Theme 2

Regulation for Bioactive loaded Nano medicine from herbal origin and their associated toxicity

Nano-niosomal Gel Formulation of Psoralen and Enhanced Anti-psoriatic Activity

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Abstract

Psoriasis is a common T-cell-mediated immune disorder characterized by circumscribed, red, thickened plaques with an overlying silver-white scale. Lack of effective delivery of drugs and undesirable skin interactions of the topical treatments are the main reasons of patient non-compliance in psoriasis treatment. Psoralen, is a major bioactive phyto-constituent from *Psoralea corylifolia* Linn (family Fabaceae) commonly known as Babchi. Psoralen is known for its photosensitizing and phototoxic effects and has been used in skin disorders. Psoralen has several pharmacological activities including antipsoriatic, anti-vitiligo, anti-fungal, anti-leucoderma, and anti-cancer. Psoralen is poorly soluble in water; therefore, the objective of present study was to develop the psoralen nano-niosomal formulation for topical use. In the present study, effects of psoralen entrapped niosomes on the drug deposition were investigated by *in vitro* permeation experiments. Niosomes are versatile carriers suitable for different routes of drug delivery application Niosomes enhances skin retention and permeation of topically applied drug. The enhanced penetration effect and smaller particle size of niosomes can be utilized to improve the bioavailability of psoralen within the skin. Enhanced drug action is attributed to the presence of therapeutic molecules at or near the target site action with UV-light which would help in reducing phototoxic side effects. Favorable rheological properties and skin-moisturizing effect ultimately increase patient compliance as compared to conventional dosage forms as like ointment, cream etc. We successfully prepared and optimized niosomes for topical delivery of psoralen for antipsoriatic activity. *In vitro* evaluation studies of niosomes revealed high encapsulation efficiency and enhanced skin permeation with remarkable topical retention of drug for prolonged period of time with considerable stability. Psoralen niosomal gel also showed good skin retention and less skin irritation thus increased safety of formulation. *In vivo* study revealed that our formulation has enhanced antipsoriatic activity as compared to marketed formulation.

Keywords: Antipsoriatic, Niosomes, anti-fungal.

Technical Presentation on High Performance Thin Layer Chromatography (HPTLC) System for the analysis of Herbal Samples

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Abstract

TLC/HPTLC is one of the useful analytical tool for the analysis of articles of botanical origin for identification, fingerprinting, adulteration, stability check and micro preparative work. We need to make a decision a correct, practical and inexpensive HPTLC configuration based on the analytical works to be performed. USP, Ph.Eur., ChP, Indian Pharmacopoeia and many other official methods recommend TLC/HPTLC is one of the useful method for the identification and fingerprinting of herbal drug and herbal drug preparation product. USP 203 chapter and Ph.Eur. define HPTLC instrument as pre-coated HPTLC plate, a device for band wise sample application, a suitable chromatogram development tank, a device suitable to transfer reagent on the plate and heating of the plate for derivatization and a device suitable to document plate images under 254nm, 366nm and visible wavelength. Recently the European Pharmacopoeia (Ph. Eur.) commission endorses semi- quantitative HPTLC testing for Traditional Chinese Medicines as an alternative quality control which could be used instead of HPLC assays. It is a marker level quantification using appropriate software which converted HPTLC chromatograms into peak profile. It is one of the favourite methods for the analysts in the other fields like Food, Forensic & Toxicology and Pharmaceutical analysis for the identification of compounds, toxic chemicals, preservatives and adulterants in a complex mixture. Sample application on the TLC/HPTLC plates is the first step of HPTLC analysis and thus determines the quality and reproducible result of the analysis. Band wise sample

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application with spray-on technique with accurate volume and positioning are the key factors to get accurate and reproducible analytical result. Variables like solvent grade, developing solvents, temperature, reagent quality, handling of the plate, transfer of reagents on the plate, heating temperature with time and proper documentation under different wavelengths are the key factors for getting reproducible and accurate result.

Keywords: TLC, HPTLC, Preservatives

Formulation and Evaluation of Topical Dosage Form Containing Leaf Extract of *Prosopis cineraria* (L.) Druce

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Abstract

Prosopis cineraria (L.) Druce (khejari) is used as folk medicine to treat various ailments. This investigation was established optimization of extraction method & development of a antimicrobial topical herbal formulation. In this study we had optimized extraction method from leaves of *Prosopis cineraria*. The various extracts were investigated for qualitative & quantitative analysis of various extracts, optimized extract was used for isolation of compound; isolated compound was characterized by IR, Mass, & NMR. The rutin enriched extracts containing micro-emulsion was prepared & loaded in to organogel for topical application. The organogel was evaluated for toxicological activity on wistar rat. A stable topical microemulsion has been developed with hydro methanolic (70%) extract and the results provided strong support for the effective antimicrobial activity. Developed microemulsion was found to be stable & toxicologically safe, making it a promising candidate for future therapeutic application for the treatment of skin infection.

