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8th Annual International Conference on IPR

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Dec. 5-6, 2023
Goa College of Pharmacy
Panaji, Goa - INDIA

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TITLE: Formulation,Characterisation and Evaluation of Mefenamic acid nanosponges

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ABSTRACT: (Not more than 250 words)

Nanosponges are formulated to enhance drug delivery by encapsulating and protecting drugs, promoting their controlled release, and improving their solubility. These nano-sized structures can also target specific cells or tissues, minimizing side effects and optimizing therapeutic outcomes.

Mefenamic acid-loaded nanosponges were created to facilitate controlled drug release, employing a Factorial Design methodology. The nanosponges were synthesized through the emulsion solvent diffusion method, using ethyl cellulose, acetone, dichloromethane, and polyvinyl alcohol (PVA). Optimization was achieved via a randomized 3^2 full factorial design with the assistance of Stat-Ease Design Expert software.
Two key factors, namely the drug-polymer ratio and stirring speed, were chosen for assessing in-vitro drug release and particle size. The optimal drug-polymer ratio was determined to be 1:1. These optimized nanosponges had a particle size of 538 nm and an encapsulation efficiency of 89.92%.
Significantly, both the drug-polymer ratio and stirring speed had a substantial impact on in-vitro drug release and particle size. Scanning electron microscopy analysis confirmed that the optimized drug-loaded nanosponges exhibited a porous spherical structure.
The optimized nanosponges demonstrated controlled drug release, with a release rate of 95.92% over a period of 12 hours. Finally, the nanosponges were encapsulated within capsules and subjected to further evaluation.

KEYWORDS: Nanosponges, Factorial Design, Mefenamic acid, Optimization, Rheumatoid Arthritis, Controlled drug delivery system.

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TITLE: Development of patient-friendly Glimepiride 3D printed tablets

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ABSTRACT:

Background: 3D printing is an additive manufacturing technique involving layer deposition of desired materials. 3D printing of pharmaceuticals has gained popularity since 2015 when USFDA approved SPARITAM, the first ever 3D printed tablets for commercial manufacturing via Zipdose technology. 3D printed tablets offer several advantages over conventional tablets, such as shape size and dose flexibility, multi-drug combination, print on demand, faster prototype development, and designing patient-friendly dosage.

Objective: Herein, we explored the development of patient-friendly Glimepiride 3D printed tablets

Methods: Drugink containing pharmaceutical-grade natural polymer, base polymer, and gelling agents were formulated as hydrogels and crosslinked with an ionic crosslinker. Printing is performed at ambient temperature in an extrusion-based 3D printer. Drying was performed via the lyophilization method to obtain a steady tablet shape. Preprinting testing of hydrogel was done for printability, viscosity, rheology, and pH. Dried tablets were tested for tablet hardness, dissolution, and content uniformity.

Results: We successfully demonstrated 3D printing at ambient conditions with the drug. The printability experiment revealed that hydrogel can be printed in various shapes and sizes. The hydrogel demonstrated shear thinning behavior, which is desired for extrusion-based 3D printing. The viscosity of hydrogels was suitable for flawless printing; tablets were formulated as chewable dosages suitable for administering tablets without water. Drug release was found to be extended compared to marketed products. Content uniformity was well within predefined criteria, and printed dried tablets had good tablet hardness.

Conclusion: We developed chewable 3D-printed tablets that can be taken without water and sidestep swallowing difficulty. Extended-release dosage can help attain maximum efficacy. Such 3D-printed tablets are indeed patient-friendly, which eases drug administration. Such patient-friendly dosages benefit patients suffering from chronic diseases like diabetes, where patients have to take medicine for life long.

KEYWORDS: Chewable tablets, extended-release, 3D printed tablets, Semi-Solid Extrusion

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TITLE: DEVELOPMENT AND EVALUATION OF A NOVEL FORMULATION

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ABSTRACT:

The purpose of this study was to formulate and optimize the cyclodextrin-based nanosponges(CDNS) and to investigate their effect on the solubility of Aceclofenac(ACF). The CDNS were prepared by the melt method and characterized suitably. Phase solubility profile with Cyclodextrin(CDs) was classified as A_L type indicating an increase in solubility of ACF with the increase in concentration of CDs. The CDNS were optimized using five centric Box Behnken design to study the effect of the independent variables viz. conc. of CD, conc. of crosslinker and reaction time which significantly influence the characteristics like percentage yield, particle size, and intensity of bond formation. ACF was incorporated into the nanosponges by the freeze-drying method and the formed binary system was then characterized by FTIR, DSC, XRD, particle size, and TEM. The results showed a significant increase in the solubility of ACF which could contribute to its overall bioavailability enhancement. The % drug loading and % entrapment efficiency were found to be 56.82±1.18% and 86.39±1.54. In FTIR a peak at around 1772.88 cm^{-1} is a distinctive feature of carbonate crosslinked CDNS. DSC, FTIR, and XRD studies revealed the entrapment of the drug within the cavities of the nanosponges. The particle size and zeta potential for drug loaded NS was found to be 1286 nm and -18.2 mV. TEM scans for ACF loaded CDNS show the encapsulation of ACF inside the nanocavities. In vitro drug release studies showed the drug release of 101.7654 % at the end of 24 hours.

KEYWORDS: β-cyclodextrin, crosslinker, freeze drying, optimization, solubility

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TITLE: Formulation and Evaluation of Extended-Release Matrix Tablet of Metoprolol Succinate Resistant to alcohol Induced Dose Dumping

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ABSTRACT:

Alcohol-induced dose dumping (ADD) is a critical concern in the development of modified release (MR) oral drug formulations, since it can result in erratic drug release, jeopardizing patient safety and treatment efficacy. The present study aimed to design and evaluate an extended-release matrix tablet of Metoprolol succinate resistant to alcohol-induced dose dumping. Metoprolol succinate, a Beta 1 selective adrenergic receptor blocker, is prescribed for various cardiovascular conditions due to its short half-life, necessitating frequent dosing. The extended-release matrix tablets were formulated using Kollidon SR, xanthan gum, and magnesium stearate via direct compression. The prepared tablets underwent rigorous testing, conforming to both pharmacopeial and non-pharmacopeial standards. The optimized formulations exhibited drug release profiles consistent with therapeutic requirements, with sustained release over 24 hours in phosphate buffer pH 6.8. The formulation demonstrated resistance to alcohol-induced dose dumping, even in the presence of 40% alcohol in the buffer, unlike the marketed product. The key to this resistance lay in the synergistic combination of Kollidon SR and Xanthan gum in a 1:1 ratio. Drug release kinetics revealed a dependence on solvent concentration and surface area, following first-order kinetics and the Hixon-Crowell model. The optimized formulation showed promising results in comparison to the marketed product, highlighting its potential for clinical use.

KEYWORDS: Alcohol-induced dose dumping, Metoprolol succinate, extended-release matrix tablet, drug release kinetics, resistance.

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TITLE: Formulation of esculin loaded transethosomal gel for taregtting skin cancer and its analytical method development and validation by QbD approach.

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ABSTRACT: (Not more than 250 words)

The objective of this study is to develop, assess and optimize transethosomal gel containing esculin, with the specific aim of targeting skin cancer. Esculin was successfully incorporated into a transethosome formulation using the ethanol injection method and its particle size, encapsulation efficiency (%EE), zeta potential (ZP) and polydispersity index (PDI) were evaluated. The formulation was further optimized using design expert software, and the selected batch was evaluated for its compatibility using DSC and FT-IR. In addition, in-vitro cytotoxicity studies and in- vitro drug release studies were conducted on optimized batch. Subsequently the optimized batch was incorporated into the gel and its pH, viscosity and ex-vivo permeation was evaluated. Furthermore, in-silico analysis was performed to explore the potential mechanism of esculin's anti-cancer activity against skin cancer. Based on the study findings, the esculin loaded transethosomal gel formulation demonstrated promising potential in migrating skin cancer and its associated conditions.

KEYWORDS: Esculin, transethosome, skin cancer, ICH, QbD.

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TITLE: **FORMULATION AND EVLUATION OF COMPRESS COATED TABLET TRAMADOL HCL FOR PULSATILE DRUG DELIVERY**

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ABSTRACT: (Not more than 250 words)

A pulsatile drug delivery approach was used to achieve drug release after a lag period in Tramadol HCl tablets formulated for the treatment of rheumatoid arthritis. The tablets consist of a core containing the active ingredient and a coating made up of Ethyl cellulose (EC) and Hydroxy Propyl Methyl Cellulose (HPMC) K4M polymers in different weight ratios. Polyvinylpyrrolidone (PVP) K30 is used as a binder in the coating. The polymer coating around the core prevents the drug from being released during the lag phase. After a required period, the coating polymers begin to erode and dissolve completely, allowing the drug to be released. The dissolution profiles of the core tablet and the compressed coated tablets were compared, and nine formulations (F1-F9) were prepared using 3^2 full factorial design. F8 (EC-155 mg, HPMC k4M-130mg as a coating agents) showed only 11% of drug release in 6 hours, making it suitable for pulsatile drug release. The data were also analyzed using 3-D response surface methodology to study the interaction of independent variables.

