GOA – CENTER FOR EXCELLENCE IN INTELLECTUAL PROPERTY

5th Annual International Conference on

Protecting and Defending IPR:

Strategies and Challenges !!

Dec. 7-8, 2020
Goa College of Pharmacy
Panaji, Goa - INDIA

G-CEIP

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Goa – Center for Excellence in Intellectual Property

Umesh Banakar, PhD, Professor and Founder

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

Message …….

At the outset, it is my distinct privilege to welcome you to the 5th 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 on December 07-08, 2020.

UPCOMING MILESTONE EVENT/CELEBRATION [ON-LINE]

Theme: ***Protecting and Defending IPR: Strategies and Challenges !!***

Goa – Center for Excellence in Intellectual Property [G-CEIP]
At present, the Goa – Center for Excellence in Intellectual Property [G-CEIP] – first of its kind in India was established in 2016. The Center focuses on addressing the immediate need(s) focusing on IP considerations with an appropriate balance of academic training, continuous updating and upgradation of knowledgebase in IP matters and providing IP services to the industry in India with an objective to provide such services globally**.**

ACCOMPLISHMENTS OF G-CEIP AS OF DATE

- The Center has completed FOUR successful years
- Four international conferences in IPR with growing participation worldwide
- Two 2-Day focused intensive training courses in IPR for scientists (IP generators)
- Research Showcase Presentations – platform for researchers to showcase their potential inventions
- Sustained and growing sponsorships
- The Center has reached six states: Goa, Maharashtra, Karnataka, Haryana, Punjab, Andhra Pradesh
- The Center has reached four global scientific forums: ISC, IPC, SPDS, FPQL
- Third 2-Day focused intensive training course in IPR for scientists scheduled for February 2021
- Many more ….

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

We cordially invite you to participate in this celebration. We look forward to seeing you !!

Warm wishes,

Prof. Umesh Banakar,
President, Banakar Consulting Services, Westfield, IN 46074 USA
Founder: Goa – Center for Excellence in Intellectual Property [G-CEIP]

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TITLE: Advanced analytical techniques of the essential oil of *Myristica fragrans* by HPTLC and LC-MS on hypertension

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ABSTRACT:

Hypertension is a long-term medical condition where arterial blood pressure is elevated while forcing heart to work harder to pump blood to the rest of body causing thickness of left ventricle. Evaluation of the antihypertensive activity of *Myristica fragrant* species was observed by HPTLC and LCMS analytical technique. The Nutmeg seeds were collected and kept for maceration upon which phytochemical screening was done especially for the main phytoconstituent terpenes – camphene and α pinene. Maceration was performed based on increasing polarity index (petroleum ether, ethanol, chloroform, ethyl acetate, water) Qualitative phytochemical test was carried out on the extracts to determine chemical constituents which showed the presence of terpenes and it was further confirmed by analytical methods of HPTLC and LC-MS. Absorbance of 254 nm was chosen for solvent system of water –formic acid (A) at 100:0.1%v/v and methanol (B) at 40:60 v/v with an isocratic flow of 1 mL /min. The separation was made on an LCMS 2020 system equipped with single quadrupole mass spectrometer with electrospray ionization ESI (+) source with the positive ionization mode which showed the peak for α-pinene showing positive ionization of 137 kJ/mol, the camphene shows the positive ionization of 136 kJ/mol. The petroleum ether extract of *Myristica fragrans* confirms the presence of essential oil by both analytical techniques employed. Hence *Myristica fragrans* can be used as natural sources of antihypertensive as they could have great importance as therapeutic agents in preventing or slowing the progress of aging and age associated oxidative stress related degenerative diseases.

KEYWORDS: Hypertension, *Myristica fragrans*, HPTLC, LC-MS, camphene and α pinene

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TITLE: SYNTHESIS, BIOLOGICAL ACTIVITIES AND QSAR STUDIES OF 4-PHENYL-1,3-THIAZOLE SUBSTITUTED IMIDAZOLIDIN-4-ONE DERIVATIVES.

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ABSTRACT

This present study deals with design and evaluation of novel thiazole substituted - 4-imidazolidinone derivatives using multistep synthetic approach and to screen for in vitro anticancer activity. Recent literature survey revealed that 1,3-thiazole substituted imidazolidin-4-one derivatives was reported for their ability to improve biological activities but so far, no activity was reported. These compounds can be obtained by 3- step synthesis. Oxazolone derivatives can be obtained by 1-step synthesis and thiazole derivatives can be obtained by 2-step synthesis. Additionally, imidazolidinone derivatives are obtained by condensation of step – 1 and 2 products using a synthetic methodology to obtain a final target compound. Spectral identification of these derived compound will be done using IR, NMR, MS. Further, analysis of drug-likeness is predicted through these 5 parameters- Lipinski rule, Ghose, Egan, Vebers & Muegge rules. As molecular docking is routinely used for understanding drug-receptor interaction, the above-derived compounds were subjected to molecular docking studies. Finally, QSAR studies of the synthesized compounds were carried out. This hypothesis provides a possible explanation of the enhanced biological activity of the derived compounds.

KEYWORDS: Imidazolidin-4-ones, Docking studies, QSAR studies.

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TITLE: SYNTHESIS AND STUDIES OF 1-SUBSTITUTED 2-METHYL-4-NITROIMIDAZOLES AS POSSIBLE ANTIMICROBIAL AGENTS

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ABSTRACT:

Six novel imidazole analogs (**3 a-f**) were synthesized, characterized, evaluated for antimicrobial studies and molecular docking studies were performed in the active site of glucosamine-fructose-6-phosphate aminotransferase PDB ID: 2VF5. Characterization of newly synthesized compound was done by using FTIR, LC-MS and ^{1}H NMR. The synthesized compounds were studied for their antimicrobial activity. Three compounds (3a, 3c & 3e) were active against all the strains of bacteria that were used, but none of them were active against the strain of the fungi used. Molecular docking studies were carried out to understand the binding mode analysis. Docking results suggested that compound (3a) was most potent and selective towards glucosamine-fructose-6-phosphate aminotransferase PDB ID: 2VF5. Compound (3a) i.e. 2-(2-methyl-5-nitro-1H-imidazol-1-yl)-3-phenyl-1-(*p*-tolyl)prop-2-en-1-one displayed better results than the co-crystallised ligand GLP in the molecular docking studies. ADME profiling of the compounds was done to determine the physicochemical and pharmacokinetic properties.