Keywords: *Prosopis cineraria*; Rutin, Microemulsion, Organogel, Topical Formulation.

Regulation and Toxicity Aspects of Nanophytomedicines used in RA and Cancer

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Abstract

Phytotherapy, is a modality of complementary and alternative medicine (CAM) ,widely gaining popularity in developing and developed countries. Numerous bioactive phytoconstituents are now in line of application for the treatment of various diseases and disorders. Among them many phytochemicals e.g. alkaloids, glycosides, polyphenols and terpenes are major class of interest. Various drugs and phytochemicals e.g. digoxin, quinine, morphine, atropine, aspirin, bromelain, colchicines, curcumin, triphala, guggalosterone etc. showed potential health effects in treatment of cancer and arthritic/ inflammatory conditions. Nanonization of phytochemicals and delivery of phyto formulations through nano carriers is used for their enhanced delivery and desired efficacy. The development of those formulations comes with a responsibility for Nanotoxicology and emerging fileds of Green nanotechnology. The current presentation focuses on the nanophytomedicines explored for the treatment of RA and cancer, regulations, toxicities and other controversies associated with the nanosystems with their future prospects.

Keywords: Nanomedicine, Toxicity, digoxin

Regulations for Bioactives loaded Nano Medicine from Herbal Origin and their Associated Toxicity

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Abstract

Pharmaceutical Nanotechnology is a rapidly developing branch of science that aims to improve medication stability and its targeting efficiency. Also, the recent increase in the use of Bioactives of herbal origin in the development of nanomedicines/nanoformulation is major breakthrough in pharmaceutical research and development. As per the World Health Organization (WHO) report, in developing countries, the basic health needs of approximately 80% of the population are met and complemented by traditional medicine. Plants have been used for medicine and nourishment since the dawn of society. Despite the various benefits, pharmaceutical companies are often hesitant to fund natural product-based drug development and instead focus on the synthetic compound library for innovative drug development. The major cause of this is the lack of knowledge and information on well-validated methods for herbal ingredient extraction, purification, and their formulation into novel drug delivery systems. Also, herbal bioactive compounds have low absorption capacity due to the absence of the ability to cross the lipid membranes because of their high molecular sizes, thus resulting in reduced bioavailability and efficacy. They exhibit high

systemic clearance, necessitating repeated applications and/or high doses, making the drug less effective for therapeutic use. Despite all these drawbacks, bioactives with herbal origin have tremendous therapeutic potential compared to synthetic medicines. Thus scientific development of regulations and standards procedure/protocols for bioactive loaded nano drug delivery systems can revolutionize the development of formulations based on natural products, bringing tools capable of solving the problems mentioned above that limit the application of these compounds on large scale in the nanomedicine. The current talk will summarize existing research and the development of new formulations, with a focus on herbal bioactive components.

Keywords: Nanomedicine, Herbal drugs, Bioactives, Novel drug delivery systems.

Dynamic Biological Processes of Nano-Assemblies: Special Emphasis on Nano-Bio Interactions

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Abstract

Nano-bio interactions are the interactions between nanoscale entities and biological systems such as peptides, proteins, lipids, DNA and other biomolecules, cells and cellular receptors and organisms including humans. Application of Nano-bio interactions in the dynamic biological processes of controllable nano-assemblies is emerging as a powerful tool to generate theranostics nanosystems. It is the unique requirement in modern medicine. However, this prospective field is still in a proof-of-concept stage due to the gaps in our understanding of interaction between complex nanosystem and complex biological system. Various stimuli responsive groups used to formulate controllable nanoassemblies which affect its biological fate and functional activity. To provide a comprehensive understanding of these interactions several key parameters have to delineate the relevant dynamic biological processes, behaviour and fate of nano-assemblies. Various challenges also associated with evaluation of nano-bio interactions of assembled nanodrugs. The study of nano-bio interactions are expected to pave the way for future development and clinical translation of precise, safe and effective nanomedicines with intelligent theranostic features.