KEYWORDS:
Pulsatile Drug Delivery, Ethyl Cellulose, Hydroxypropyl Methyl Cellulose, lag phase, 3^2 full factorial design

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TITLE: Development and Evaluation of Luliconazole Niosomal Transdermal Drug Delivery System.

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ABSTRACT: (Not more than 250 words)

According to earlier research, using niosomes as drug carriers, particularly for antifungal drugs, produces greater results than using alternative carriers. Niosomes has the capacity to encapsulate both hydrophilic and hydrophobic pharmaceuticals, as well as their prolonged stability in circulation. This work aimed to prepare and evaluate luliconazole niosomal gel for antifungal activity. In this study, niosomes containing luliconazole were prepared by thin film hydration technique using non-ionic surfactant (Span 60 and Tween 80) and cholesterol at different concentrations. The prepared formulations were evaluated for optical microscopy, drug entrapment efficiency, drug content, in-vitro drug release study, and stability studies. The ratio 2:1 of span 60 and cholesterol showed better results. Hence it was optimized as the final vesicle formulation. The FTIR study concluded there was no interaction between Luliconazole and any of the excipients. The niosomes gel was evaluated for various parameters of all the formulations. The 1% Carbopol 934 gel shows the best and most promising results. The niosomal gel formulation could be a useful dosage form to increase efficacy by the transdermal route. The potential of a secure and efficient therapy for difficult clinical applications is made possible by the development of niosomes with target specificity. Therefore, niosomes gel may be considered the best vesicular carrier for the effective delivery of luliconazole through the skin.

KEYWORDS: Niosomes, Antifungal, Luliconazole, Carbopol Gel, Span 60, Tween 80, Cholesterol, Thin film hydration.

TITLE: Hyaluronic Acid Functionalized Graphene Quantum Dots Nanocomposites of Capecitabine for Targeted Delivery and Cancer Cell Imaging

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ABSTRACT: (Not more than 250 words)

Background: Recently, there has been a lot more focus on nanoparticle-based drug delivery methods. Graphene quantum dots (GQD) were used as drug carriers and cancer cell imaging agents in this context. In order to achieve the effective and specific targeting hyaluronic acid was used which helps in reaching the drug to final destination.

Objective: The aim of the study was to obtain effective and target specific graphene quantum dots using hyaluronic acid as targeting agent.

Method: One-step hydrothermal strategy was used to synthesize strong blue fluorescence, stable and water soluble Sulphur and nitrogen co-doped graphene quantum dots with citric acid as carbon source and Thiourea as source of Sulphur and nitrogen. Catechol moiety, dopamine hydrochloride was conjugated to hyaluronic acid and attached to graphene quantum dots which will adopts its intriguing adhesive characteristics.

Results: The prepared graphene quantum dots were confirmed by UV spectroscopy, FTIR, SEM and TEM analysis. The complexation of hyaluronic acid and dopamine was confirmed by NMR spectroscopy and the drug loading on nanocomposites was calculated and found to be 99.61 %. The effect of graphene quantum dots and graphene quantum dot-hyaluronic acid- capecitabine was evaluated by MTT test and cell imaging.

Conclusion: The prepared novel GQD-HA-CAP nanocomposite has promising future in specific drug targeting and tumor cell imaging of breast cancer because of its increase bioavailability, low toxicity, fluorescence imaging, enhance stability and good therapeutic efficacy.

KEYWORDS: Graphene quantum dots, hyaluronic acid, capecitabine, targeting, cancer cells, fluorescence, drug release.

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TITLE: Bilayer Gastro-retentive tablets consisting combination of Ivabradine hydrochloride and Trimetazidine dihydrochloride

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ABSTRACT: (Not more than 250 words)

Coronary artery disease is most prevalent and leading cause of death worldwide which impairs patient's quality of life and rises country's burden on economic and healthcare system. Ischemia involves multiple pathogenesis therefore its management needs systematic and tailored approach. Generally angina patients have comorbidities like diabetes, COPD or develop intolerance to beta blockers. Ivabradine is selective if channel blocker, pure heart rate lowering agent and Trimetazidine dihydrochloride is cardioprotective agent shows anti-ischemic action without hemodynamic changes, however both drug have shorter half-life hence multiple administration requires to maintain therapeutic drug concentration.

At present there is no gastro-retentive bilayer tablets available in market consisting Ivabradine and Trimetazidine combination for the treatment of angina. Therefore main objective of present research was to develop and evaluate once daily bilayer gastro-retentive tablets consisting of Ivabradine hydrochloride and Trimetazidine dihydrochloride.

Bilayer gastro-retentive tablets were formulated using direct compression and floating approach. Drug-excipient compatibility were studied by DSC and FTIR. Immediate release of Ivabradine hydrochloride was developed using Avicel PH 112, Vivasol, Klucel EXF and Trimetazidine dihydrochloride floating layer was formulated using Kollidon SR, Benecel K100 M, Xanthan gum and Sodium bicarbonate.

Best immediate release formula displayed disintegration time 15 seconds with 100% drug release within 5 minutes and gastro-retentive layer showed floating lag time less than 1 minutes, more than 24 hours of total floating time and controlled the 100 % drug release up to 18 hours. Based on result it can be concluded the bilayer tablets successfully formulated, further design of experiment can be applied to obtain flexible design space.

KEYWORDS: Angina, Combination therapy, Bilayer tablets, Gastro-retentive tablets, Ivabradine hydrochloride, Trimetazidine dihydrochloride, Floating approach

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TITLE: **Bioavailability Enhancement Of A Poorly Soluble Drug Used In The Treatment Of Hyperuricemia And Gout By Solid Dispersion Technique.**

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ABSTRACT: (Not more than 250 words)

Febuxostat is a poorly soluble drug used in the management of hyperuricemia and gout.The objective of the present study is to enhance the solubility of Febuxostat by solid dispersion technique with the help of different polymers (Beta cyclodextrin ,soluplus® , HPMC E5 and kolliphor P407) in various drug:carrier ratios using solvent evaporation method. Characterization of solid dispersion for physical appearance, percentage yield, drug content, saturation solubility studies and dissolution studies, etc was carried out.

Saturation solubility studies revealed that there was an increase in solubility of the solid dispersion compared to pure drug. *Invitro* release profiles of all solid dispersions were comparatively evaluated and studied against pure febuxostat drug. Formulation SD20, having drug: kolliphor P 407 (1:9 ratio) (SD 20) showed a higher dissolution rate but at this concentration the dispersion had a gel-like appearance, thereby limiting its yield.

Hence it could not be used for further studies. Hence SD 18 (1:5 drug:kolliphor P407) is chosen as an optimized formulation for further studies because there is no loss of drug and also shows an increase in solubility and dissolution compared to pure drug. The powder X-ray diffraction study and scanning electron microscopy (SEM) studies exhibited conversion of crystalline drug to amorphous form in solid dispersion. The study demonstrated that solid dispersion are highly effective technique to increase solubility, dissolution and bioavailability of a poorly soluble BCS class II drug febuxostat.

KEYWORDS: Febuxostat (FBX), Solid Dispersion (SD), Hyperuricemia, Gout, Solubility studies.

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TITLE: FORMULATION AND CHARACTERISATION OF A NOVEL DRUG DELIVERY SYSTEM

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ABSTRACT:

BCS class IV medicines create difficulties for ideal treatment because of their low absorption and restricted water solubility. The aim of this study was the formulation and evaluation mesalamine-loaded cyclodextrin-based nanosponges based colon targeted tablet for solid oral formulation. The primary goal is to enhance solubility, stability, and overall patient compliance of the drug Mesalamine (MES). The study explores the potential of CDNS to achieve effective drug delivery to the colon, improving therapeutic impact while mitigating side effects. Preformulation studies authenticate the drug, and molecular docking studies, phase solubility studies guide the selection of β-cyclodextrin (βCD) as a suitable polymer for CDNS synthesis. The formulation development employs a Box Behnken design to optimize the CDNS formulation. Mesalamine was loaded into optimized β-Cyclodextrin nanosponge formulations by freeze-drying and characterized for physicochemical properties. The MES-loaded CDNS that provided highest drug loading capacity and entrapment efficiency (57.98%, 77.6% respectively) was morphologically examined using transmission electron microscopy (TEM). Also, Particle size, zeta potential, differential scanning calorimetry (DSC), Fourier transform infra-red (FTIR), powder x-ray diffraction (PXRD) studies, *in-vitro* release, were evaluated. The optimize blank CDNS and MES-loaded CDNS showed particle size 1207 ± 1.41 nm, 1165.66 ± 2.84nm. The DSC and FTIR analysis confirmed the complexation of MES with CDNS. Further, MES-loaded CDNS are formulated into colon-targeted tablets using Eudragit S100 as a pH-sensitive polymer. The tablets exhibit desired physicochemical characteristics and demonstrate prolonged drug release compared to pure MES and marketed tablets.