KEYWORDS: Imidazoles; Synthesis; Molecular docking; Binding mode analysis; ADME.

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TITLE : *In silico* approach towards development of thiazolidinedione and rhodanine scaffolds as Antitubercular agents.

AUTHORS : Snehal Rajendra Thakar, Deepali Amol Bansode
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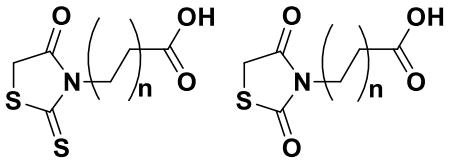
ABSTRACT:

Tuberculosis is one of the most severe disease, it is second leading cause of death Worldwide. The current treatment does not hold the nerve of the disease. Sulfonated compounds exhibit potent binding ability towards receptors. Previous results show sulfonated compounds exhibit good pharmacological activities. ***In silico*** studies shows carboxylic acid derivatives of Thiazolidinedione/ Rhodanine exhibit potent binding affinity towards KatG (PDB ID: 1SJ2). KatG is enzyme catalase-peroxidase which is activates Isoniazid for further biological action. The results shows propionic derivatives exhibit potential pharmacological activities.



Reference: Devi PB, Samala G, Sridevi P, Saxena S. Structure-Guided Design of Thiazolidine Derivatives as Mycobacterium tuberculosis Pantothenate Synthetase Inhibitors. 2014;1–11.

KEYWORDS: Thiazolidinedione, Rhodanine, Osiris data warrior, PDB, TB, Fluorinated, etc.

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TITLE: FORMULATION, CHARACTERIZATION AND EVALUATION OF MICELLAR LOADED COMPLEX OF *CUMINUM CYMINUM* TO TREAT RESPIRATORY INFECTIONS

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ABSTRACT:

Respiratory infection (RTI) is a viral spreading disease and it transmits from individual to individual, particularly in youngsters. The treatments are available but have so many limitations. To treat RTI, the phyto-constituent antibacterial drug cuminaldehyde (*Cuminum Cyminum* L.) was selected but it exhibits low bioavailability, poor water-solubility and is rapidly eliminated from the body. To overcome these issues, novel drug delivery (nanoparticle) based micellar loaded complex approach was adopted. In this study, the micellar (CM) was prepared by mixing of cuminaldehyde and soya lecithin using anti-solvent precipitation technique and further the micellar loaded complex (CLMC) was prepared by loading of micellar (CM) in aqueous solution of chitosan. The physical compatibility studies by DSC and FT-IR, demonstrated the confirmation of CLMC with soya lecithin and chitosan. The optimized CLMC and CM were irregular particle shapes and crystalline structures, with a mean particle size of 279.10±0.02 nm, 296.24±0.10 nm and zeta potential of -8.18 mV, -8.77 mV, respectively. The % entrapment efficiency and % drug loading of CLMC (72.13±0.26 %, 06.46±0.01 %) and CM (89.09±0.20%, 08.05±0.19 %) was found efficiently. The *in vitro* release rate of CM (88.09±0.41 %) was slower than CLMC (89.02±0.06 %) in pH 7.4 phosphate buffer up to 24 h by diffusion process (Korsmeyer Peppas model). Furthermore, CLMC has shown the potent *in vitro* antioxidant activity, susceptible antibacterial activity and significant anti-inflammatory activity as compared to CM against stress, microbial infection (*S. aureus* and *E. coli)* and inflammation which were causable reason for the respiratory infections. CLMC has shown the significant bioavailability and more efficient hematological parameters value on rabbit blood against the incubation of bacterial organism. CLMC may have the effective potential to treat RTI.

KEYWORDS: Respiratory tract infection (RTI); Complex of micellar loaded of cuminaldehyde (CLMC); Cuminaldehyde Micellar (CM); Cuminaldehyde (C).

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TITLE: IVET EMULGEL

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ABSTRACT:

Animal's lice are an emerging social problem, not only in economically poor countries but also in practically all other societies. IVERMECTIN EMULGEL is veterinary product which is used as anti-parasitic against ticks and lice. Emulgel are defined as "semisolid system in which a liquid phase is constrained within a polymeric matrix in which a high degree of physical and chemical cross-linking introduced". Currently soft gelatin capsules manufacturing units make use of gelatin to make in situ shells of soft gelatin capsules. After forming a capsules, a 'perforated sheet of gelatin' remains which is within microbiological limits. This sheet is bye product can be used to make an 'Emulgel'. Ivermectin is used to treat wounds caused by infestation with small mites that live under the skin.

In present study Ivermectin is used in the emulgel formulation as a drug which can kill parasite infestation and subsequent wounds to the animals & soft gelatin shows stypic effect simultaneously. Emulgel (o/w type) was prepared by using gelatin in aqueous dispersion medium and Ivermectin (poorly soluble in water) was dissolved in liquid paraffin (dispersed phase). From the many batches, one batch was selected as it shows good evaluation parameters.

Keywords: Emulgel, Ivermectin, Antiparasitic, Gelatin.

TITLE: Development and characterization of cocrystals of apixaban for bioavailability enhancement

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ABSTRACT:

The objective of the current study was to develop new co-crystals of Apixaban (APX) to improve its solubility and permeability. Twenty one conformers were selected for preparation of cocrystals and prepared and their saturation solubility was determined. From those Nine cocrystals found to have higher saturation solubility as compared to other i.e (NHS, PPZ, PPZC, VL, CFFN, PHTH, RES, ISN and BS) Cocrystals were selected for their in vitro diffusion study, and from those APX-CFFN Cocrystal found to have highest solubility and permeability as compared to other and its ex-vivo permeability on chicken intestinal membrane was performed. Hence, Apixaban, Caffeine selected for further (APX-CFFN Cocrystal) preparation and evaluation. In vivo study of APX-CFFN Cocrystal on wistar han rats were performed. It was revealed from XRD and DSC studies that the drug was present in then crystalline phase and APX-CFFN Cocrystal found to have new crystalline phase. FTIR study indicates no interaction between conformer and drug. SEM analysis shows that prepared cocrystals (APX-CFFN Co-crystal) appeared as prismatic crystal. The molecular interaction between APX and caffeine was further studied by Raman spectroscopy. In-vitrostudy of pure APX and its cocrystals indicates higher drug flux from co-crystals than the free APX (4.99%). After 8 h, the permeation of APX from APX-CFFN was almost 3-fold than that of pure APX. Ex vivo permeation study shows percentage Cumulative APX permeated was 14.16% and 39.49% APX diffused from the APX and APX-CFFN Co-crystals, respectively in 8h, Flux of Apixaban (APX) and APX-CFFN Co-crystals is 71.36 µg/cm2/h and 559.09 µg/cm2/h respectively clearly indicating faster permeation of APX from the cocrystals. In-vivo study APX-CFFN co-crystals have shown significantly higher bioavailability (AUC0–t12881.556±934.013 ng h/mL) as compared to pure APX (AUC0–t 3505.95±258.910 ng h/mL). The time to reach Cmax (tmax) and Cmax were 1.0833333±0.204 h and 1647.3925±193.798 ng/mL, respectively, for the APX-CFFN co-crystals, while pure APX solution showed the same parameters as (0.91667±0.204 h and, 486.059±120.852 ng/mL, respectively). In vivo pharmacokinetic study indicated that liquid APX-CFFN co-crystals showed prolonged circulation time when compared to pure APX solution. Further tablets were prepared and the drug release of APX from the tablets (> 80%) was considerably increased when compared to the pure APX (55%) in both pH conditions phosphate buffer(pH 6.8) and phosphate buffer (pH7.4) after a period of 45 min.We conclude that the present investigation is an alternative approach for optimizing physicochemical and pharmacokinetic properties of BCS class-III drugs without changing its molecular structure and intrinsic bioactivities.

KEYWORDS:
Permeability, Cocrystals, Bioavailability, Raman spectroscopy, Diffusion, *In-vivo* study, *Ex-vivo.*

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TITLE: FORMULATION AND EVALUATION OF HERBAL CONTAINING AN ANTIFUNGAL DRUG FOR THE TREATMENT OF DANDRUFF INDUCED BY FUNGUS

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ABSTRACT

Dandruff is a common skin condition causing flaking skin and itchy scalp. Dandruff can affect the scalp or any area on the body that grows hair. The skin of the scalp is very thick that contains numerous glands. Malazessia is a yeast like fungus which lives in the healthy scalp of adults. Sometimes it may irritate skin on the scalp and more cells to grow. Wrightia tinctoria belonging to the family apocynaceace is a small deciduous tree distributed in central and peninsular India. It's used for the treatment of jaundice, seizures, wounds, leukemia, gynaecological disorders, psoriasis, eczema, scabies etc. Gels are relatively newer class of dosage form created by the entrapment of large amounts of aqueous or hydroalcoholic liquid in a network of colloidal solid particles. In spite of many advantageous of gel, a major limitation is the difficulty in delivering of hydrophobic drugs. So to overcome the limitations emulgels are prepared. When gel and emulsions are combined, the dosage form is referred to as emulgel. Emulgels for dermatological use have some favourable properties such as easily spreadable, emollient, longer shelf life .Emulgels using Wrightoria tinctoria oil can be useful to persons suffering from fungus induced and some other types of dandruff associated with scailing.

KEYWORDS: Wrightia tinctoria, Malazessia, herbal emulgel

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TITLE: Novel long retentive mucoadhesive Posaconazole ophthalmic suspension development with help of sodium alginate and carrageenan polymer system

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ABSTRACT

Ophthalmic solutions undergo rapid clearance from eye due to instant tear drainage, lower volume of cul-de-sac and lesser contact time with eye. These drawbacks of ophthalmic solutions results in less efficacious product or requires repeated dosing. Repeated dosing of formulation leads to lesser patient compliance and adverse effects. Limited information is available on polymer synergy used in ophthalmic formulations. There was a need to identify synergies among various polymeric ingredients which could increase adhesiveness for development of sustained release ophthalmic formulations. Formulation adhesiveness is the function of viscosity being directly proportional; it plays a major role to sustain the drug release by increasing the contact time in eye with help of muco-adhesive forces or by polymer inter-penetrated network (IPN). Choice of selection of polymeric ingredients were based on their individual viscosities. Significant synergies were considered for those combinations which have higher viscosities compared to their individual viscosities at lower concentrations. Sodium alginate and carrageenan synergistic polymer system was identified with help of design of experiments. Using this synergistic polymer system long retentive posaconazole ophthalmic suspension was developed with help of quality by design (QbD). The developed formulation was characterized for homogeneity, pH, particle size, viscosity, osmolality, rheology study, mucoadhesive strength, contact angle, assay of posaconazole and benzalkonium chloride, impact on degradation product due to sterilization of vials, in-vitro drug release, eye irritation test and pharmacodynamic efficacy. A stable long retentive posaconazole ophthalmic formulation was developed based on principles of quality by design and as per industrial standards.

KEYWORDS: Polymer, Posaconazole, Ophthalmic

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TITLE:
Comparative study on in-vitro acid neutralization by natural products from plants /animal origin.

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ASTRACT:

Hyperacidity means, excessive formation of acid in stomach. The currently used drugs for treatment of hyperacidity are aluminum hydroxide and magnesium trisilicate, omeprazole, lansoprazole, ranitidine etc. These drugs are effective antacids but are associated with many adverse effects such as rebound acid secretion, diarrhea and constipation. The present study evaluates and compares antacid effect of broccoli, radish, cucumber, lemon juice and curd in an artificial stomach model which are known to alleviate hyperacidity. Vatier's artificial stomach model was used to the determining duration of consistent neutralization on artificial gastric acid and Fordtran's titration model was used todetermine neutralization capacity in-vitro against artificial gastric acid. This study disseminate that pH value of test samples are independent of temperature and cold milk and broccoli have highest antacid activity than ENO and NaHCO2. The present work concludes that natural food ingredients used in study exhibits significant antacid activity, justifying their use as essential dietary components to counter hyperacidity.