Keywords: Nanosystem, Nano-assemblies, Stimuli responsive groups, Theranostics

Post COVID management: Pragmatic approach of Herbal medicine

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Abstract

COVID-19 can result in prolonged illness and persistent symptoms, even in young adults and persons with no underlying medical conditions who were not hospitalized. As of now, there is limited evidence of post-COVID sequelae and further research is required and is being actively pursued. A holistic approach is required to follow up care and well-being of all post-COVID recovering patients. After acute COVID-19 illness, recovered patients may continue to report a wide variety of signs and symptoms including cough, low-grade fever, and fatigue, all of which may relapse and remit, shortness of breath, chest pain, headache, neurocognitive difficulties, muscle pains and weakness, gastrointestinal upset, rashes, metabolic disruption (such as poor control of diabetes), thromboembolic conditions, and depression and other mental health conditions. Skin rashes can take many forms including vesicular, maculopapular, urticarial. Various herbs and herbomineral drugs including Rasayana drugs which play a vital role in post COVID-19 and specially herbomineral drugs require in minimal dosage, accounting to the quicker action of drug, easy for administration, act as a Rasayana with high potency. The herbo-metallic formulations containing gold Bhasma plays a key role in overall efficacy, Research works had been proved that the herbo-metallic formulations containing gold bhasma helps to regulate antigen-specific immune response as nanoparticles of gold possess immunomodulatory, free radical scavenging, antistress, analgesic and antioxidant properties

Keywords: COVID-19, medicinal plants, Bhasma, herbal medicine, neurocognitive

Formulation of Herbal Hair Mask

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Abstract

The hair is the most fragile component of the human body.

As a result, we created a hair mask formulation to take care of them. The ingredients in the hair mask were chosen based on their hair-related advantages. Hair masks are used to eliminate filth that has accumulated in the hair. Hair masks contain coconut oil, which is used to apply the mask on the hairs. The hair mask created is 100% chemical-free. It contains only natural substances that are safe for our hair.Hair is a vital element of the body and serves as a health indicator. Hair masks can aid to hydrate our tresses. They are especially good for hair that's dry or damaged. Hair masks can help to restore the health of our scalps and strengthen our hairs. These hair masks can be prepared at home, have no drawbacks, and are useful. We can make this mask using anything we have on hand. This product is critical for those whose hair is extremely thin or whose hair is damaged. When our hair is in good condition, it enhances our whole appearance. There are many different types of masks on the market, but they all contain chemicals. Chemicals are also harmful to our hair. As a result, we've created a chemical-free product. This mask is incredibly simple to make.

Keywords: Hair mask, natural substances, vital element

Qbd Based Optimization of Herbal Bioactive Compound Loaded Solid Lipid Nanoparticles

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Abstract

Most of the herbal bioactive compounds have limitation of lower bioavailability. An approach to increase the bioavailability is by combining the advantage of nanotechnology with drug delivery system and developing nanocarriers. Solid lipid nanocarriers are advantageous in higher drug entrapment of lipid soluble herbal components. This research work was planned to develop *Jasminum Sambac* extract loaded SLN. Formulation variables were optimized by QbD approach, the Box-Behnken Design was chosen to optimize the process parameters. In the development of these SLN, Beta-Sitosterol was extracted from *Jasminum Sambac* by maceration method, loaded in SLN by homogenization and ultrasonication method for improving the anti-inflammatory and analgesic properties of the formulation for the treatment of edema. The formulation was optimised for the ratio of Drug: Lipid; various lipid ratio; various surfactant mixture ratio. SLNs were the characterized for physiochemical, size, zeta potential and *in-vitro* diffusion. The accepted precision and accuracy of the drug release was obtained about 94% within 25hr at a temperature of 37ºC. Cumulative drug release obeyed the uniform release pattern. JS extract and BS loaded SLN results allow us to aim for further improvement in the SLN formulation for better treatment.

Keywords: Solid Lipid Nanoparticles, Jasminum Sambac, Beta-Sitosterol(BS), Polydisperse Index(PI), Quality by Design(QbD).