KEYWORDS: Nanosponges, β-cyclodextrin, irritable bowel syndrome, solubility, colon

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TITLE: FORMULATION AND EVALUATION OF A TRANSDERMAL DRUG DELIVERY SYSTEM BASED ON THE PRINCIPLES OF QUALITY-BY-DESIGN

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ABSTRACT:

The development of nanosponge (NS) has become a crucial step in solving some challenges, such as drug toxicity, low bioavailability, and predictable drug release. Antimicrobial drugs in topical formulations are an intriguing option for the prevention and treatment of wound infections. Mupirocin (MUP) is a topical antibiotic used to treat both primary and secondary skin infections. It has a wide range of treating both gram-positive and gram-negative microorganisms. MUP has some side effects like blistering, crusting, irritation, itching, redness etc if used for a prolonged period of time or when the dose of the drug is increased, and its potential efficacy is hampered due its short half-life, high protein binding and different resistance. Thus, the aim of the research was formulation and evaluation of MUP-loaded CDNS for topical application, which will enhance the drug release with lesser side effects. The Interfacial condensation method was chosen for synthesising the blank CDNS using Diphenyl carbonate as a crosslinker. The Box Behnken design was employed in the StatEase Design-Expert Software to optimise the formulation. The optimised batches of MUP-loaded xerogel formulation and MUP-loaded CDNS released more than 90% drug in just 150 mins (2.5 hrs), with only 3.41% and 5.41% of the drug getting permeated into the skin from the optimised batches of MUP-loaded Xerogel formulation and MUP-loaded CDNS respectively.

KEYWORDS: cyclodextrin, nanosponges, antimicrobial, xerogel. antibiotic

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TITLE: FORMULATION, CHARACTERIZATION AND EVALUATION OF SOLID DISPERSION FOR CNS DRUG LOADED IN TRANSDERMAL PATCH

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ABSTRACT: (Not more than 250 words)

Bromocriptine Mesylate (BM) solid dispersion (SD) was formulated and loaded into matrix type transdermal patch, which was optimized and characterized. BM is an anti-Parkinson's agent, belonging to the Biopharmaceutics Classification System (BCS) Class II, having low aqueous solubility and high permeability. The solubility and bioavailability of BM were enhanced by preparing SDs using 2 different types of carriers such as Hydroxy propyl beta cyclodextrin (HP-β-C) and Hydroxy propyl cellulose (HPC) individually and in combination, by Solvent evaporation and Kneading method. The optimized SD was selected based on %yield, %drug content and in vitro dissolution data. The SD prepared by kneading method using the combination of 2 carriers in a drug carrier ratio of 1: 0.5 :3 (F4), exhibited the highest percentage yield of 97.640 ± 0.7692 %, percentage drug content of 98.770 ± 0.8129 % and in vitro drug release of 98.85 % in 60 mins. Hence, F4 was used in the formulation of the transdermal patches. The design of experiment (DoE) was considered using 2^3 Full factorial design, and conc. of HPMC K4M, Eudragit RL 100 and Propylene glycol were selected as the independent variables. A formula for 8 runs was generated, which was formulated using the solvent casting method. Diffusion study and folding endurance were selected as the Dependent variables (Response variables). Based on the response data the system generated a formula for the optimized transdermal patch (E9) which was then evaluated on various parameters such as thickness, weight variation, %drug content, tensile strength, %elongation, folding endurance, surface pH, in-vitro diffusion study, ex-vivo permeation study and skin irritancy study. Based on the results obtained, it was concluded that BM-SD loaded transdermal patch was successfully developed with a markedly improved dissolution profile, avoidance of extensive first-pass metabolism, improved patient compliance, effective and safe for use.

KEYWORDS: Bromocriptine Mesylate, Transdermal patch, Solid dispersion, Kneading method, 2^3 Full factorial design, ex-vivo permeation study, Skin irritancy study.

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TITLE: FABRICATION, CHARACTERIZATION AND EVALUATION OF MEMBRANE MODULATED TRANSDERMAL PATCH FOR BCS CLASS II DRUG

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ABSTRACT:

Tizanidine HCl is a short acting skeletal muscle relaxant with bioavailability of 34% and has a half-life of 2.5 h, thus requires frequent dosing to maintain the therapeutic level of drug in the body. Transdermal patches offer several advantages which can overcome the drawbacks associated with the oral administration of the drug. The main aim of the study is to formulate a membrane modulated transdermal patch for TZH by solvent evaporation method. Varying formulations of transdermal patch were prepared and optimized by applying 2^3 full factorial design. The effect of different concentrations of HPMC K4M (X_1), sodium alginate (X_2) and tween 80 (X_3) was studied on % drug release and folding endurance. The optimized transdermal patch was characterized for pH, folding endurance, tensile strength, % moisture loss, % moisture uptake, swelling index and drug content, the results of which were 6.5 ± 0.1, 320.33 ± 1.52, 272.33 ± 2.08 g/cm^2, 4.35 ± 0.608, 3.52 ± 0.82, 77.7 ± 0.006% and 98.43 ± 0.409 respectively. In-vitro diffusion study obtained after 24 h was found to be 62.34 ± 0.86 and after 72 h was 97.72 ± 0.43. In-vitro permeation study was conducted using human cadaver skin for 24 h and the % drug permeation was found to be 58.33 ± 1.1%. The formulated patches showed no sign of irritation in rats. The optimized transdermal patches found to be stable at 25ºC ± 2ºC and 60 ± 5 % RH for a period of 4 months. The results of the study indicate that the patches have the potential to provide sustained release of the drug and thus will improve bioavailability and patient compliance.

KEYWORDS: Tizanidine HCl, skeletal muscle relaxant, transdermal patch

TITLE: DEVELOPMENI, CHARACTERISATION AND EVALUATION OF MODIFIED RELEASE FORMULATION CONTAINING ANTISPASMODIC DRUG

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ABSTRACT:
Antimuscarinic agents are commonly used in the pharmacological treatment of overactive bladder (OAB). However, oral administration of Tolterodine tartrate (TT), an antimuscarinic agent having antispasmodic activity, is associated with poor patient compliance due to frequent dosing and the occurrence of anticholinergic side effects, particularly dry mouth, constipation, headache, and blurred vision. To overcome these limitations, the present study aimed to develop a modified release bilayer transdermal patch containing TT as an alternative route for drug delivery. The modified release bilayer transdermal patch was successfully developed consisting of an immediate release layer using HPMC E15 to achieve the therapeutic drug concentration in a short period of time and controlled release layer using HPMC K4M and Eudragit RLPO to maintain the drug concentration for the desired period of time. Through a 2 level Full Factorial design, the bilayer transdermal patch formulation was optimized based on in vitro drug release and folding endurance. The optimized transdermal patch exhibited desirable physicochemical properties, such as appearance, drug content, weight uniformity, thickness, surface pH, swelling index, moisture content, moisture loss, tensile strength, elongation at break and water vapour transmission rate. The in vitro drug release study demonstrated a burst release of 29.92 ± 0.27% within the first hour and cumulative release of 81.84 ± 1.91% over 72 h, with a diffusion controlled release pattern supported by the Korsmeyer-Peppas' plot. Furthermore, the ex vivo permeation study using human cadaver skin showed that the patch effectively delivered TT into the systemic circulation, with 74.09% of the drug permeating at 24 h and a flux of 0.0156 mg/cm2 /h. The patch exhibited good biocompatibility and safety, as confirmed by the skin irritation study, with no signs of edema, erythema, or skin irritation. Stability testing demonstrated that the optimized transdermal patch remained stable over a 4-month period at 25ºC ± 2ºC, maintaining its general appearance, drug content, and tensile strength. In conclusion, the developed TT transdermal patches present a promising alternative for drug administration in the treatment of OAB. The developed transdermal patch offers the potential to minimize side effects, improve patient compliance, and enhance therapeutic outcomes. Further studies exploring the pharmacokinetic profile of TT delivered through the transdermal patch can provide a more comprehensive understanding of its systemic availability and bioavailability, supporting its potential as an effective treatment option for OAB.