KEYWORDS:

Rebound acidity, Neutralization, Antacid activity, Artificial Gastric acid

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FORMULATION AND EVALUATION OF HERBAL EMULGEL USING NATURAL POLYMERS

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ABSTRACT:

Semisolid formulations are topical dosage form used for the therapeutic, protective or cosmetic function. They may be applied to the skin or used nasally, vaginally etc. The purpose of the study was to formulate an emulgel containing Minoxidil as drug for hair growth with the use of gelling gents like chitosan and fucoidan. Minoxidil is 2, 6-diamino -4-piperidinopyramidine-1-oxide chemically. It is an antihypertensive drug, a powerful vasodilator which act by direct relaxation of arteriolar smooth muscle. In this work, first gelling agents are selected for the formulation of emulgel. Main polymers which are selected are chitosan, xanthan gum, sodium alginate and fucoidan. By various evaluation tests, chitosan-fucoidan combination were selected as the gelling agents for the preparation of emulgel. Fourier transform infrared spectroscopy was performed to identify any physicochemical interaction between drug and polymers. The various evaluation parameters such as pH, viscosity, spread ability, drug content, in vitrodrug release etc. were conducted. Release kinetics by various models of best formulation were studied.

KEYWORDS: Emulgel, Minoxidil, chitosan, fucoidan

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TITLE: DESIGN, FABRICATION AND EVALUATION OF NANO AND MICRO PARTICLES BASED INHALABLE SYSTEMS FOR TREATMENT OF PULMONARY TUBERCULOSIS.

AUTHORS: VIPUL SANSARE[1, 2*], PRITI RAY[1], DEEPA WARRIER[1], UJWALA SHINDE[1]

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ABSTRACT

Tuberculosis (TB) was declared to be a global emergency with emergence of Multidrug Resistant TB (MDR-TB) and Extensively Drug Resistant TB (XDR-TB). Rifampicin is one of the first line drugs used in treatment of MDR-TB. Particulate carriers like nanoparticles and microparticles are biocompatible, non-toxic for internalization by macrophages, and can provide sustained drug release. This study focuses on design of rifampicin loaded nanoparticles and microparticles followed by its characterizing effervescent DPI with effervescent pair (citric acid and sodium bicarbonate). The drug and stabilizer concentration in nanoparticles was successfully optimized using 3^2 factorial design using DESIGN EXPERT. The rifampicin nanoparticles and microparticles were further converted to spray dried powder using effervescent carrier.
The mass median aerodynamic diameter and fine particle diameter of both spray dried formulations were similar and suitable for deep lung deposition. These findings are suggestive that effervescent technique can be successfully employed to improve redispersibility of rifampicin nanoparticles. Optimized RIF-microparticles revealed particle size (6.597±0.2023µm), zeta potential (-27.1333±0.3215mV) and good entrapment efficiency (67.5±4.88 %). *In-vitro* cytotoxicity study in macrophage cell-line RAW 264.7 by MTT cell viability assay revealed 30% decrease in cell viability with RIF- microparticles, whereas RIF solution showed only 6% reduction in cell-viability. Blank- microparticles demonstrated similar toxicity effect to that of RIF- microparticles, indicating toxicity of components of RIF- microparticles. In-vitro uptake study in Murine Macrophage Cell-line RAW264.7 revealed that uptake of RIF was higher for RIF- microparticles as compared to RIF solution.

KEYWORDS: Pulmonary tuberculosis, Rifampicin, Nanoparticles, Microparticles, Cellular uptake study, MTT assay

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TITLE: Enhancing biopharmaceutical attributes and antimalarial efficacy using Lipocomplex of lumefantrine

AUTHORS: RIPANDEEP KAUR[1], VARUN GORKI[2], OP KATARE[1], NEELIMA DHINGRA[1], RANJOT KAUR[1], MONIKA CHAUHAN[1], BHUPINDER SINGH[1]

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ABSTRACT: Lumefantrine (LF), an antimalarial drug, possesses activity against almost all human malarial parasites, but the *in vivo* activity of this molecule gets thwarted due to its low and inconsistent oral bioavailability (i.e., 4-12%). According to various reports, the intake of fat containing milk enhance the bioavailability of LF. However, during the infectious state, the patient could not comply with an adequate diet, resulting in therapy failure. Considering the aforesaid issues of therapy, the current studies entail the development of lumefantrine phospholipid complex (LPC). The solid-state characterization (FTIR, SEM, X-RD, hot stage microscopy) revealed the transformation of LF crystalline state to amorphous solid form thereby significantly improved the aqueous solubility of LF. The cytotoxicity studies on Hela and fibroblast cell lines demonstrated the safety of the LPC with selectivity index of 2065 and 4442 respectively. *In vitro* antimalarial activity against *P.falciparum* unravelled the potential of phospholipid based formulation to kill the parasite at, as 2.5 times lower IC_{50} value of LF was achieved. Significant enhancement in C_{max} and AUC by LPC *vis-à-vis* conventional LF suspension was obtained in pharmacokinetic studies. The results of differential leukocyte count and cytokine assay has delineated the immunoregulatory role of LPC along with a profound antimalarial activity with nearly 98% chemosuppression and over 35 days of survival.

KEYWORDS: Plasmodium, malaria, parasite, bioavailability, crystalline, amorphous, phospholipid, complex

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TITLE: QbD-Enabled Development of Solid Lipid Nanoparticles for Co-delivery of Sorafenib and Chrysin with Improved Biopharmaceutical Performance

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ABSTRACT: (NOT MORE THAN 250 WORDS)

The current studies were undertaken to investigate plausible synergistic potential of sorafenib (SFN) and chrysin (CHR) in combination as SLNs for cancer treatment. Initially, co-crystals of CHR were developed using neat grinding and vapour saturation techniques. Preliminary solubility studies of CHR and SFN in various solid lipids were carried out to choose the apt lipid. Taguchi OA screening design was employed during pre-optimization studies, while systematic optimization studies were carried out using a CCD. The optimized SLNs were thoroughly characterized for particle size, drug release and morphology. Cellular uptake studies of the SLNs in Caco-2 cell lines indicated greater uptake of the lipidic formulation as compared to the control. Cellular cytotoxicity assay indicated slowing down of the late apoptotic phase and necrotic phase of the cell cycle in MCF-7 cell lines when treated with SLNs co-loaded with SFN and CHR. Pharmacokinetic studies of SFN and CHR indicated that the drug plasma profile of rats administered with the optimized SLNs were able to significantly augment the oral bioavailability of both SFN and CHR. Pharmacodynamic study, following 28 days of administration of SLNs, showed notable reduction in the breast tumor size. The inhibitory action of CHR on the hepatic metabolic enzymes that are known to metabolize SFN, may have attributed in reducing first-pass metabolism of SFN, and hence improving upon its overall bioavailability to significant extent. Thus, concurrent intake of plant bioactive with promising antioxidant and anticancer potential may have further potentiated the anticancer activity of SFN.

