHYDROQUINOLIN-3-YL)ETHANONE**

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SECOND AUTHOR- Riya Swar.*
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ABSTRACT:

The present work deals with the synthesis of a series of **substituted 1-(4methoxy-1-phenyl/methyl-2-thioxo-1,2-dihydroquinolin-3-yl)ethanone** [IVa/b(15)] derivatives and evaluation of their anticonvulsant. The sequence of reactions consists of the initial synthesis of 1-(4-hydroxy-1-phenyl/methyl-2-thioxo-1,2-dihydroquinolin-3-yl)ethanone (IIa/b) from 3acetyl-4-hydroxy-1-phenyl/methyl quinolin-2(1H)-one (Ia/b) using P4S10/Al2O3 as thionation agent; followed by methylation of the hydroxyl group at 4th position of 1-(4-hydroxy-1-phenyl/methyl-2-thioxo-1,2-dihydroquinolin-3-yl)ethanone (IIa/b) with dimethylsulphate to produce 1-(4-methoxy-1-phenyl/methyl-2-thioxo-1,2-dihydroquinolin-3-yl)ethanone (IIIa/b) which were further subjected to **Crossed-aldol condensation** using different ketones to form dimer; substituted 1-(4-methoxy-1-phenyl/methyl-2-thioxo-1,2dihydroquinolin-3-yl)ethanone (IVa/b[1-5]). All the synthesized compounds were characterized by IR and NMR spectral data. All the synthesized derivatives were tested for their anticonvulsant activity in mice at the dose of 100 mg/kg body weight. Among all the synthesized compounds, compound (IVa-1), (IVa-2), (IVb-1) and (IVb-4) exhibited prominent **anticonvulsant activity** as it showed significant increase in latency to clonic and tonic seizures and 83% protection as compared to control group. Diazepam was used as a reference standard at the dose of 85mg/kg body weight. Molecular docking studies of the title compounds substituted 1-(4-methoxy-1-phenyl/methyl-2-thioxo-1,2-dihydroquinolin-3-yl)ethanone [IVa/b(1-5)] were carried out using Molegro Virtual Docker (MVD-2013, 6.0) software. Docking of the synthesized compounds with metabotropic glutamate receptor mGluR7 binding site (PDB ID: 3MQ4) exhibited favorable results. The MolDock Score of compound (IVa-2) showed highest binding affinity as compared to active ligand 2-[(2-carboxycyclopropyl)-3-(9H-xanthen-9-yl)-D-alanine and reference standard Diazepam.

KEYWORDS: Quinolin-2-one, crossed-aldol condensation, anticonvulsant.

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TITLE: THIAZOLE DERIVATIVES OF LINOMIDE FOR ANTI-CANCER



**AUTHORS- FIRST AUTHOR- Priyanka Tiwari
SECOND AUTHOR- Harishchandra Naik*
THIRD AUTHOR- S.N. Mamledesai**

**COLLEGE ADDRESS: Rajaram and Tarabai Bandekar College of
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ABSTRACT:

The current research work deals with the design, synthesis and characterization of a series of 6-substituted-4-hydroxy-1-(2-substituted thiazol-4-yl)quinolin-2(1H)-one derivatives and evaluation of their in vitro anticancer activity against MDA-MB (Breast cancer) and A549 (Lung cancer) cell lines.

The sequence of reactions consists of the initial synthesis of substituted 4-hydroxyquinolin-2(1H)-ones I(a-d) which were further subjected to condensation with chloroacetyl chloride to give 6-substituted-1-(2-chloroacetyl)-4-hydroxyquinolin-2(1H)-ones II(a-d) and finally condensation with thiourea or thiamide through Hantzsch's thiazole synthesis to yield twelve derivatives of 6-substituted-4-hydroxy-1-(2-substituted thiazol-4-yl)quinolin-2(1H)-ones [III(a-d)(1-3)]. All the synthesized compounds were characterized by UV, IR, ¹H NMR, ¹³C NMR & Mass spectral data. Molecular docking studies of the title compounds for 6-substituted-4-hydroxy-1-(2-substituted thiazol-4-yl)quinolin-2(1H)-one derivatives [III(a-d)(1-3)] were carried out using Molegro Virtual Docker (MVD-2013, 6.0) software. The synthesized compounds exhibited well conserved hydrogen bonds with one or more amino acid residues in the active pocket of EGFRK tyrosine kinase domain (PDB ID: 1m17) for anticancer docking study. The MolDock Score of compound 2-(4-(4-hydroxy-6-methyl-2-oxoquinolin-1(2H)-yl)thiazol-2-yl)hydrazin-1-ium iodide (III(d)-2) was -102.535 which was comparable to that shown by the standard Erlotinib ligand -116.362 for anticancer docking and was found to be the most cytotoxic as compared to the other synthesized derivatives, with IC₅₀ values of 346.12 µg/ml against A549 (Lung cancer) cell line and 6-substituted-4-hydroxy-1-(2-substituted thiazol-4-yl)quinolin-2(1H)-one {III(d)-3} with IC₅₀ values of against MDA-MB (Breast cancer) of 452.14 µg/ml