Keywords: Antispasmodic, Bilayer, Modified release, Overactive bladder, Antimuscarinic, diffusion, physicochemical, biocompatibility, pharmacokinetic.

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TITLE: Nanosuspension Loaded Mouth Dissolving Film

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ABSTRACT:

In recent years many scientists are focusing to develop nano formulation to enhance bioavailability of poorly soluble drug. Nanosuspensions is one of the approaches to increase solubility and bioavailability of BCS class 2 and Class 4 drug. There are many techniques to formulate nanosuspensions but High Pressure Homogenization method is most widely used as it applicable for many drugs and having several advantages over other methods. Formulated nanosuspension can be evaluated by parameters like Particle size, Surface charge (Zeta potential), crystalline state and particle morphology, Saturation solubility and Dissolution velocity, pH, Viscosity. Nanosuspensions have many applications and it is used by various route viz Oral, Parenteral, Pulmonary, Ocular, Topical. In this work, Mouth Dissolving Films were prepared using Nanosuspension formulations in order to optimise dissolution properties of lipophilic, poorly soluble drug Raloxifene HCL is the selective benzothiophene estrogen receptor modulator (SERM) which also have lipid lowering effect and activity against osteoporosis. Raloxifene HCl nanosuspensions were prepared using a High-Pressure Homogenizer, and then encapsulated in to films by solvent casting method by adding film forming polymer and other ingredient directly to the Nanosuspension. This study aimed to develop and evaluate the formulation of Mouth Dissolving Film containing Raloxifene HCl nanosuspensions for enhanced bioavailability and better compliance.

KEYWORDS: Nanosuspension, High Pressure Homogenization, Bioavailability, Mouth Dissolving Film

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TITLE: DEVELOPMENT AND EVALUATION OF PULSATILE DELIVERY SYSTEM

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ABSTRACT:

The main objective of the present study was to design and evaluate controlled release pulsatile drug delivery system containing dexlansoprazole for the treatment of peptic ulcer. In this study, PDDS prepared by pulsincap technology it contain cross linked hard
gelatin capsule shell, optimized immediate release tablet, hydrogel plug prepared by direct compression, sodium alginate beads prepared by ionotropic gelatin method also contain coating of capsule by dip coating method. The prepared formulation were evaluated by physical parameter, dissolution, swelling index, disintegration time , alginate beads – entrapment efficacy, in vitro drug release, particle size. Result-The FTIR studies concluded that there was no interaction between dexansoprazole and excipient. in tablet -the ratio (1:2) of drug and super disintegrant show better result .for hydrogel polymer HPMC K15M show desired swelling time. The stability study of capsule carried out as per ICH guidelines the F2 tablet (1:2) ratio and 2% sodium alginate beads shows better result. From the present research work, it was concluded that the preparation ofpulsatile drug delivery system of dexlansoprazole through pulsincap technology can give drug release in pulse manner that is first immediate release, lag time and sustain action.

KEYWORDS: dexlansoprazole, Pulsatile drug delivery, immediate release tablet, sodium alginate beads, Peptic ulcer.

TITLE: Formulation and Evaluation of Microemulsion Based Gel of Antifungal Drug

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ABSTRACT:

The objective of the research is to formulate and evaluate a Microemulgel system loaded with the antifungal drug Itraconazole microemulsion for effective treatment of skin infections. Optimized microemulsion batches were selected through a pseudo-ternary phase diagram (using isopropyl myristate (IPM), tween 80, and PEG 400 as oil, surfactant, and co-surfactant, respectively), followed by stability studies and characterization. As a gelling agent, xanthan gum is used. The characteristics and stability of an itraconazole microemulsion-based gel were studied, and in vitro drug diffusion of the optimized MEG was conducted. Isopropyl myristate was used as the oil, tween 80 as the surfactant, and PEG 400 as the co- surfactant to produce the microemulsion. With a Smix ratio of 3:1, the largest clear microemulsion zone was identified. The drug content, Viscosity, and zone of inhibition were found to be in the desired range. It was found that the droplet size of optimized formulations was within the desired range (<200nm). The prepared microemulgel was discovered to have good spreadability and texture (from selected microemulsion batches). and it was found that the optimized microemulsion gel (MEG 3) had a 94.12% in vitro drug diffusion rate. When compared to the microemulsion (ME 2) and the conventional gel, the drug from MEG 3 Gel showed far better in vitro antifungal studies. Similar to this, it was discovered that MEG 3 Gel's zone of inhibition(against Candida albicans) had a larger diameter than the microemulsion batch (ME 2). Furthermore, according to the stability investigations, the formulation was stable across a range of temperatures. Itraconazole-loaded microemulsion-based gel could be used effectively for the treatment of topical fungal infections.

KEYWORDS: Microemulsion, Pseudo ternary Phase diagram, Candida albicans, Co-surfactant, Microemulgel, Smix.

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TITLE: ENHANCEMENT OF SOLUBILITY OF GLIMEPERIDE AND ITS

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ABSTRACT: (Not more than 250 words)
A weakly water-soluble medication is defined as a substance with a solubility of less than 1 part per 10,000 parts of water. The medicine with poor solubility exhibits numerous issues with in-vitro formulation. Therefore, it is crucial to increase these medications' solubility by using various solubility improvement procedures. As A BCS class II medication that is essentially insoluble is glimepiride .There was very little information available for preparation of solidified dispersion by a solvent evaporation approach for glimepiride-urea, however it was discovered that this technique is promising for improving solubility. In the current study, the similar approach was prepared employing the carriers urea and PEG 6000 to increase the solvability of glimepiride. In-vitro solubilization rates are greater for the robust formulation. phosphate buffer solution containing pH 6.8, the in-vitro dissolving ability of glimepiride and its equivalent solid dispersions was assessed. When differentiate to the pure medication, the solid dispersion GUS3 (glimepiride: urea; 1:3) showed the greatest increase in solubility.
According to the findings of current study, the poorly soluble medication glimepiride may be prepared as a solid dispersion using carriers such urea and PEG 6000 to increase the rate of dissolution. Higher in-vitro dissolving rate is demonstrated by the robust formulation of solid dispersion with solvent evaporation by urea. The creation of a solid dispersion using urea and PEG 6000 increased the dissolving properties. The stability research, which lasted three months, was done in accordance with ICH requirements using the best produced solid dispersion formulation. This study shows how making solid dispersions by solvent evaporation improve poorly soluble substances' solubility,dissolution, and bioavailability.

KEYWORDS: Keywords: solubility, solid dispersion, glimepiride, solubility enhancement.

TITLE: Formulation and Evaluation of Nanosuspension Loaded Nanogel

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ABSTRACT: (Not more than 250 words)

During nose-to-brain administration of drug, a nanogel system containing nanosuspension is a promising method that will reduce dosage and frequency of dosing while also enhancing the drug's bioavailability. The goal of the current work was to develop an intranasal route for the effective delivery of Nortryptiline HCl (NTH) that would reach the brain through the olfactory and trigeminal nerves, hence improving the therapeutic efficacy. The nanoprecipitation-ultrasonication process was chosen to prepare the nanosuspension, which was then added to the insitu gelling polymer solution. This was followed by high pressure homogenization. Gellan gum was used to produce a nanogel that was optimized for nanosuspension loading. The optimized formulation exhibits a high entrapment effectiveness of 92.30 ± 2.23%, an average particle size of 10-100 nm, a decent PDI value, and increased solubility. Following ionic interactions, the formulation containing 0.5% gellan gum exhibits good gelation properties and the necessary viscosity to adhere at the nasal mucosa. It was discovered that in vitro drug release exceeded drug solution over a 60-minute duration. Studies on viscosity and spreadability provide superior outcomes for obtaining a good residence time. As a result, it has been shown that the insitu nanogel is among the greatest methods for delivering drug toward the brain in nanoform.