KEYWORDS: Lipidic nanocarriers, bioactive, co-administaration, antioxidant, cyotoxicity, optimization, pharmacokinetics

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LIPID NANOPARTICLES OF CEFTAZIDIME FOR TARGETING BACTERIAL LUNG INFECTIONS FOLLOWING NEBULIZATION

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ABSTRACT:

Cephalosporins, owing to their limited permeability, achieve modest concentrations in the respiratory tract, upon parenteral administration. This results in switching over to continuous intravenous infusion or providing higher doses of drug to maintain drug levels above MIC of the bacteria, which are often associated with poor patient compliance and systemic adverse events. To combat these issues, inhalation of cephalosporins has been gaining importance for the suppression of *Pseudomonas* infection in the lungs, as well as for the treatment of pulmonary exacerbations. The current investigation, therefore, entails the development of inhalable lipid nanoparticles incorporating ceftazidime and a water soluble mucoadhesive polymer along with phospholipid, using thin film hydration, and following the principles of QbD, step-by-step. Central Composite Design was used to optimise the formulations. The optimized formulation has a particle size range of 210 to 240 nm, and 47.4 to 50.2 %. The data of FTIR, X-RD reveals the incorporation of ceftazidime into lipid nanoparticles. Furthermore, the nanoparticles safety and uptake were assessed on A549 and Calu-3 models. In a nutshell, the study describes the methodology and potential of a lipid nanoparticles in futuristic inhalation nanomedicine for the management of bacterial lung infections.

KEYWORDS: Lungs, Inhalation, Cephalosporin, *Pseudomonas aeruginosa,* Next-generation impactor, Surface activity

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TITLE: FORMULATION AND EVALUATION OF GASTRO FLOATING TABLETS FOR SUSTAINED RELEASE OF BACLOFEN

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ABSTRACT:

Background: Gastro-floating systems are retained in the stomach for a prolonged period. The objective of the present study was to formulate gastro floating tablets for the sustained release of Baclofen.

Methods: The physicochemical parameters like hardness, weight variation, in vitro dissolution studies, and floating lag time (FLT) were performed to optimize the Gastro-floating tablet formulations. Results: Post compression parameters were in pharmacopieal limits. The FLT of optimized formulation was found less than 5 min and floated on the test media (0.1N HCL) for up to 24 hours. In vitro release study stated that 98% drug was released at 12 hours. From the results of in vitro release kinetics, peppas model was found best fit due to the correlation coefficient (R) greater than 0.95. Based on the release exponent results (<0.45) showing a Fickian release mechanism where, the drug release was diffusion controlled. The hardness of tablet created a enormous effect on the floating behavior, for this reason its influence on FLT was evaluated. The FLTs were 5 min for the tablets with a hardness of 8 kg/cm2, which indicates that the FLT decreased with an increase in the hardness.

Conclusions: the formulated Gastro-floating tablets showed good buoyancy properties, thus could be a promising formulation for improving bioavailability and decreasing drug toxicity.

KEYWORDS: Baclofen, Gastro floating, floating lag time, hardness, buoyancy

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TITLE: FORMULATION DEVELOPMENT AND CHARACTERIZATION OF PIROXICAM INCLUSION COMPLEXATION

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ABSTRACT: (NOT MORE THAN 250 WORDS)

Over last few years, interest in the physical and chemical properties of inclusion complexes has grown considerably. One of the most important reasons for this is the relevance that inclusion complexes have to enzyme- substrate and drug- receptor interactions. The aim of this study was to enhance the solubility of Piroxicam using its inclusion complexation. The inclusion complexation of Piroxicam with β-cyclodextrin were prepared at 1:0.5, 1:1, and 1:2 w/w (Piroxicam/ β-cyclodextrin) ratios by Physical mixture, co-grinded mixture, kneading, solvent evaporation method. The interaction of Piroxicam with the β-cyclodextrin was studied by differential scanning calorimetry (DSC), Fourier-transform infrared (FTIR), and X-ray diffraction (XRD), Scanning electron microscopy studies (SEM) analysis. The inclusion complexations of Piroxicam with β-cyclodextrin exhibited enhanced saturation solubility and dissolution rate of Piroxicam than that of pure drug.

KEYWORDS: Co-grinded mixture, Physical mixture, kneading, solvent evaporation.

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TITLE: STUDY OF PHARMACOLOGICAL EFFECT OF ETHANOLIC EXTRACT OF *TRIKATU* (EET) ON LEARNING AND MEMORY IN RATS.

AUTHORS: Vedant Naik [a],Harshad Vernekar [a], Aniket Naik [a], Almas Mulla [a] ,
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ABSTRACT: The current study was conducted to evaluate the effect of ethanolic extract of *Trikatu* (EET) on learning and memory in rats. This effect was assessed using Elevated Plus maze, Y Maze and Novel Object Recognition. The phytochemical constituents present in ethanolic extract were also evaluated. The ethanolic extract, at doses of 500 mg/kg and 1000 mg/kg, was administered to rats by oral route. Piracetam was used as a standard drug for learning and memory which was administered intraperitoneally. The test doses were administered continuously for a period of seven days. The animals were subjected to the above mentioned tests and the observations were recorded at different time intervals on the first, fourth and seventh day. The results were statistically analyzed using one way ANOVA by Dunnett's test. From the results it was concluded that EET at both doses, 500mg/kg and 1000mg/kg were found to have significant learning and memory enhancing activity. Further *in vitro* analysis is required to understand exact mechanism of improved learning and memory.

KEY WORDS: learning, memory, *trikatu* , Y maze, Elevated plus maze, Novel object recognition

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TITLE: EVALUATION OF NEUROPHARMACOLOGICAL EFFECTS OF ESSENTIAL OIL OF *Cymbopogon citratus*

AUTHORS: Aniket Naik [a] ,Vedant Naik [a], Harshad Vernekar [a], Nikita Gaonkar [a] , Vedita Hegde Desai [a *]

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CORRESPONDING AUTHOR: Vedita Hegde Desai

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ABSTRACT: The present study was carried out to evaluate the effects of Essential oil of *Cymbopogon citratus* (EOCC) on learning and memory in rats using Y Maze, Elevated Plus Maze and Novel Object Recognition Test.Two doses of Essential oil of *Cymbopogon citratus* i.e 500mg/kg and 1000mg/kg were administered to the rats by oral route using oral gavage. The control used was distilled water. Piracetam (200 mg/kg) was used as a standard. The control, test and standard substances were administered for 7 days. The results were statistically analysed using one way ANOVA by Dunnett's test. From the results it was concluded that EOCC at both doses were found to have significant learning and memory enhancing activity. The property of enhanced learning and memory could be due to presence of flavonoids and terpenes which crosses the blood brain barrier and inhibits Acetylcholinesterase enzyme in the brain region. Further *in vitro* analysis are required to understand exact mechanism of improved learning and memory.