KEYWORDS: Anti-cancer Activity, Breast Cancer, Lung Cancer, Quinoline-2-one, EGFRK tyrosine kinase domain, Erlotinib ligand, Docking

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TITLE: DESIGN, SYNTHESIS AND IN-VITRO ANTI-ALZHEIMER ACTIVITY OF 3-BROMO-6-SUBSTITUTED-1-[(4SUSTITUTED)-BEZENESULFONYL]-QUINOLIN-2(1H)-ONE



AUTHORS: FIRST AUTHOR: Veda Narvekar
SECOND AUTHOR: Shilpa Tawde*
THIRED AUTHOR: S N Mamle Desai. (Department of Chemistry, PES's RTBCOP, Ponda-Goa)

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ABSTRACT: The present work deals with the synthesis of a series of 3-bromo-6-substituted-1-[(4-sustituted)-benzenesulfonyl]-quinolin-2(1H)-one {IIIa-d (1-3)} derivatives and evaluation of their in vitro **anti-alzheimer** and in vitro anticancer activity. The sequence of reactions consists of the initial synthesis of 3-bromo-6substituted-4-hydroxyquinolin-2(1H)-one {II a-d(1-3)} by treating 6substituted-4-hydroxyquinolin-2(1H)-one {I a-d(1-3)} with bromine in glacial acetic acid. Further coupling of {II a-d(1-3)} with substituted aromatic sulfonyl chlorides yielded the titled compounds **3-bromo-6-substituted-1-[(4sustituted)-benzenesulfonyl]-quinolin-2(1H)-one** {IIIa-d (1-3)}. All the synthesized compounds were satisfactorily characterized by IR and NMR and mass spectral data. Molecular docking studies of the title compounds {IIIa-d (1-3)} were carried out using Molegro Virtual Docker (MVD-2013, 6.0). **Docking** studies of all the synthesized compounds using CDK5 binding site (PDB ID: 1ung) revealed favourable results. Compound (III d – 3) with highest MolDock score showed similar binding pattern as that of the active ligand alosine-A. All the derivatives were evaluated for their in vitro anti-alzheimer's activity by Ellman's method. Among all the derivatives, 3-bromo-4-hydroxy-6-methyl-1((4-nitrophenyl) sulfonyl) quinolin-2(1H)-one(IIId-3) was the most active compound with IC₅₀ value of 32.81µg/mL which was comparable to the IC₅₀ value of standard drug donepezil (30 µg/mL).

KEYWORDS: Anticancer activity, 3-bromo-6-substituted-1-[(4sustituted)-benzenesulfonyl]-quinolin-2(1H)-one, Docking.

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TITLE: Physiochemical and Phytochemical screening of ethnomedicinal plants with Hepatoprotective potential.

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ABSTRACT:

In the present study, three medicinal plants prescribed by traditional healer for hepatoprotective ailment i.e *Ricinus communis* (leaves), *Microcos paniculata* (leaves) and *Tinospora cordifolia* (stem) were evaluated for physiochemical parameters and phytochemical screening. Physiochemical parameters such as moisture content, foaming index, swelling index, ash value and extractive value were determined. Phytochemical screening was carried out using methanolic extract of plants. The results of physiochemical parameters were comparable to that of standard values. Physiochemical screening showed presence of saponin, steroids, alkaloids, flavanoids and glycosides in *Ricinus communis*, whereas in *Microcos paniculata* flavanoids, saponins, carbohydrates, triterpenoids, carbohydrates, tannins were determined and in *Tinospora cordifolia* showed presence of carbohydrates proteins, tannins, flavanoids, saponins, glycosides, steroids, terpenoids and alkaloids.

KEYWORDS: Hepatoprotective, Physiochemical, Phytochemical screening, *Ricinus communis*, *Microcos paniculata*, *Tinospora cordifolia*.