KEYWORDS: Nanosuspension, Intranasal delivery, Brain targeting, Insitu gel, Homogenization

TITLE: Formulation of Niosomal gel for transdermal drug delivery and Its Evaluation

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ABSTRACT: (Not more than 250 words)

These days, the most common environmental risk factor for periodontal diseases is acknowledged to be smoking or tobacco-related habits (chewing tobacco). Atorvastatin Calcium (ATV) is a well-known lipid-lowering drug, but recent studies have discussed its pleiotropic effects, such as anti-inflammatory, anti-bacterial, etc. When treating periodontics issues, scaling and root planning a non-surgical procedure that removes dental tartar and smoothes root surfaces can be used in conjunction with this anti-inflammatory effect. The study's objectives are to create and assess ATV-niosomes, incorporate them into a gel-based formulation with the help of a suitable gelling agent, and evaluate them for a number of parameters. The Thin-film hydration method was used to create the niosomal vesicles. Gel was prepared using the dispersion method, and an in-vitro drug release study was conducted using a Franz-diffusion cell. The entrapment efficiency of ATV-niosomes was found to be the highest, up to 84%. The vesicles formed showed stable and homogenous behaviour as indicated by their zeta potential of (-18 mV) and PDI of (0.106). The optimised gel with 1% Carbopol 934 showed up to 8 hours of in-vitro release after Zero Order release. Also, the gel showed antimicrobial activity against P. aeruginosa and S. aureus. As a result, we reach the conclusion that 1% Carbopol 934 gel containing ATV-niosomes showed a longer effect than plain ATV and can be used as a useful addition to scaling and root planning to improve periodontal health.

KEYWORDS: Gel; Niosome; Periodontitis; Atorvastatin; Nanovesicle

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TITLE: 'Enhancement of Bioavailability of some bio actives by self-Nano emulsifying drug delivery system'

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ABSTRACT: (Not more than 250 words)

Some bioactive compounds naturally found in grapes, peanut and berries those carries good anticancer property, but possess low/ poor water solubility. The self- nano emulsifying drug delivery system (SNEDDS) is a type of liquid-lipid nanocarrier through which we can enhance aqueous solubility and its bioavailability when taken orally. This study reports the preparation and optimization of a SNEDDS formulation and characterization, loading with drug (DRUG-SNEDDS). SNEDDS composed of olive oil, Tween 80 and polyethylene glycol 400. DRUG-SNEDDS was prepared via homogenization of emulsion containing oil, surfactant and co-surfactant. Ternary phase diagrams were plotted for Km1, Km2 and Km3. For plotting the ternary phase diagram, water titration method was carried out and according to the results of titration further batches of different composition were prepared. Total 09 formulations were prepared (F-1 to F-9) and evaluated by using different evaluation parameters, like UV analysis, particle size and zeta potential, PDI, IR spectra, etc. F-1 batch was optimized through the evaluation parameters. The average particle size of DRUG-SNEDDS was 100.9 nm, zeta potential of -14mV and polydispersity index of 0.4. All the excipients were shown compatibility with each other. Further studies need to be conducted to assess the pharmacokinetics, pharmacodynamics and anticancer potential of Drug loaded SNEDDS in in-vivo to confirm its efficacy for cancer therapy.

KEYWORDS: SNEDDS, bioactive agent, ternary phase diagram, Drug- loaded SNEDDS, etc.

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TITLE: Formulation and Evaluation of Niosomal Vesicles Loaded Gel For Transdermal Delivery

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ABSTRACT: (Not more than 250 words)
Mometasone Furoate (MF) is a glucocorticoid used to treat eczema, psoriasis, allergies, and skin rash, it is also used to relieve itching, redness, and swelling. When administered via the nasal route, the bioavailability of MF is claimed to be less than 11%. Encapsulating the active medicinal substance in niosomes can improve bioavailability by improving both physical and biological stability the study's purpose is to create a non-ionic surfactant-based vesicular system by loading mometasone furoate, inserting it into a gel-based formulation using an appropriate gelling agent, and testing it. The thin film hydration process, was used to create the niosome vesicle. The dispersion procedure and Franz-diffusion cell were used to prepare gel for in vitro drug diffusion investigations. Based on the findings of the research, Mometasone Furoate niosomal gel was created by loading different concentrations of Carbopol as a gelling agent into Mometasone Furoate niosomes that were created using the thin film hydration method, cholesterol, and span 60. The formulation is stable, as evidenced by the niosomes zeta potential of -24 mV. The average niosome size was measured to be 252.7 nm, and the polydispersity index (PDI) was reported to be 0.409. In comparison to the plain MF, the modified formulations gel performance with 2% Carbopol showed higher flux rate and in-vitro diffusion for seven hours. It may be concluded that niosomal gel is the most effective vesicular carrier for the effective transdermal delivery of mometasone furoate.

KEYWORDS: Niosomes, Transdermal, Gel, Non-ionic Surfactant, Vesicles, Mometasone Furoate, Carbopol,Span-60

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TITLE: Design and Development of Nanoparticles loaded *in-situ* gel for Enhanced and

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ABSTRACT: The objective of the present study was to develop *in-situ* gelling ocular formulation of Loteprednol Etabonate nanosuspension to improve the solubility and to enhance drug contact time with the ocular surface and to improve overall bioavailability. Loteprednol Etabonate, BCS class II drug which has poor solubility and limitations such as drug loss through lacrimation, nasolachrymal drainage. These complications can be overcome by preparing a nanosuspension and developing *in-situ* gelling system to increase the contact time of drug with the corneal surface.

Antisolvent precipitation- ultrasonication method was adopted for the preparation of Loteprednol Etabonate nanosuspension which was further incorporated into the *in-situ* gelling polymer matrix.. These were evaluated for particle size, zeta potential and PDI. The optimized nanosuspension prepared showed good particle size of 215nm, zeta potential of 0.336 and PDI of 35.9. The optimized nanosuspension was incorporated into *in-situ* gelling base. The optimized formulation was broadly characterized for various physical parameters like *in-situ* gelation, rheological properties and *in-vitro* drug release, TEM, DSC, XRD studies.

In conclusion, nanosuspension loaded *in-situ* gel is a promising approach for delivery of drugs via ocular route in order to increase drug permeation through cornea and thus improving overall drug bioavailability.

KEYWORDS: Loteprednol Etabonate ; nanosuspension; solubility enhancement; *in-situ* gel.

TITLE: Design, Development and Evaluation of Transfersomal Nanogel

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ABSTRACT: (Not more than 250 words)
Urticaria is an autoimmune disease that affects a large number of people. The goal of the study is to better understand how to treat urticaria by improving the bioavailability of a transfersomal nanogel loaded with ebastine. Using the thin film hydration method, the drug Ebastine, soy lecithin, and edge activator Tween 80 were used to produce the flexible transfersomes. Using the dispersion process and an appropriate concentration of the gelling agent Carbopol 934, the transfersomal nanogel was produced. Transfersomes and their gel were evaluated based on a number of parameters. With an entrapment efficiency of 79.92%, the Ebastine loaded transfersome exhibited the highest efficiency. The formulation was shown to be stable based on the transfersomes zeta potential of -18.9 mV and polydispersity index (PDI) of 0.103. It was found that 83.67% of the transfersome gel contained drugs. 1% transfersomal gel was formed. Using a zero-order kinetic model and demonstrating in-vitro release for up to eight hours, Carbopol 934 demonstrated the greatest results. Based on conducted microbiological experiments, the Ebastine transfersomal gel exhibits a favourable anti-microbial effect against S. aureus. These vesicular transfersomes penetrate the skin effectively because they are more flexible than other vesicular systems. It will be the best approach available in the future for transdermal drug delivery.

KEYWORDS: Transferosome, nanogel, ebastine, transdermal drug delivery system

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TITLE: Formulation And Evaluation of Nepafenac Emulgel For Ocular Drug Delivery: An Ex Vivo and In Vivo Study.

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ABSTRACT:

Introduction: Emulgels, known for their unique combination of properties from both emulsions and gels, have attracted significant interest from the pharmaceutical and cosmetic industries for their versatility and usefulness. **Purpose:** This research aims to design and assess a novel emulgel containing nepafenac for ocular drug delivery. **Materials and Methods:** Extensive literature research guided the formulation. Novel emulgel formulations (F1 to F9) blended an O/W emulsion with castor oil, oleic acid, linseed oil, and a self-emulsifying agent i.e. poloxamer 188. The gel phase employed Pluronic F-127, HPMC K 15M alone, or their combination. The O/W phase was integrated into the gel to form the emulgel. **Results:** Emulgels offer benefits like ease of application, improved drug penetration, ingredient stability, and controlled, prolonged drug delivery. Its characteristics include a pH of 7.2, a refractive index of 1.356, 75.12% transmittance, a viscosity of 1347 units, a particle size of 224nm, and a zeta potential of -24. In-vitro drug release showed sustained release for 8 hours, with no histological changes. HET CAM and rabbit ocular irritation tests indicated no irritation. Sterility testing confirms the absence of contamination, and stability studies uphold consistent characteristics over time. **Conclusion:** The newly developed nepafenac emulgel holds promise for efficient ocular drug delivery. With favourable physicochemical properties, sustained drug release, tissue compatibility, and a robust safety profile, it presents a strong candidate for future developments in ocular therapies, potentially expanding the treatment options for ocular conditions.