KEY WORDS - Lemongrass, CNS, Essential oil, Memory and learning, Neuropharmacological effects

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TITLE: STUDY OF NEUROPHARMACOLOGICAL ACTIVITY OF ETHANOLIC EXTRACT OF *GREWIA HIRSUTA* ON CNS IN RATS

AUTHORS: Harshad Vernekar [a], Vedant Naik [a], Aniket Naik [a], Madhuri Naik [a] , Vedita Hegde Desai [a *]

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Memory is the operation through which living beings are able to recollect the occurrences and utilise it to respond to their surroundings. Learning is the capability to obtain novel information or skills through experience or instructions. The current study involves the screening of the ethanolic extract of *Grewia hirsuta* (EEGH) for its effect on learning and memory. Different animal behavioral models: Elevated Plus Maze (EPM), Y Maze and Novel Object Recognition Test (NOR) were used.

EEGH in doses of 250mg/kg and 500mg/kg, was administered orally to the rats. The standard drug, Piracetam (200 mg/kg), was administered intraperitoneally. Distilled water was used as control. The doses were administered continuously for seven days. In EPM, both, EEGH 250 mg/kg and EEGH 500 mg/kg showed significantly shorter transfer latency on 8th day on elevated plus maze compared to Control.

In Y Maze, both, EEGH 250 mg/kg and EEGH 500 mg/kg showed significantly shorter transfer latency on Day 1, 4 and 7 compared to Control. In NOR, EEGH 250 mg/kg showed good working, short term and long-term memory whereas EEGH 500 mg/kg showed good short term and long-term memory in comparison with the Control. It may thus be concluded that the ethanolic extract of *Grewia hirsuta* showed effect on learning and memory at both the doses. Further investigations, using more experimental paradigms, are required to confirm its potential activity.

KEY WORDS: Nootropics, Learning, Memory, CNS, *Grewia hirsuta*

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TITLE: ISOLATION OF FLAVONOIDS AND BIFLAVANOIDS FROM *RHUSSUCCEDANEA*

AUTHORS: Rhea Ann Roy, Sandesh Kulkarni*, Arun B Joshi, AnantBhandarkar

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ABSTRACT

RhussuccedaneaL Mold also knows as the Wax tree or Karkatshringi in Sanskrit. is a deciduous shrub belonging to the family Anacardiacea. It is primarily found in Asia and East Asia. From the literature survey it was learnt that the plant is rich in biflavonoids, flavonoids and tannins. Pharmacological activity such as anti-inflammatory, anti-tussive, anti-emetic and cytotoxic activity were also reported form the plant.

In this study, the methanolic extract, acetone soluble and acetone insoluble fractions obtained from methanolic extract were subjected for the determination of total phenolic content (TPC) and total flavonoid content (TFC) and *in vitro* DPPH and H_2O_2 radical scavenging assay. Preliminary phytochemical screening revealed the presence of steroids, alkaloids, glycosides, saponins flavonoids, tannins and carbohydrates.

The acetone soluble fraction showed highest phenolic content of 6.674 mg GAE/g, and flavonoid content of 3.170 mg QUE/g, indicating that the acetone soluble fraction is rich in phenolic compounds. The *invitro* antioxidant activity revealed that the acetone soluble fraction exhibited IC_{50} value of 4.992 ± 0.75µg and 46.159 ± 1.1466µg in DPPH and H_2O_2radical scavenging assay respectively.

Phytochemical investigation of the acetone soluble fraction of the methanolic extract of *R. succedanea*, led to the isolation of compounds viz: **Quercetin, and Amentoflavone**, and were characterized by FTIR, ^{1}HNMR,^{13} CNMR, and Mass spectroscopy.

KEYWORDS: *RhussuccedaneaL.*, biflavonoids, *in vitro* antioxidant activity, totalphenolic content, total flavonoid content,amentoflavone,

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TITLE: Physicochemical, Phytochemical and antioxidant potential of ethnomedicinal plants used in hepatotoxicity

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ABSTRACT:

The ethnomedicinal plants used in the treatment of hepatotoxicity by the traditional healer of Bicholim- Goa were identified as *Ricinus communis* (Euphorbiaceae), *Microcos paniculata* (Tiliaceae) and *Tinospora cordifolia* (Menispermaceae). The selected plants were evaluated for physicochemical parameters, phytochemical screening. Evaluation of total phenolic content, total flavonoidal content and *in-vitro* antioxidant activity were carried out for methanolic extract and juices of respective plants.

Physiochemical parameters such as moisture content. foaming index, swelling index. ash value and extractive value were determined using dried powdered of plant material. Phytochemical screening of methanolic extract of the selected plants revealed the presence of steroids. alkaloids. glycosides. flavonoids, tannins, volatile oil and carbohydrates. Phenolic content was evaluated by Folin ciocalteu method and Flavonoid content was evaluated by aluminium chloride colorimetric technique. Antioxidant activity were evaluated by DPPH and Hydrogen peroxide scavenging activity for both extract and juice of the selected plants.

Total phenolic content was found to be highest in *Microcos paniculata* methanolic extract (17.009 mg GAE/g) and in *Tinospora cordifolia* juice (8.4 mg GAE/g). Total flavonoid content was found to be highest in methanolic extract of *Ricinus communis* (13.0007 mg QUE/g) and in juice of *Microcos paniculata* (3.97 mg QUE/g). DPPH radical scavenging activity was found to be maximum in methanolic extract of *Microcos paniculata* (IC=58.61 ug/ml) and in juice of *Ricinus communis* (233.28 ug/ml). Hydrogen peroxide radical scavenging activity was found to be maximum in methanolic extract of *Tinospora cordifolia* (ICS=28.07 ug/ml) and in juice of *Ricinus communis* (ICS=187.696 ug/ml).