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TITLE: Larvicidal screening and isolation of moieties from *Erythrina indica*

AUTHORS: Kushwaha Singh R, Raut Dessai N, Bhandarkar A, Joshi AB, Gurav S, Mohanty A*.

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ABSTRACT:

Erythrina indica belonging to Fabaceae is a native of coastal forest communities from East Africa, through South east to Australia. The bark of *E. indica* was extracted with 70% ethanol and subjected to preliminary larvicidal activity using 3rd instar larvae of *Anopheles stephensi*. The ethanolic extract of *E. indica* showed 28% and 72% mortality after 24 and 48 hours. This extract was further fractionated with ethyl acetate and subjected to open column chromatography which gave compound RSK-1 which was identified as 2-(5', 7-dihydroxy [2'',2''-(3'',4''- dihydroxy)-dimethyl pyrano]-(5'',6'', 3', 4'') flavanone using spectroscopic techniques.

KEYWORDS: *Erythrina indica*, Larvicidal activity, *Anopheles stephensi*,

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**TITLE: SCREENING OF ANTICANCER AND ANTI-OXIDANT
ACTIVITY OF LEAVES OF ANNONA RETICULATA
ON EAC INDUCED SOLID TUMOR**

**AUTHORS: AISHWARYA N.M¹, NAGARATHNA P.K.M²,
KASHIKANTH YADAV³, GODFREY.A⁴**

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ABSTRACT:

Cancer is the most serious public health problems in both developed and developing countries due to limited success in clinical chemotherapy . It is estimated that about 12.5% of the world population dies as a result of cancer (WHO, 2004). Due to the conventional therapies which cause serious side effects, there is a need to utilize alternative concepts or approach to the prevention of cancer . Studies have demonstrated that when chemotherapy and herbal medicines are combined, they raise the efficacy level and lower the toxic reactions .The aim of the current study was to evaluate the in vivo anticancer and anti-oxidant activity of leaves methanolic extract of *Annona reticulata* in Ehrlich Ascites Carcinoma induced solid tumor. To screen the anticancer activity of *Annona reticula*, tumor cells (1x10⁶ cells/mice) were injected into the hind limb intramuscularly for solid tumor formation on day zero. A day of incubation was allowed for multiplication of the cells and the treatment started from day 1 for a period of 14 days. Group 2 served as EAC control group, whereas Group 3 served as standard group which receives Standard drug 5-FU (20mg/kg/ip), & Group 4 & Group 5 served as treatment group which receives test drug A (low dose - 100mg/kg/po) & test drug B (high dose – 200mg/kg/po), doses were calculated as per OECD guidelines 420. During the treatment, the different groups were checked with different parameters like Mean survival time, %increase in life span, average body weight, tumor size, on 15th day the blood was withdrawn for hematological parameters like RBC, WBC, Hb count, SGOT, SGPT, ALP, and liver was isolated for histopathological studies. There was a significant decrease in the solid tumor volume in the tumor-induced mice after treatment with the extract. The hematological parameters were also normalized by the extract in tumor-induced mice. These observations are suggestive of the protective effect of Methanolic extract of leaves of *Annona reticulata* against Ehrlich Ascites Carcinoma (EAC) induced solid tumor. Similarly in vitro antioxidant activity was carried out on different models and results showed a significant activity at 200mg/kg body weight.

Key words: Ehrlich Ascites Carcinoma, 5-Fluorouracil, *Annona reticulata*

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TITLE : ETHNOLOGICAL VALIDATION OF
'MURCCHANA' PROCESS WITH REFERENCE TO
'ASHWAGANDHA GHRITA'
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ABSTRACT:

Background: *Withania somnifera* (L.) (family-Solanaceae), known as 'Indian ginseng' or 'Ashwagandha' is acclaimed as an effective adaptogen, immunomodulator, aphrodisiac, sedative etc. 'Ashwagandha ghrita' is a recognized ghee based Ayurvedic formulation. In some ancient texts, murcchana process is suggested for preparation of Ashwagandha ghrita.

Objective: Considering various benefits of ghee and 'Ashwagandha ghrita', this study was undertaken to evaluate probable effects of murcchana process on ghrita preparation with reference to time and storage conditions.

Materials & Methods: Ashwagandha ghrita samples were prepared separately using plain ghee (Indian cow's ghee) and murcchana ghee. These formulations were stored separately in different glass bottles at room temperature and 40°C/75%RH. Organoleptic characters (colour, odour, taste, texture and touch) and physicochemical parameters (acid value, peroxide value, iodine value, saponification value, unsaponifiable matter, refractive index and specific gravity) were determined after 3, 6, 9 and 12 months. Plain ghee and prepared ghrita were subjected for antioxidant evaluation by various *in-vitro* methods.