KEYWORDS: Ocular drug delivery, Nepafenac, Novel emulgel, *ex vivo* permeation, Ocular irritancy, emulgel.

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TITLE: Novel Drug Delivery System For Treating Fungal Infection

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ABSTRACT:

Sertaconazole is an imidazole antifungal agent used for the treatment of fungal infections caused by a wide range of dermatophytes and fungi. It has a very low water solubility resulting in poor absorption. The aim of this study is to develop a formulation of spanlatics which are elastic nanovesicles to improve the topical delivery of Sertaconazole and hence improve the absorption and decrease relapse and drug resistance. The Sertaconazole loaded spanlastics were formulated by the ethanol-injection method using edge activator (Tween 80) non-ionic surfactant (Span 20). The effect of ratio of the edge activator and non-ionic surfactant as well as sonication time on particle size was studied. The said spanlastics had particle size in the range of approx. 200 to 350 nm and polydispersibility index values between 0.1 to 0.3.

The drug entrapment efficiency was in the range of 60 to 80%. Stability studies were performed for nine months. The formulations were found to be stable with respect to their particle size. Antifungal activity was studies using zone of inhibition technique which also showed better antifungal activity than the corresponding marketed formulation.

Hence the nanovesicles could prove as promising candidates for antifungal therapy to treat recurrent fungal infections.

KEYWORDS: Sertaconazole, antifungal therapy, spanlastics

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TITLE: ELECTROSPUN NANOFIBER FILM FORMULATION AND ASSESSMENT USING BUCCAL DELIVERY

AUTHORS: SUSHMITA PRASHANT NIKHARGE
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ABSTRACT:

Glibenclamide (GLB), is a second-generation oral sulfonylurea. It is more effective and safer than the first-generation agents but suffers from poor aqueous solubility and substantial first pass metabolism. The aim of this research is to formulate and evaluate electrospun nanofiber film for enhancement of solubility and bioavailability of GLB via buccal delivery system. Thus, encapsulating GLB in strings of electrospun nanofibers could have benefits such as consistent and sustained release of GLB into the buccal cavity. Pre-formulation studies included authentication of the drug (GLB) by UV spectroscopy, Fourier Transform Infrared spectroscopy (FTIR), melting point, DSC. GLB shows maximum absorbance at 229 nm by UV spectroscopy. FTIR shows all the characteristic peaks which confirms the identity of the drug. Also, DSC thermogram shows sharp endothermic peak at 175.4°C which indicates purity of the sample. A nanofiber batch of PVP and Ethyl cellulose in the ratio of 2:3 in the (total polymer concentration of 12.5%) respectively resulting in the highest drug release and entrapment efficiency was selected for further optimization using Central Composite Design with the help of StatEase® Design-Expert Software. The optimised batch GLB loaded Nanofiber film was further evaluated for percent entrapment efficiency, DSC, FTIR, folding endurance, weight variation, thickness, fiber morphology and size, in vitro drug release, ex vivo drug permeation and mucoadhesion strength. The drug release from the nanofibers was found to be more than double than that from the pure drug indicating that the system would be beneficial in improving the oral bioavailability of GLB.

KEYWORDS : Nanofibers, Antidiabetic , Ethyl Cellulose , Polyvinyl Pyrrolidone.

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TITLE: Formulation and Evaluation of Water-Soluble Oral Dispersible Film by Solvent Casting Method

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ABSTRACT:

The study delves into the formulation and evaluation of antiemetic water-soluble oral dispersible films using the solvent casting method. These films represent cutting-edge technology in oral disintegrating dosage forms, comprising thin, edible, water-soluble polymers shaped in various dimensions. Unlike traditional tablets, these films dissolve rapidly on the tongue, eliminating the risk of choking and simplifying administration. Despite their advantages, challenges such as limited drug loading and taste masking options exist. The research specifically focuses on developing oral films containing Ziprasidone HCL for managing manic attacks and bipolar disorder. To enhance drug absorption, the formulation incorporates bio-enhancer quercetin, along with essential components like polymers, plasticizers, sweeteners, saliva stimulants, and flavorings. These films, designed to hydrate and adhere swiftly to oral mucosa upon contact with saliva, offer a promising solution for efficient drug delivery, bridging the gap between conventional tablets and innovative oral dosage forms.

KEYWORDS: Dissolution, antiemetic, fast disintegrating membrane, drug release kinetics, oral dispersible film

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TITLE: Formulation and Evaluation of Nanoemulsion Loaded Gel for the Treatment of Pain and Injury

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ABSTRACT: (Not more than 250 words)

An abnormal increase in muscle tone or stiffness, known as spasticity, is a disease that can cause pain or discomfort and impede speech or movement. Disturbance of the inhibitory descending spinal motor pathways can result in malfunction of the higher motor neurons, which can cause spasticity. The current effort aims to formulate metaxalone loaded in a nanoemulsion and assess it for many parameters. To relax muscles and reduce pain and discomfort brought on by sprains, strains, and other muscle injuries, metroxalone is used in conjunction with physical therapy, rest, and other interventions. To determine the oil-to-surfactant ratio, a pseudo-ternary phase diagram was plotted using the phase titration method. Using a Franz- diffusion cell, an in-vitro drug release investigation was carried out after the nanoemulsion was created using the high-speed homogenization approach. The optimized batch exhibited the maximum entrapment effectiveness, up to 93%, and the globule formed displayed stable and uniform behavior as shown by the zeta potential (-33 mV) and PDI (0.321). Additionally, it demonstrated up to eight hours of in-vitro release after zero order release. Consequently, we draw the conclusion that metaxalone-containing nanoemulsion demonstrated a longer effect than plain metaxalone and can successfully function to enhance muscular conditions to relieve pain and injury.

KEYWORDS: Nanoemulsion, Metaxalone, Gel, Spasticity**.**

TITLE: QBD-GUIDED PHOSPHOLIPID-TAGGED BOSWELLIC ACID NATUROSOMAL DELIVERY FOR EFFECTIVE RHEUMATOID ARTHRITIS TREATMENT

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ABSTRACT:

Studies have reported the potential role of Boswellic acids (BAs), bioactive pentacyclic triterpenes from *Boswellia serrata*, in treating rheumatoid arthritis (RA). However, poor water solvency and limited oral absorption are restricting factors for its better therapeutic efficacy. The above facts were speculated, and the present investigation was undertaken to improve poor aqueous solubility, colloidal stability, and low bioavailability of BAs by engineering their naturosomal delivery. Nanonized naturosomes were developed and subsequently analyzed to show their physicochemical and functional features employing the quality-by-design approach. The solubility analysis of Boswellic acid naturosomes (BANs) revealed a 16 times improvement in aqueous solvency compared to BS extract (BSE). The zeta potential and dynamic light scattering findings of BANs have demonstrated their colloidal stability with regulated nano-size particles. Additionally, compared to BSE (~31%), in-vitro dissolution experiments showed that >99% of pentacyclic triterpenes were released from BANs. Studies on ex-vivo permeation showed that BANs' permeation (>79%) significantly improved over BSE's (~20%). In-vivo efficacy studies using CFA-prompted arthritis in rodents showed a critical expansion in body wt and an undeniable reduction in paw thickness, paw volume, and TNF-α treated with BAN compared to the arthritis control and BSE-treated group. These findings suggest that BANs can help treat RA drugs by demonstrating their efficacy in further clinical research to validate the significant improvements.

Keywords: *Boswellia serrata*; Rheumatoid arthritis; Bioavailability; Naturosome; TNF- α

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TITLE: MACROPHAGE RECEPTOR TARGETED MICROPARTICULATE DRY POWDER INHALATION SYSTEMS FOR TUBERCULOSIS DRUG THERAPY

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ABSTRACT:

Tuberculosis (TB), a pulmonary infection caused by *Mycobacterium tuberculosis* (*M.tb.*), is more prevalent in Asian and African regions (underdeveloped with poor healthcare facilities). Current approach to combat TB involves 6-9 months-long oral/parenteral combination therapy with antitubercular drugs (ATDs). However, insufficient concentrations of ATDs at infection site, associated side-effects and patient incompliance have lowered the success rate of drug therapy and led to emergence of resistant *M.tb* strains.