Analytical Cleaning Method Validation for the Quantification of Fluticasone Furoate by RP-HPLC

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Abstract

A cleaning validation utilizing swab sampling and rinse solution procedures, and HPLC for the qualitative and quantitative analysis was performed. Fluticasone furoate cleaning validation is an in-house method of analytical validation and is not official in IP, BP and USP. Hence, the research work was to develop and validate reverse phase high performance liquid chromatography (RP-HPLC) method to quantify fluticasone furoate in nasal spray formulations. The developed method was validated according to the ICH guideline with respect to system suitability, accuracy, precision, LOD and LOQ, specificity, linearity, and robustness. An isocratic condition of mobile phase comprising acetonitrile: methanol: buffer in a ratio of 48:04:48, v/v at a flow rate of 1.2 ml/min over RP C-18 (Hypersil (BDS), 250 × 4.6 mm, 5µm) column at ambient temperature was maintained. Accepted accuracy for rinse and swap method were obtained at 83.77%-96.92% and 74.79%-85.55% respectively. The method validation was performed according to the approved protocol. On the basis of the experiments the performance characteristic meets the acceptance criteria. Hence the HPLC method used for the determination of fluticasone furoate content after cleaning of equipment during product change over stand validated.

Keywords: RP-HPLC, Fluticasone Furoate, Nasal Spray, Relative Standard Deviation, Validation.

Latest Development In Excipient Science In Herbal Delivery

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Abstract

The Herbal or natural excipients have a great advantage over their synthetic analogues as these are non-toxic, less expensive and freely available. The increasing awareness about these herbal excipients, which are manly polymers of natural origin, the pharmaceutical industries is getting more inclined towards their use in formulation development. Excipients are defined as 'the substance used as a medium for giving a medicament. New excipients are defined according to the 2005 FDA Guidance on Nonclinical Safety Evaluation of New Excipients. The requirements for safety data submission for new excipients used in different classes of products for different durations are outlined in the guidance. Currently, the development of new excipients is linked to the development and approval of new drug products that contain them. New excipients that are used in US-approved drug products become listed in the FDA Inactive Ingredients Guide (IIG) database. Thereafter, US Pharmacopeia monographs for the new excipients are proposed. New excipients are reviewed and become accepted in the same way in Europe and Japan, except that there is no equivalent IIG database. Excipient are primarily used as diluents, binders, disintegrate, adhesives, glidants and sweeteners in conventional dosage forms like tablets and capsule. As the establishment of toxicity and approval from regulatory authorities poses a problem with synthetic excipient, of late more interest is being shown by researchers in herbal excipients.

Keywords: Herbal Excipient, Excipient Science, Drug Delivery, Pharmaceutical Excipient, Herbal Drug Technology

Mucilage's For Development of Nanoparticle in Herbal Delivery

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Abstract

Herbal medicines have been widely used all over the world since ancient times and have been recognized by physicians and patients for their better therapeutic value as they have fewer adverse effects as compared with modern medicines. And the new development for nano-sized drug delivery systems of herbal drugs has a potential future for enhancing the activity and overcoming problems associated with plant medicines. Hence, integration of the nanocarrier as a NDDS (Novel drug delivery systems) the traditional medicine system is essential to conflict more chronic diseases like asthma, diabetes, cancer, and others. For the fabrication of nanoparticle formulation mucilage could act as a biomarker as the mucilage's from natural sources like carrageenan, thaumatin, lard, storax, agar, gum acacia, tragacanth and many more are used in many pharmaceutical formulations, plant-based gums and mucilage are the key ingredients due to their bioavailability, widespread accessibility, non-toxicity, and reasonable prices. So, as the mucilage help in nanoparticle formation which had come forward as the capable approach in drug delivery systems for the well-organized delivery of drugs utilized in the treatment of various diseases such as cancer and this novel drug delivery system is advantageous in delivering the herbal drug at predetermined rate and delivery of drug at the site of action which minimizes the toxic effects with the increase in bioavailability of the drugs.

Keywords: Herbal medicines, mucilage's, nanoparticles, pharmacology, herbal drug delivery

Preparation and characterization of A*lstonia scholaris* based silver Nanoparticles by green synthesis approach

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Abstract

Natural resources basically herbal drugs are a good source of drug discovery and development from ancient time to current time. Rationally we are applying different approaches and techniques for development of new drugs and formulations. Nanoparticles are the only type of structures within the size in nm range. The atoms are bonded together within a structural radius of < 100 nm can be considered nanoparticles. Green synthesis based nanoscale materials are defined as a set of substances where at least one dimension is less than approximately 100 nanometer is one millionth of a millimeter- approximately 100,000 times smaller than the diameter of a human hair. In The present work described as a simple, green, and fast approach for the synthesis of silver nanoparticles using methanolic floral extract of *Alstonia scholaris* (AS-AgNPs). The role of plant based floral extract was identified as both reducing as well as capping agent in the synthesis of AS-AgNPs. Stable AS-AgNPs were formed by treating 10 % of *Alstonia* scholaris floral extract with the aqueous solution of AgNO3 (1 mM). The formation and morphology of AS-AgNPs was confirms by UV–visible spectroscopic analysis, Fourier transform infrared spectroscopic analysis, X-ray diffraction micrograph, FE SEM and particles size analysis.