Results: Changes were observed in organoleptic characters and physicochemical parameters of plain ghee and Ashwagandha ghrita formulations. Alterations in these parameters were more pronounced at high temperature and on long storage. Ashwagandha ghrita prepared with murcchana process exhibited better antioxidant potential in all *in-vitro* methods.

Conclusion: The murcchana process was found to be beneficial towards quality of ghrita, so Ashwagandha ghrita must be prepared along with murcchana herbs.

KEYWORDS:

Cow ghee, Ashwagandha ghrita, *Withania somnifera*, Stability studies, Physicochemical evaluation, Organoleptic evaluation

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TITLE: EFFECT OF VIRGIN COCONUT OIL ON LEARNING AND MEMORY IN RATS.

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ABSTRACT: The present study was carried out to investigate the effects of virgin coconut oil on learning memory in rats. The animals were divided in four groups. Each group consisted of 6 animals. Morris Water Maze, Elevated Plus Maze, Novel Object Recognition Test (NORT) and Y Maze were used to evaluate cognitive enhancing activity of VCO in rats. VCO 2ml/kg and VCO 4ml/kg were administered orally via gavage method. Piracetam (200mg/kg) was used as standard drug and was administered intraperitoneally. Hyoscine Butylbromide (1mg/kg) was administered intraperitoneally to induce amnesia in rats. VCO 2ml/kg and VCO 4ml/kg showed significant improvement in learning and memory in all four behavioural models. In Morris Water Maze, VCO treated rats showed shorter transfer latency to platform, longer time spent on platform and longer time spent in platform quadrant. In EPM, rats treated with VCO showed significant reduction in transfer latency. In Novel object recognition test, VCO treated rats showed higher time spent in exploring novel object and better discrimination for familiar and novel object. The readings using Y Maze showed large variation among the groups itself, a concrete conclusion from this behavioral model could not be obtained. The results suggested that VCO 4ml/kg was sufficient enough to establish improvement in learning and memory and showed better protection from amnesia in rats

KEYWORDS: Virgin coconut oil, Morris water maze, Y maze, Elevated Plus maze, NORT

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**TITLE: STATISTICAL OPTIMIZATION OF THE MEDIUM
COMPONENTS TO ENHANCE PRODUCTION OF
THE ANTIBACTERIAL METABOLITE PRODUCED
BY *BACILLUS* SP. STRAIN BGUMS27**

AUTHORS: MANASI PAWASKAR¹ AND SAVITA KERKAR^{1*}

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ABSTRACT:

Bioactive metabolites from microbial sources have gained popularity due to their implications in human welfare. Rapidly multiplying *Bacillus* strains are known to produce potent bioactive compounds in order to compete with other organisms for their survival. Thus, our study focuses on enhancing the yield of an antibacterial metabolite produced by a hypersaline *Bacillus* sp. BGUMS27 against *Methicillin Resistant Staphylococcus aureus* (MRSA) using a statistical approach RSM (response surface methodology). Mannose as a carbon source, Soy peptone as a nitrogen source and Sodium chloride influenced the production of the antibacterial metabolite which was studied using (RSM). Highest yields were obtained with the concentration of 1% (w/v) mannose, 0.4% (w/v) soy peptone and 0.3% (w/v) sodium chloride in the medium. In addition, soy peptone showed a strong positive effect on the inhibition response of the metabolite. The yield of the metabolite from the optimized media obtained by RSM method (451.8µg/ml) was twice than that obtained from one-variable-at-a-time method (231.5µg/ml). Thus, RSM proved to be an effective statistical optimization approach for maximizing the yield of the metabolite from *Bacillus* sp. BGUMS27.

KEYWORDS: *Bacillus*, optimization, RSM, antibacterial

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TITLE: Recent Developments on Supplementary Protection Certificate (SPC) Regulation in Europe and Its Comparative Analysis with Patent Term Extensions of Australia, Canada, and USA.

AUTHORS: Mayur Kardile^{1†}, Archana Roy¹, and Manthan Janodia²

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ABSTRACT: Supplementary Protection Certificate (SPC) is a type of Intellectual Property Right which extend the patent term and is applicable to approved specific pharmaceutical and plant protection products in European Union (EU). On July 01, 2019, Regulation (EU) 2019/933 of May 20, 2019 came into force. It is also referred as “the SPC Manufacturing Waiver” Regulation and was published in the Official Journal of the EU on Jun. 11, 2019.