Alveolar macrophage (AM) receptor-targeted microparticulate systems, delivered by inhalation to alveolar region of lungs, can be expected to deliver copious amounts of ATDs locally within infected AMs. The objective of the present research was to study AM receptor-targeted biopolymeric microparticulate dry powder inhalation (DPI) of three ATDs (Rifampicin, Isoniazid, Gatifloxacin), included in therapeutic regimens for pulmonary as well as MDR-TB, as per WHO guidelines. *In-vitro* lung deposition study with Andersen Cascade Impactor revealed that these 1-5 micron-sized microparticles had good fine particle fraction (35-77%). Sustained release of entrapped drugs was observed in simulated lung fluid and artificial lysosomal fluid. No cytotoxicity was observed in RAW 246.7 murine macrophage cell line; the microparticles were internalized by these cells within 1 hour of exposure. The formulations depicted lower MICs compared to plain ATDs. Single-dose 14-day acute inhalation toxicity in rats revealed no signs of toxicity. Pharmacokinetic studies in rats showed longer pulmonary residence times for all three drugs, with levels maintained above MIC for 24-48 hrs.

Thus, the developed DPI formulations had the potential to decrease mycobacterial burden at the infection site, minimize dosage frequency, and achieve effective pulmonary deposition—all attributes necessary for successful tuberculosis treatment.

KEYWORDS: DPI, macrophage-receptor targeting, tuberculosis, alveolar macrophages

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TITLE: Development and Evaluation of Deferasirox Loaded Nanoparticles for the Treatment of Breast Cancer: Evaluation In-Vitro and Cell Line Study.

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ABSTRACT: (Not more than 250 words)

The aim of the study was to study the potential efficacy of antitumor activity of nanoparticles loaded with Deferasirox In the current research work, nanoparticle loaded with Deferasirox were developed and evaluated to study its efficacy using breast cancer cell line. Nanoparticles of Deferasirox were prepared by solvent evaporation method using EthocelTM as a polymer and Kolliphor® P 188 as a surfactant. 23 factorial design used with concentration of polymer, concentration of surfactant and rpm as independent variables and percentage of entrapment efficiency and percentage of drug release as dependent variables. All formulations were prepared and evaluated for particle size, spectral studies, thermal studies, drug entrapment efficiency and in-vitro drug dissolution studies. In-vitro cell viability study on breast cancer cell line (MCF-7) was performed by MTT assay Developed nanoparticles possess the particle size 428.3 nm and PDI 0.626. Optimized formulation showed 82.62±1.04 maximum drug release after 6 h in a controlled manner and entrapment efficiency 72.64±0.24. The FTIR spectral studies and DSC thermogram indicated that there was no interaction between the drug and polymers used. Thus, Deferasirox nanoparticle formulation showed the anti-tumoral activity against human breast cancer cell line (MCF7) as per outcome of cell line study Nanoparticles of Deferasirox were stable and could be promising drug delivery for cancerous cells.

KEYWORDS: Breast Cancer, Tumor Activity, Nanoparticles, Cell Line.

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TITLE: Cost Effective & Promising Medication;Danazol Vaginal Suppositories In Treatment of Uterine Disorder Endometrosis

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ABSTRACT:

Endometriosis, an uterine disorder occurring in women of reproductive age of 25-40 associated with symptoms like severe menstrual cramps anxiety, infertility and depression. Currently used oral medication (hormones, muscle relaxant, pain killers) not effective in controlling side effects due to **pharmacokinetic** problems and associated with side effects like weight gain, depression, body hair, irregular bleeding. According to The Indian Centre for Endometriosis (ICE); one in 10 women suffers from endometriosis;176 million women in India suffers from this disorder. The disease condition may also increase the risk of ovarian cancer. Chronic endometriosis treatment by repeated administration of **NSAIDS**, **contraceptives** by oral route which is associated with various severe side effects like nausea, absence of periods, anxiety, joint pain, depression and mood changes. Hence todays market/industry will require better alternative for effective medical treatment of endometriosis. **Suppositories** would be a better option in terms of **bioavailability** and release of drug. By considering the applications of vaginal administration, industry can formulate the effective vaginal dosage form of effective drug; danazol to provide the cost effective, convenient, better adjuvant in endometriosis treatment. Low dose of drug is required for vaginal treatment as compared any oral medication as dense network of blood vessels results faster drug absorption with steady blood levels hence not required frequent administration. Low dose, faster and steady drug levels in blood and no side effects would be the positive aspects of vaginal therapy for controlling chronic condition of endometriosis. **Suppositories** were prepared by the fusion method danazol as a drug, PEG 6000:PEG 4000 which are in 60:40 concentration.Prepared suppositories evaluated with parameter like FTIR, UV Spectrometry, XRD,DSC, Disintegration Time, Content Uniformity, IN-VITRO Drug Released, Stability Study,etc.Preformulation and formulation studies indicates that danazol vaginal suppositories prepared by using PEG grade by fusion method is an cost effective and promising medication in endometriosis treatment.

KEYWORDS: Endometriosis, Pharmacokinetic, Bioavailability, NSAIDS, Suppositories, Contraceptives

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TITLE: EVALUATION OF READABILITY AND DESIGN OF PATIENT PACKAGE INSERTS IN NON-PRESCRIPTION MEDICINES IN INDIA

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ABSTRACT: (Not more than 250 words)

Self-medication with non-prescription medicines is a popular and convenient means of self-care by patients. A Patient Package Insert is one of the important means of conveying appropriate information about the medicine to the patient. This can help the patient in appropriate use of the medicine, and to take decisions relating to self-care. This becomes even more important when the medicine to be taken is a non-prescription medicine, and the patient is the one who makes a choice as to which medicine s/he will take, and for what conditions and in what dosages. However, concerns have been raised about the suitability and readability of the information in the inserts. Many countries have in place guidelines or regulations which provide specifications as to how such inserts should be, in terms of content, ease of reading, and design. In India, we do not have any such specifications in place. Also, in India, finding such package inserts is very rare. This research paper aims to systematically evaluate the readability and design features of patient package inserts that we found in 10 non-prescription medicines in India across various therapeutic categories. We evaluated them for readability, design, suitability of information, using established readability and design assessment formulas. It was found that the information in most of these inserts was inadequate, and not presented in a proper manner. The ease of reading the information was varied, and most of them did not meet the suggested readability level of fifth-to-seventh grade.

KEYWORDS: patient package inserts, non-prescription medicines, readability, design

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TITLE: Pharmacological Evaluation of Methanolic Extract of Leaves of *Artocarpus lacucha* Roxb. Ex-Buch.-Ham. for Anxiolytic Acitivity

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ABSTRACT: *Artocarpus lacucha* Roxb. Ex-Buch.-Ham. belonging to the family Moraceae is a deciduous tree distributed throughout the Indian subcontinent and South East Asia. It is popularly known as 'monkey fruit' and possesses exceptional phytochemical, nutritional and valuable pharmacological properties. The aim of the present study was to evaluate the pharmacological potential of the methanolic extract of *A. lacucha* leaves for anxiolytic activity. Elevated plus maze (EPM), Light and dark, Mirror chamber apparatus and Auto-track models were utilized to evaluate the effects of the plant on the central nervous system in rats. The methanolic extract of *A. lacucha* leaves (MEAL) was prepared by maceration and two doses i.e. 100mg/kg and 200mg/kg were administered to Wistar Albino Rats to evaluate CNS effects using diazepam as standard. In EPM, both the test doses showed significant antianxiety activity. From the results of Light and dark model it was evident that MEAL Dose-200mg/kg demonstrated better anxiolytic activity as compared to MEAL Dose-100mg/kg. In the Mirror chamber apparatus, MEAL Dose-200mg/kg showed significant anxiolytic activity as compared to control. In the Auto-track Model both the test doses showed significant anxiolytic activity. From this study a clear conclusion can be drawn that methanolic extract of A. *lacucha* leaves shows significant anxiolytic activity.