Keywords : *Ricinus communis ,Microcos paniculata, Tinospora cordifolia* antioxidant activity.

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TITLE: Endophytic Fungal Constituents from *Phyllanthus amarus*

AUTHORS: Divya Singh, Uma Nadkarni*, Arun B Joshi, Anant Bhandarkar

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ABSTRACT:

Endophytes are organisms, fungi or bacteria that live inside a plant in a mutualistic relationship. These endophytes act as reservoir for new drug discovery and thus help to improve plant animal and human health. *Phyllanthus amarus* (Schum, and Thonn.), popularly known as Bhuiamla is an important plant of Indian Ayurvedic system and Unani medicine. It consists of the whole plant of *P. amarus* belonging to the family, *Phyllanthaceae.* The plant is distributed throughout tropical and subtropical parts of India. Therapeutically, it is used as an astringent, stomachic, diuretic, etc. and shows a variety of pharmacological activities such as hepatoprotective, antibacterial, antioxidant anti-inflammatory, antiviral, analgesic and anti-hyperglycemic activity. Literature survey revealed that no substantial work has been carried out on isolation and characterization of phytoconstituents from the endophytic extract of *P. amarus*. The current study aimed to carry out isolation, characterization, determination of phenolic and flavonoidal content and antioxidant activity from the endophytic extract of *P.amarus*. Four compounds were isolated from the butanolic endophytic extract of *P.amarus* leaves using column chromatography. The characterization of these phytoconstituents were carried out using, IR, ^{1}HNMR, ^{13}C NMR and MASS spectroscopic data. These isolated phytoconstituents were characterized as Amarosterol A, Ursolic acid, Hypophyllanthin and Phyllanthin. This is the first report of the isolation of the components from the butanolic endophytic extract of *P.amarus.*

KEYWORDS: *Phyllanthus amarus, Phyllanthaceae,* Endophyte, Amarosterol A, Ursolic acid, Hypophyllanthin, Phyllanthin.

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TITLE: PATENT TERM EXTENSION (PTE) REGIME IN AUSTRALIA: AMENDMENTS AND ANALYSIS OF GRANTED, PENDING, AND REFUSED PTE APPLICATIONS.

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ABSTRACT:

Innovator pharmaceutical companies are required to conduct clinical trials for getting their products approved from regulatory authorities. This process requires huge amount of investment of time and money. To recover these investments, pharmaceutical companies are awarded with the possibility of extending the patent term covering such products. This extension of term is known as 'Certificate of Supplementary Protection' (CSP) in Canada, 'Patent Term Extension(s)' (PTE) in United States of America (USA) and Australia, and 'Supplementary Protection Certificate' (SPC) in Europe. This article provides in-depth evaluation of PTE regime in Australia. Section 70 to 79 A of the Australian Patents Act relate to PTE. It also covers comparative analysis of number of PTE applications granted, pending, refused or withdrawn. This article provides analysis of type of patents referred in PTE applications, PTE applicant-wise analysis, and terms of granted PTEs. About 91% PTE applications out of the total PTE applications were granted, about 4% were refused and the remaining about 5%

applications are awaiting decision**.** Comprehensive summary of legal cases which involved challenge to PTE decision is also provided. Learnings from these legal cases has potential to act as guidance for future decisions regarding PTE applications.

KEYWORDS:

Patent Term Extension (PTE), Therapeutic Goods Administration, Australian Register of Therapeutic Goods (ARTG), AUSPAT

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TITLE: RISK ASSESSMENT: A KEY FOR QbD PROJECTS

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ABSTRACT:(NOT MORE THAN 250 WORDS)

As a first phase in the QbD project, the risk assessment activity during development can have a major effect. Not only can it jeopardise the QbD project, it can also postpone the introduction of a new product. "The impact of a poor risk assessment may be serious."

QbD starts with Risk Identification. At the end of the QbD Risk Assessment activity, a priority list of "Critical" Quality Attributes (CQA) and "Critical" Process Parameters (CPP) will be given. Starting with high-risk quality attributes and process parameters, space design studies are conducted using DOE. These "plan space studies" are projects created by the risk assessment. Based on the outcomes of these studies and indirect research (prior information and experience, literature review, clinical evidence, etc.), the risk index can be revised by reverting to the initial risk assessment. Risk assessment should be revised at each point of the life cycle of growth. Risk Assessment ties QTPP, CQA, CPP and Control Strategy together. We call this Quality Risk Management in the ICH Q9 guideline.

KEYWORDS:

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CURRENT STATUS, CHALLENGES AND PREVENTIVE STRATEGIES TO OVERCOME DATA INTEGRITY ISSUES IN THE PHARMACEUTICAL INDUSTRY

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ABSTRACT:

The pharmaceutical industry is currently one of the most dynamic among all industries. At present, it is striking with various compliance issues and challenges like never before due to there is an increased regulations, push towards harmonization and especially management of Data Integrity (DI), which were indirectly connected to the public health. According to the Bioresearch Monitoring Program, there were 3738 warning letters related to DI from the decade year of 2009 to 2019, which was found that it's in ascending. DI weakness is identified, either as a result of audit or regulatory inspections, whereas companies with multiple sites were failed to ensure appropriate corrective and preventive actions through implementation of guidelines and observed risk notifications to the regulatory authorities. The DI related current GMP violations have leads to several regulatory actions, including warning letters and import alerts, which are hazardous to the company's long-term prospects along with serious consequences. There were many uncovered serious cases on DI related problems, which is all about the one's handling by maintaining good documentation practice. The research findings of the study involve the number of issues within data integrity in cGMP aspects and the root causes were addressed based on a FDA warning letters. The concept of data integrity in quality, regulatory expectations, present state of compliance and challenges were explored to suggest appropriate remedial and proactive measures to avoid DI issues further. The importance of DI, strategies and guidelines/recommendations to overcome from unknowing DI mistakes were addressed in this study.

KEYWORDS: Data integrity, Issues, Root causes, Strategies, and Recommendations

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TITLE: A study on IP Policy of HEIs in India

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ABSTRACT:

Background: Higher Education Institutions (HEIs) constitutes universities and research institutions (knowledge bases) are prominent in creation of knowledge and innovations in any country. These innovations are engine of economic growth; whereas, Intellectual Property Rights (IPR) are fuel to it. Effective utilization of IP created in HEIs is underpinning for consistent economic growth in developed nations. HEI's IP policy is corner stone which significantly decides the inventions' viability from lab to market. Lack of supportive HEI IP policy cripples the innovation system. Despite having high potential intellectual capital and institutions to lead the world in technology, HEIs in India are performing low due to inadequate IP policies.