The Regulation was thoroughly studied during this research work and was compared with similar Regulations of Australia, Canada, and USA. During the study various aspects of these Regulations like term of protection, eligibility, fees, nature of protection provided by these Regulations, advantages and disadvantages were studied and compared with each other. This research work provides comprehensive information regarding the new Regulation of European SPC and its comparative analysis with United States of America and Australian Patent Term Extension (PTE) and Canadian Certificate of Supplementary Protection (CSP). It was found that on one hand, this new European Regulation provides exemption to Europe based Generic and Biosimilar companies to Manufacture products for Export and Stockpiling purpose during the SPC period and on the other hand, it reduces the period of indirect exclusive rights of Innovators. It has opened a door for European medicine manufactures to i) enter the market on day 1 after expiry of SPC and ii) export their products to such Countries where SPC is not in force or is not awarded. Few significant differences were observed from Country to Country v.i.z. maximum term of protection (e.g. 5 years in Australia, 5.5 years in EU, 5.5 years in USA, 2 years in Canada), eligibility criteria, possibility of paediatrics extension of protection (e.g. 6 months in USA and EU whereas Australia and Canada does not allow extension due to Paediatric studies), export exemptions (e.g. EU and Canada allows export during whereas Australia and USA do not allow), stock piling (e.g. Australia, Canada and USA do not allow, whereas in EU it is possible). Various important aspects of Regulations and research findings are discussed in this poster.

KEYWORDS: Certificate of Supplementary Protection, Marketing Authorization, New Drug Application, Patent Term Extension, Patent Term Adjustment, Regulatory Review Period, Supplementary Protection Certificate

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TITLE: COLLABORATIVE LEARNING EXPERIENCE BETWEEN GOA COLLEGE OF PHARMACY, PANAJI-GOA AND ST. LOUIS COLLEGE OF PHARMACY, ST. LOUIS-USA

AUTHORS: VEDITA HEGDE DESAI*, MS. RAKSHITA PARAB*, DR. MADHUSUDAN JOSHI*, DR. KENNETH SCHAFFERMEYER, DR. STEPHENIE LUCAS****



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ABSTRACT: MOU between Goa college of Pharmacy, Panaji-Goa and St. Louis college of Pharmacy, St. Louis-USA was signed on 6th Nov 2018 by the President of St. Louis college of Pharmacy, USA.

Pharmacy education in USA: Pharm D (integrated course of 7yrs).

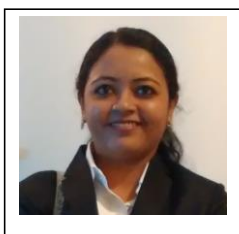
They have some excellent teaching –learning techniques using moodle databases. Teachers upload their teaching material on the database, Students are supposed to read the material before they attend the class. First five minutes of their class is a test on the topics covered for the last lecture and its only the core concepts that are explained in the form of case studies and discussions. Their practical work is more of skill based learning, their focus is more on the community practice rather than industry orientated learning. They have a well-equipped library with databases like Scopus, Embase, EBSCO, Lexi comp online, Daily Med, Micromedex etc.

Pharmacy Practice in USA: Dispensing of medication is based on individual dosage regimen that is calculated as per the need and diagnosis made by the physician, patient counseling is the primary job of a pharmacist in US. Administration of vaccines is also done at the pharmacy by the pharmacist and a thorough record of each patient is kept for any reference in the future.

Some of the major areas of concern where pharmacist play a key role are smoking cessation, use of contraceptives, diabetes care, hoarding of medication, misuse of opioids, alcohol consumption etc.

KEYWORDS: teaching-learning techniques, patient counseling, skill based learning, databases.