Keywords: Nanoparticles, *Alstonia scholari,* Green Synthesis and Silver **N**anoparticles.

Transethosomes: A Recent Approach on Transdermal Drug Delivery of Herbal Active Constituents

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Abstract

Transdermal drug delivery is considered a better alternative to oral administration of herbal drug. Transethosome is one of the transdermal drug delivery systems to deliver herbal drug for better penetration. Transethosomes are non-invasive delivery carriers that enable drugs to reach the deep skin layers and the systemic circulation, although transethosome systems are conceptually sophisticated, they are simple in their preparation, safe for use and a combination that can highly expand their application. Transethosome are gaining popularity in designing drug delivery systems for topical and transdermal use for their capability to reach deep skin layers and systemic circulation. Transethosome have both ethanol and penetration enhancer due to which drug penetrates through stratum corneum by increase fluidity of cell membrane lipids. The present review includes the advantages, application, mechanism of penetration, method of preparation and characterization of transethosome.

Keywords: Transethosomes, Herbal, Penetration

Formulation and Optimization of Boswellic Acid loaded Microsponges gel for the treatment of Arthritis

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Abstract

Arthritis is an intra-articular inflammation, which may be the result of various etiological factors. Arthritis comprises a diverse group of disorders that are primarily caused by pathology of synovium, articular cartilage and supporting various subcomponent structures. The main objective of this research work was to formulate and characterization of Boswellic Acid loaded polymeric Microsponges for topical. The polymeric microsponges formulation were prepared by nontoxic Quasiemulsion solvent diffusion techniques. The prepared formulation was characterized for its entrapment efficiency which was found to be 91.65%, and with 5 µm particle size. Drug release followed the zero-order kinetics., in 8 hrs. about 56.57%. drug release.

Keywords: Arthritis, Microsponges, Boswellic acid, Eudragit L100, Quasiemulsion

Formulation and characterization of mouth dissolving film of eugenol

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Abstract

Number of pharmaceutical dosage forms are available in the market but, every dosage form has shown some drawbacks like chocking problem of tablets and painful parenteral dosage form. Fast dissolving oral film hasmany advantages related to disintegration, dissolution and bioavailability over these existing dosage forms.In addition to this, film avoids first pass metabolism due to pre-gastric absorption and fast onset of action improved bioavailability lower the dosing. In present study we have formulate the oral mouth dissolving film of Eugenol and to perform its characterization studies that would be useful in oral cavity to protect against microbial infection. Formulation of oral thin films involves API, plasticizers, polymers, taste masking agent etc.These ingridients are used to formulate mouth dissolving film by solvent casting method Solvent casting method is the most preferred method comparison to other methods because it offers great thickness and uniformity of the films. Oral films are evaluated and characteristics for various parameters like thickness, folding endurance, surface pH, in-vitro dissolution test, transparency test, muco-adhesion etc.

Keywords: Dosage forms, Bioavailability, In-vitro dissolution test, muco-adhesion.

Formulation development and characterization of galactose conjugated nanoparticle of paclitaxel for effective treatment of hepatocellulacarcinoma

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Abstract

In this work we have performed synthesis of novel type of targetable polymeric conjugates with a sugar moiety (galactose) for potential application for liver-specific drug delivery. The simple and effective synthesis of PLGA-

galactose conjugate by esterification of the end carboxyl groups has been reported galactose conjugated PLGA nanoparticles of paclitaxel to be specifically recognised by human hepatocellular carcinoma (HepG2) cells and assess nanoparticle cytotoxicity. Paclitaxel loaded galactose conjugated PLGA nanoparticles were prepared using an emulsion method and characterized for morphology, (SEM) particle size, zeta potential, encapsulation efficiency, loading capacity, in-vitro drug release. The produced paclitaxel loaded PLGA -galactose conjugated nanoparticles are spherical in shape with a size of 206nm a drug encapsulation efficiency of 96%.

Keywords: Paclitaxel, Human hepatocellular carcinoma (HepG2), Nanoparticles.