Objectives: This study aims to assess the IP policy and innovation practices of knowledge bases in India using a structured questionnaire tool.

Results: Response rate in the survey is 36.6%. 10 HEIs responded in the survey have implemented IP policies specifying ownership of IP, but only 7 of them are providing incentives to inventors. Despite having collaborations with industries, leveraging IP through collaborations is seen meager.

Conclusion: Lack of supportive incentives to the inventors, linkages with industries, facilities and skilled IP professionals were found to be major barriers among knowledge bases. Institutional IP policy shall be framed to promote industry linkages with universities resulting in successful IP generation and technology transfer.

KEYWORDS: HEI IP policy, Technology transfer, innovation

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TITLE: ROLE OF COMPUTER SYSTEM VALIDATION IN PHARMACEUTICAL INDUTRY

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ABSTRACT:

Computer validation should address the scientific correctness of the application software, the business objectives of the organization, and the concerns of regulatory agencies. It is a balance between a practical and cost effective system that must develop the confidence that the system is under control, to validate the computer system and computer assists software in pharmaceutical field. It is the process by which all aspects of a process are shown to meet all quality requirements, and comply with applicable rules and regulations regarding product quality, safety and traceability. A computer System for tracking the lot numbers of pharmaceuticals that are administered to patients. It is the technical discipline that pharmaceutical and life science companies use to ensure that each information technology application fulfills its intended purpose. For a process supported by a computer system, we can say that computer system validation provides documented proof that the system will repeatedly and reliably do what it is designed to do, is "fit-for-purpose", and complies with the applicable rules and regulations. Consequently, the methods provide a means to perform validation on an integrated level whereby the quality control unit can ensure data and product integrity, minimize cost, improve GMP compliance and 21 CFR part 11 regulation which impact on product quality, safety, identity or efficacy that subject to GxP rules. It is likely that the future will see convergence of computer system validation terminology and techniques as a common technical discipline across other industry sectors as well.

KEYWORDS: Computer System Validation, 21 CFR, Validation in Pharmaceuticals.

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TITLE: IMPORTANCE AND STEPS TO MINIMIZE DATA INTEGRITY IN PHARMACEUTICALS

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ABSTRACT: (NOT MORE THAN 250 WORDS)

Pharmaceuticals have started to rely to a great extent on computers and automated systems these days, whether in terms of production, laboratory release testing or several other tasks involved. As a result, a renewed emphasis has been placed on the concept of Data Integrity. Data has never been easy to handle as it requires different steps in life cycle from generation to destruction. It is important that data is not only processed but also secured from various means. The process of generating, processing, archiving, retrieving and destroying a data is referred to as the data life cycle. The degree to which all information in the data lifecycle is complete, reliable and correct is called Data Integrity and is equally important to both paper(manual)and electronic data.Regulatory authorities have put more stress on data integrity issues because they found some serious cGMP violation which could alter the product quality ,safety and efficacy. The impact of unprotected records can be dangerous for its reliability and quality.Good Documentation Practices (GDP) is key to ensuring data integrity and a primary part of quality management system.Principles of data security and integrity had to be standardized in order to regulate them and achieve better processes and higher quality products. Many regulatory agencies have specified that data should be ALOCA.that is Attributable to person generating the data ,Legible and permanent, Contemporaneous, Original, Record and Accurate.Record maintenace is entirely different from data integrity.All these led to the increased importance of data security and integrity in pharmaceuticals over the last few years.

KEYWORDS: Data integrity,ALCOA,Good Documentation Practices

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TITLE: PATENT LANDSCAPE OF BIOSURFACTANTS, THEIR INDUSTRIAL DEMAND AND MARKET RESEARCH

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ABSTRACT:

Biosurfactants refer to an environmentally friendly alternative to synthetic surfactants that are manufactured by microorganisms and plants. These molecules are amphiphilic compounds that can lower the surface tension of liquid interfaces, facilitating enhanced foaming and mixing. As such these 'wonder molecules' can be utilised in a variety of ways in many diverse industries including cosmetics, pharmaceuticals, oil recovery, agriculture and more. Despite the versatility of applications for the molecules, scant research has been undertaken to investigate and map any trends in the research and development of biosurfactants. As such a systematic review of the patent documents available on the database search engine Espacenet was conducted. Various data mining techniques were used to highlight patents relating to biosurfactants. Relevant patents were reviewed and categorised for further analysis. Early conclusions were that there is an upward trend in the number of patents being granted year on year. The subject of many of the patents was the development and production of biosurfactants or enhanced oil recovery. Where specified within the patents rhamnolipids and sophorolipids are most common. Surprisingly this research suggests that South Korea has both the most patents and diversity in the industrial areas that these patents relate to. The European jurisdictions in this research were found to have fewest patents overall. In terms of sectors of industry, it was development and production of biosurfactants was found to be the most common. Commercial literature allowed some forecasting of these trends. Due to the Covid-19 pandemic is likely to cause an increase in the pharmaceutical and healthcare industry and the cleaning and detergent industry.

KEYWORDS: Biosurfactant, Patent Analysis, Market Research

TITLE: Application of Doctrine of Equivalents in Pharmaceutical Patent

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ABSTRACT: (NOT MORE THAN 250 WORDS)

Abstract

Background: Patent is the legal document to protect the originality of the invention. It prevents the invention from infringement to protect the patentee rights. The use of a patent draft without the permission of the patentee comes under infringement and has to give monopoly. Patent infringement is categorized into two terms literal infringement and doctrine of equivalent. A patent's scope is not limited to its literal terms but includes all the related claims as described in the patent application. The doctrine of equivalence depends on the actuality and is based on all element rule.

Methods: The databases were investigated through online literature and patent drafts based on the doctrine of equivalents in the pharmaceutical sector.

Result and Conclusion: The paper highlights the scope, tests, limitation, its position in a different country, the current scenario in the pharmaceutical sectors. It provides a balance between a fair patent and the notice provided to the public by the patent, together with a balance between innovation opportunities and risk costs. It is a term developed by the judiciary which serves the fair function of preventing an infringer from purloining an invention's profit.

KEYWORDS: Doctrine of equivalents, infringement, claims, innovation.