**2 Day Professional Development Program
Intellectual Property: Prosecution to Litigation
Part III: Asserting Exclusive Rights to IP**



TITLE: Comparative Study of Patent Opposition Procedures in Europe, Australia and South Korea

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ABSTRACT:

Here, an attempt is made to study patent opposition procedures in Australia, Europe and South Korea, analyze and compare the differences in the opposition procedures in the three geographies. Attempt is also made to delve the importance of opposition procedures as a tool to challenge weak patents in these countries. The patent opposition scenario in Australia has changed with the implementation of Raising the Bar Acts 2012. In Europe since the inception of EPO, the European nations have widely used opposition procedures. The South Korean patent office has implemented changes in the opposition procedures in 2017 wherein now South Korea has post grant opposition procedure. Study indicates that there exist substantial differences in the patent opposition procedures in Australia, Europe and South Korea in terms of timelines, basis of opposition, patentability criteria etc. The study of patent opposition procedures is particularly more important in the pharmaceutical sector as society benefits when frivolous patents do not block the entry of cost effective medicines, this is particularly important for the generic pharma industry across different regions. For this reason, it is necessary to study the administrative structure, and compare and contrasts the patent opposition systems in these regions. Patent Opposition procedures might enable access to affordable medicines for millions of people in the developing world. It may also help the easy and early access of generic medicines in different regions.

KEYWORDS: Patent Opposition, South Korea, Australia, European Patent Office (EPO), Generic

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**TITLE: REVIEW ON ETHOSOMAL-LOADED HYDROGEL
FOR TRANSDERMAL DRUG DELIVERY SYSTEM**

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ABSTRACT:

Transdermal drug delivery is a forward-looking approach which complements the constraints of standard drug delivery systems such as oral and injectable techniques. This delivery path enables both easy and painless delivery of drugs and a continuous release profile. Ethosomal hydrogel or Nano hydrogel is an innovative approach for transdermal drug delivery system which combines the benefit of both hydrogel as well as ethosome in delivery of drugs. Hydrogels possess a degree of flexibility very similar to natural tissue due to their significant water content and also helps in skin hydration which is one of the most important factors in determining the rate of percutaneous absorption of a given solute. The uses of carriers system, such as ethosomes have demonstrated promising results in transdermal drug delivery capable of delivering drugs to the deeper skin tissues more effectively and efficiently. This review highlights and presents an overview on ethosomal-loaded hydrogel, method of preparation, characterization, evaluation and application ethosomal hydrogel.

Keywords: Transdermal drug delivery system, Hydrogel, Ethosome, Ethosomal-loaded hydrogel, Crosslinking, Phospholipids.

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TITLE: - GST PERSPECTIVES OF INTELLECTUAL PROPERTY.

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ABSTRACT:

World Health Organization says 'Intellectual property' (IP) means, the overall term for property in the creation of the mind, including inventions, literary and artistic works, but also images, and designs. On July 1, 2017 the major step taken by Government of India was an implementation of 'Goods and Service Tax (GST). This content is intended to know some broad spectrum perspectives and impact of GST on intellectual property and related rights. It also focused on some major and minor changes impacting IP before and after implementation of the GST. Initially IP sometimes passed through double taxation when the same transaction was subjected to both sales tax and service tax due to the industry being cautious so as to avoid penalties of avoiding tax due to well defines and specified classification, With the advent of GST, the need to classify transactions involving IP as either relating to rendering of service or sale/deemed sale of goods was absolved. The introduction of GST at nascent stage, it is still to be seen as to how the implementation is carried forward. The GST has brought about a positive change by doing away with the need to classify transactions as either relating to goods or services. The detailed discussions are mentioned statistics with respect to accessed references to have sense and depth of GST impact on IP.

KEYWORDS: - Intellectual property, Goods and Service Tax, Sale, Service, Statistics.

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**TITLE: Tuberculosis, Current scenario, Treatment,
Its drawbacks and future prospectives**

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Deepali Bansode, Kakasaheb Mahadik**

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ABSTRACT:

Tuberculosis (TB) is one of the top ten causes of mortality and morbidity Worldwide. At present 10.0 million people around the World acquire TB disease, out of which 1 million cases occurred in infants and children. 1.6 million TB-related deaths worldwide, including 0.3 million infected with HIV. Multidrug-resistant TB (MDR-TB) remains a public health crisis, WHO estimated that there were 0.6 million new cases with resistance to rifampicin. 82 % had MDR-TB. Globally, TB incidence is declining about 2 % per year, which should be accelerated to 4-5 % to reduce TB risk. Increased number of drug resistant TB cases has prompted to think for the treatment alternatives for TB. The anti-TB agents are prescribed in combination as per the guidelines given by WHO. The Directly Observed Therapy Short-course (DOTS) program is followed for the treatment of TB. The patients are grouped according to site and severity of disease, sputum smear condition and patient history. The current treatment cannot hold the nerve of disease. To change the scenario, we need to focus on alternative treatment options and discovery of new drugs.

KEYWORDS: Tuberculosis, MDR-TB, XDR-TB, WHO, DOTS.