Effect of Drug-Polymer Ratio on Particle Size, Dispersibility Index, and Drug Entrapment Efficiency of Nanogels Loaded with Montelukast

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Abstract

Montelukast is an anti-allergic drug commonly used to treat upper respiratory tract infections, including asthma. It antagonistically binds to leukotriene D4 receptors which are present throughout the body. Oral administration leads to unwanted systemic effects, which can be reduced if this drug is administered locally through the pulmonary route. Pulmonary administration of dry drugs leads to hypersensitization, which may aggregate inflammatory responses. The rationale of this work was to develop biocompatible montelukast loaded nanogels providing long-term effects. In the development of nanogel, a modified emulsification diffusion method was selected. The effect of the drug-polymer ratio on particle size, dispersibility index, and drug entrapment efficiency was studied. The particle size, zeta potential, and entrapment efficiency results were 107.9±7.2, 37.3±1.5, and 52.2±7.6, respectively. From the results, it was found that the drug-polymer ratio positively affects the results. Montelukast-loaded nanogels allow us to aim for further improvement in formulation for better treatment of asthma and allergy.

Keywords: Nanogels, Topical drug delivery, Montelukast, Asthma, Hypersensitization.

Targeted Delivery of Nanoparticles for the Treatment of Bone Cancer

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Abstract

Bone metastasis of malignant solid tumors has become one of the most serious complications, especially in breast cancer, which was particularly challenging for early detection and treatment in clinical practice. The CaSR has a pivotal role in bone and mineral metabolism, as it regulates parathyroid hormone secretion, urinary Ca2+ excretion, skeletal development and lactation. We have formulated a Targeted Delivery of Nanoparticles for The Treatment of Bone Cancer because coating of calcium work as ligand for CaSR Receptor. Formulation of calcium coated polymeric nanoparticle of doxorubicin hydrochloride to the target of CaSR by solvent evaporation method. Characterization of calcium coated nanoparticle of doxorubicin Hcl SEM (scanning electron microscopy), zeta size, zeta potential, entrapment efficiency, in-vitro drug release.

Keywords: Cancer, Targeted delivery, Nanoparticles

Formulation and Evaluation of Quetiapine Immediate Release Solid Oral Doses Form"

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Abstract

The scenario of pharmaceutical drug delivery is rapidly challenging, but conventional pharmaceutical dosage forms are still dominating. Tablets formulations are mostly preferred because of low cost of manufacture, package, shipment, and increased stability and virtual tamper resistance. The main goal of this study was to develop a stable formulation of antipsychotics Drug Quetiapine as an immediate-release tablet. Preformulation studies were conducted and ingredients for formulation were drug Quetiapine (Active), (filler), mannitol MCC RQ101 (filler) and magnesium stearate was used as a lubricant. As per the literature, Drug Quetiapine is a white powder which is freely soluble in water. It belongs to biopharmaceutical classification system (BCS) class 4 compound. Immediately release tablet is the best candidate for a wide range of therapeutic agent. To complete all this requirements the

immediate - release tablet of drug Quetiapine was formulated. It was a challenge to develop the optimise formulation of drug Quetiapine. By using the factor section factorial design, we found the optimised formulation. Direct compression parameter where optimised through the full factorial design. Various other process parameter like optimization and milling speed, optimisation lubrication time, Optimization of compression parameter were also performed throat OFAT trials. The optimised formulation was found to be stable in accelerated stabilities study.

Keywords: Antipsychotics, Quetiapine, ingredients, Preformulation.

Formulation and evaluation of gastoretentive floating captopril loaded hollow microsphere

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Abstract

To core objective of this work was to formulation and evaluation of captopril loaded hollow microspheres for controlled release. Captopril is rapidly absorbed orally and has a bioavailability of 75%. The duration of action after a single dose is 6 to 8 hrs. Due to its relatively short half- life a controlled release captopril formulation would bring benefit to patient, including reduction in frequency of administration, increase patient complaints and effectiveness of treatment reduction in plasma concentration fluctuation as well as a reduction in side effect. Emulsification technique accompanied by solvent evaporation method employed for manufacturing of captopril loaded microsphere where the less density so due to this it float on the gastric fluid so prolonged gastric retention can improves the bioavailability.

Keywords: Captopril, Microsphere, gastric retention.

Formulation and Evaluation of Quetiapine Immediate Release Solid Oral Doses Form

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Abstract

The scenario of pharmaceutical drug delivery is rapidly challenging, but conventional pharmaceutical dosage forms are still dominating. Tablets formulations are mostly preferred because of low cost of manufacture, package, shipment, increased stability, and virtual tamper resistance. The main goal of this study was to develop a stable formulation of antipsychotics Drug Quetiapine as an immediate-release tablet. Preformulation studies were conducted and ingredients for formulation were drug Quetiapine (Active), (filler), mannitol MCC RQ101 (filler) and magnesium stearate was used as a lubricant. As per the literature, Drug Quetiapine is a white powder which is freely soluble in water. It belongs to biopharmaceutical classification system (BCS) class 4 compound. Immediately release tablet is the best candidate for a wide range of therapeutic agent. To complete all these requirements the immediate - release tablet of drug Quetiapine was formulated. It was a challenge to develop the optimise formulation of drug Quetiapine. By using the factor section factorial design, we found the optimised formulation. Direct compression parameter where optimised through the full factorial design. Various other process parameter like optimization and milling speed, optimisation lubrication time, Optimization of compression parameter were also performed throat OFAT trials. The optimised formulation was found to be stable in accelerated stabilities study.

Keywords: antipsychotics, Quetiapine, ingredients, Preformulation

Formulation and Biological Evaluation of Anti-scar Activity of Herbal Cream in Swiss Albino Rats

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Abstract

Skin scarring is a complex process induced by damage to the skin layers and injuries to the tissue.lentil is a natural and easily available plant in indiabelongig to *fabacae* family. Lentils have strong antioxidants, anti-inflammatory and wound healing activity,Amino acids are the chief ingredient of the red lentil which is responsible for anti-scar activityit also contains saponins, vitamin-E and oleonolic acid having anti-scar property. The present paper deals with the formulation and evaluation of anti-scar cream containing red lentil extract. Aqueos extract of red lentil seeds was evaluated for anti-scar activity in swiss albino rats which was shown significant antiscar activity. Aqueos extract was used to develop cream which has shown excellent skin compatibility. The present results demonstrate that the dried extract of red lentil has a good potential for anti-scar cream formulation in cosmetic product development.

Keywords: Biological evaluation, Extraction, Anti-scar activity, Compatibility, *in-vivo* study.

Formulation and Evaluation of Polyherbal Antimicrobial Tooth Gel

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Abstract

Maintaining oral hygiene is an important aspect of everyday life, to have good oral health various dental products are used like tooth powder, tooth paste, tooth gel etc. Out of them now a days tooth gel is popular among people due to its good cleansing property to extract the dental plaque and food from the teeth. It is more appropriate and safer to formulate anti-microbial polyherbal tooth gel with reduced side effects than available dental products such as synthetic and herbal preparations. The aim of study is to formulate and characterize polyherbal anti-microbial tooth gel for the treatment of oral cavities, mouth ulcers and other types of dental diseases. Hydroalcoholic extract of equal mixture of 10 herbs was evaluated its antimicrobial activity against *S. mutans*bydisc diffusion method and used it for tooth gel formulation.After this study it can be concluded that, the above formulated anti-microbial herbal tooth gel is totally capable of maintaining the oral hygiene, mouth ulcer, etc.

Keywords: Oral hygiene, tooth gel, antimicrobial activity.

Formulation Development and Evaluation of Floating tablet Effervescent Vs Non-Effervescent

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Abstract

The present studies discuss about the development and evaluation of floating drug delivery system of Tetrabenazine. Available immediate release dosage forms do not have the property to retain in the stomach, probably the solubility and dissolution may have affected. Tetrabenazine is soluble in acidic pH. So, a formulation design that will allow the drug to be remain in the acidic environment of the stomach will have better solubility and dissolution. Afloating drug delivery system (Floating tablet) with both effervescent and non-effervescent technology has been proposed. Both the development strategy has been found suitable to retain the dosage form in the stomach. Main principle of the effervescent system works by generating gas with the use of Sodium Bicarbonate and Citric Acid. The other strategy, i.e. non effervescent systems utilizes low molecular weight polymers in the formulations with bulk density less than 1, which allows the dosage form to float. The prepared effervescent formulations showed a drug release profile up to 10 hours, whereas the non-effervescent formulation showed a drug release over a period of 16 hours.

Keyword: Formulation Development, Tetrabenazine, Floating tablet.

QBD-based approach on Solid Dispersion Extended-release system: Formulation, Characterization and pharmacokinetic Assessment

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Abstract

The present research work was aimed for an innovative study to explore the best among the better carriers for preparing solid dispersions (SDs) using novel microwave fusion technique by taking Ganciclovir (GCR) and Lopinavir (LPR) as model drugs. Ganciclovir is a DNA polymerase inhibitor used to treat cytomegalo virus and herpetic keratitis of the eye. Ganciclovir is used to treat complications from AIDS-associated cytomegalovirus infections. Lopinavirisan HIV-1 protease inhibitor used in combination with ritonavir to treat human immune deficiency virus (HIV) infection. Quality by Design (QbD), A current trend employed to develop and optimize various critical pharmaceutical processes using successful carriers of Poly Ethylene Glycols, Poly Vinyl Pyrrolidone, Poloxamers and Urea for increasing the solubility of GCR and LPR. AHPLC technique was established for the instantaneous assessment of the optimized combination of GCR and LPR with controlled release formulations. For this in addition to physicochemical studies, accelerated stability studies, *in vivo* pharmacokinetic assessment were also performed. Significant in vivo enhancement has been established using solid dispersion technique. All the parameters favored enhancing the solubility and dissolution of the GCR &LPR

Keywords: Solubility, Dissolution, Solid dispersion, Lopinavir, Ganciclovir.

Formulation Development and Evaluation of Canagliflozin Tablet by Solid Dispersion Technique using QbD approach

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Abstract

The need of study is to develop and evaluate Canagliflozin tablets by solid dispersion technique using QbD approach. In the present work, the anti-diabetic Canagliflozin drug is selected to develop solid dispersion to enhance the dissolution as the drug belongs to BCS class IV (Low solubility and Low permeability). Appropriate preformulation characteristics along with method development using UV spectroscopy method were performed. For improvement of solubility of the poorly soluble drugs solid dispersion technique was adopted. Kneading process of solid dispersion was selected using hydrophilic polymers Poloxamer 188P. For 300mg Tablet, 100mg Canagliflozin, 100 mg Poloxamer 188P and other ingredients were used. As per the QbD approach, eleven number runs were selected with different formula. The optimized formulations weres elected for preparation of tablet. The tablets were evaluated with referred experimental protocol. The animals were injected with streptozotacin (60 mg/kg) to produce diabetes in the experimental animals. Animals with more than 250 mg/dL of blood glucose were considered diabetic. Because of this, canagliflozin tablets formulated in a solid dispersible form have a higher dissolving rate and bioavailability. The tablet was non-toxic in a 2000 mg/kg acute oral toxicity investigation based upon the comparative reports of biochemical and haematological parameters obtained through the blood report withdrawn from both control and test group.All theparameters favored enhancing the solubility and dissolution of the Canagliflozin through the solid dispersion process.

Keywords: Solubility, Dissolution, Solid dispersion, Canagliflozin, Kneading.

A Novel Stability indicating chromatographic Method development and Validation of Controlled Release Tofacitinib Citrate Tablets by RP-HPLC Method

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Abstract

Tofacitinib citrate is the first choice of Janus kinase (JAK) inhibitor for the treatment of Rheumatoid arthritis. Tofacitinib citrate inhibits the phosphorylation and activation of JAKs. A novel reverse phase high performance liquid chromatography (RP-HPLC) method was developed for detection and quantification of related substance and assay for Tofacitinib citrate from a controlled released oral tablet dosage form. Based on the preliminary optimization of chromatographic conditions Kromasil 100-5 C18, 150 mm x 4.6 mm.i.d. 5m Particle size was identified as suitable column and Phosphate Buffer: Acetonitrile = 80:20 (pH-6.8) was selected as mobile phase. The UV spectrum has been recorded on ELICO SL-159 make UV–Vis spectrophotometer model UV-2450 for selection of wavelength. A suitable wavelength of 292 nm was identified as scanning of drug substance. Novel Stability indicating Chromatographic method significantly showed linearity in the range study of 7.5-22.5 µg/ml. As per ICH guidance, analytical method was developed by keeping in mind that the purity as well as assay of drug during storage with different temperature and humidity condition should be determined by using validated stability- indicating methods and can be determined the presence of drug in its process and degradation impurities in product. Chromatographic method validation was done for precision, accuracy, LOD, LOQ and specificity as per recommended International Conference on Harmonization (ICH) guide-lines. Proposed method development was used for the determination of Assay and degradation impurities in the regular quality control analysis for the Controlled Release Tofacitinib Citrate Tablets.

Keywords: Tofacitinib citrate, RP- HPLC, method development, Method validation, ICH.