KEYWORDS: *Artocarpus lacucha* Roxb, anxiolytic, Elevated plus maze, Light and dark, Mirror chamber, Auto-track

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TITLE: EVALUATION OF ANXIOLYTIC ACTIVITY OF ACETONE FRACTION OF *HAMELIA PATENS* LEAVES IN RATS

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ABSTRACT: (Not more than 250 words)

Hamelia patens commonly known as Scarlet bush is a significant medicinal plant which is native to America. It belongs to the family Rubiaceae and is used to treat several diseases including athlete's feet, wound healing, asthma, nervous shock, eczema, headache, scurvy, inflammation, dysentery, uterine and ovarian affliction. The aim of the study was to determine the anxiolytic effects of acetone fraction of *Hamelia patens* in rats. Wistar albino rats (250-250g) were employed for the study. The acetone-enriched biofraction of *Hamelia patens* (AEHP) was prepared by fractionating the ethanolic extract with acetone. The anxiolytic activity of the AEHP at doses of 100mg/kg and 200mg/kg body weight in rats were evaluated using elevated plus maze (EPM), light & dark model (LDM) and mirror chamber test (MCT). The study was conducted for a period of 7 days using four groups. Group I served as control (distilled water), Group II received intraperitoneal Diazepam(2mg/kg), Group III and Group IV were administered orally 100 and 200mg/kg body weight of AEHP. In EPM model, AEHP 200mg/kg demonstrated 14.26 ± 2.24% increase in time spent in open arm. In light and dark model, AEHP 200mg/kg showed 102.66 ± 24.9 seconds increase in time spent in light area, while in mirror chamber test it exhibited increase in time spent in mirror chamber to 132 ± 25.152 seconds as against the control and standard. The pharmacological screening of acetone enriched fraction of *Hamelia patens* revealed that 200mg/kg depicted profound anxiolytic activity in all the experimental models tested.

KEYWORDS: *Hamelia patens*, anxiolytic, acetone, Rubiaceae

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TITLE: Pharmacological evaluation of leaves of *Chamaecostus cuspidatus* for anxiolytic activity in rats

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Abstract:

Anxiety is defined by modifications to mood, behavior, physiological function, and cognitive performance. Pharmaceuticals derived from natural sources have nearly the same therapeutic potential as synthetic medications (Serotonin reuptake inhibitors and benzodiazepines) with fewer adverse effects. The aim of this study was to evaluate the phytochemical and pharmacological screening of acetone enriched fraction of ethanolic leaf extract of *Chamaecostus cuspidatus* (AECC) in Wistar rats. The AECC was administered orally to the rats at a dose of 200mg/kg and 400mg/kg. Diazepam (2mg/kg) was taken as the standard. The elevated plus maze (EPM), light and dark model, mirror chamber and opto-varimex auto track system were used to assess anxiolytic behavior. The results were statistically analyzed by one way ANOVA by Dunnett's test. In EPM both the doses of AECC showed significant increase in % open arm entries (OAE) and % time spent in open arm (TSOA). In the light and dark model the highest activity was observed for the 200mg/kg dose with a value of $p<0.01$ with increased activity for number of entries in light chamber (NLE) and time spent in light chamber (TSL). In the mirror chamber the dose of 400mg/kg elicited better anxiolytic activity while a shorter distance travelled and ambulatory time was observed in autotrack at dose 200mg/kg possibly due to CNS depressant activity. The acetone enriched fraction demonstrated significant pharmacological activity, which was attributed to the flavonoids present in the fraction, which primarily act by modulating the GABA- BZD chloride ion-channel receptors, which mediate the anxiolytic effect.

Key words: Anxiety, *Chamaecostus cuspidatus*, acetone enriched fraction.

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TITLE: CRITICAL EVALUATION OF SOME CLINICAL TRIAL PROTOCOL IN GOA

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ABSTRACT: (Not more than 250 words)

BACKGROUND: The protocol is the cornerstone of any clinical trial, most crucial document required to acquire approval from the regulation authorities to conduct the clinical trial. The clinical trial protocol aids in determining the trial's feasibility. Inadequate information, variability in the format and content of the protocol not within regulatory framework may lead to such clinical trial misconduct.

METHODOLOGY: Study carried out in phases:
Phase 1: literature survey on history, ethical regulation of clinical trials.
Phase 2: Regulatory requirement to conduct clinical trial
Phase 3: Selection of protocol source
Phase 4: Evaluation of clinical trial based on ICH-GCP guidelines

RESULT: Some elements of the protocol evaluated lacked adherence to established regulatory standards used when drafting protocols. Format as well as order of the protocol content was not according to established guidelines. Most of the protocols missed out on important information such as follow-up procedure for patients, study endpoints, schematic diagrams for trial designs, procedure for reporting, deviation from original statistical plan and termination of trials.

CONCLUSION: Research reveals that the variation in structure and content of the protocols analyzed. This can be as a result of the protocol development team's neglect, a lack of familiarity of the regulatory guidelines, a failure to analyze the phases in protocol development or a lack of time allocated to writing an effective protocol. The team must first develop a concept protocol before investing time in developing a full protocol, it will prevent failure at a later stage.

KEYWORDS: Clinical trial, Protocol, Literature survey, evaluation, ICH-GCP guidelines.

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TITLE : NEUROPHARMACOLOGICAL EFFECTS OF *Artemisia pallens* Wall. ESSENTIAL OIL IN RATS.

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ABSTRACT:

Artemisia pallens, or Davana, is recognised for its aromatic oil and is a food flavouring agent. The study assessed the anxiolytic action of Davana essential oil by inhalational exposure. A 1% dilution of Davana essential oil was formulated by mixing 2 drops with 10 ml of food-grade sunflower oil as a carrier. Four groups containing 6 rats of either sex were selected. Control (Group-I) received distilled water orally. Standard (Group-II) received intraperitoneal Diazepam (2mg/kg). Two groups (III, IV) were exposed to Davana oil inhalation for 10 and 20 minutes, respectively. The study used Elevated Plus Maze, Light and Dark, Hole-Board and Mirror Chamber Models to evaluate Davana essential oil's anti-anxiety effects in rats. Results indicated that both Davana-exposed groups showed anxiolytic effects compared to the control group, with Group IV showing better results. The % Open Arm Entries (OAE) in Elevated plus maze post 1 hour of administration on Day-7 for Group I were 1.59±1.00, while Group IV exhibited a significantly higher % OAE of 23.70±1.82. Therefore**,** the study shows that inhalational exposure to Davana essential oil has anti-anxiety effects in rats. Prolonged exposure (Group-IV) was found to be more effective. These effects may be due to compounds like geraniol and linalool in Davana oil, known for their Central Nervous System modulatory activity. However, the study highlights the need for further research to understand the specific compounds responsible for underlying mechanisms.

KEYWORDS: *Artemisia pallens*, Anxiolytic, Inhalational exposure

TITLE: Evaluation And Comparison Of Pharmacological Activities Of Pandanus Odorifer (Forssk.) Kuntze By Inhalation And Oral Route In Rats

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ABSTRACT: Pandanus odorifer (Forssk.) Kuntze, also known as kewda (fam. Pandanaceae), has been utilized in Ayurvedic medicine to cure a wide range of illnesses. A pollen grain extract was studied to see if the plant produced any of effects in light of the potential that pollen grains from the flower may induce allergies or hay fever in some individuals. The pollen grain extract of Pandanus odorifer did not cause any allergic reactions in rats during the seven-day trial period, according to the modified Irwin test. Investigating its pharmacological activities via inhalation (aromatherapy) and oral routes in rats was the goal of this investigation, for which marketed preparations of the plant, Kewda water (at two doses: 250 mg/kg and 500 mg/kg) and Pandanus odorifer essential oil were chosen. The test samples used were Kewda water and essential oil of the plant. Distilled water served as the control; diazepam (2 mg/kg) served as the positive control. Various laboratory animal models such as the elevated plus maze, light and dark model, mirror chamber apparatus, hole board apparatus, and optovarimex autotrack system were used in the study. Results were analysed using Dunnett's test and two-way ANOVA. In this study we found that the test groups which received drug via oral and inhalation route showed anti-anxiety activity. From the results, we conclude that this anti-anxiety effect of Pandanus odorifer might be due to its CNS depressant action.

KEYWORDS: Pandanus odorifer, essential oil, kewda water, antianxiety, CNS depressant, Spontaneous motor activity, pollen grains

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TITLE: A Case of Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS) syndrome due to multiple drugs

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ABSTRACT:

Adverse drug reactions (ADRs) are unexpected reactions to an administered medication at the right dosage and manner. Drug rash with eosinophilia and systemic symptoms syndrome (DRESS syndrome) is a scarce type of ADR with complicated clinical features involving several organ systems of the body, the most frequently involved organ being the liver, followed by the kidney and lungs. Timely detection and diagnosis followed by withdrawal of the causative agent is utter most important to reduce the number of related morbidity and mortality. The presented case is of a 42 years lady, with a history of leflunomide intake and symptoms of DRESS syndrome. The suspected causative agents were withdrawn and the patient was managed symptomatically. Leflunomide drug has the potential to cause DRESS syndrome and thus should be dealt cautiously. The causality assessment of the ADR was done using the WHO-UMC scale and Naranjo's assessment scale and was found to be a probable reaction. The presented case contributes to the existing literature about this exceptional clinical presentation.

KEYWORDS: Drug Reaction with Eosinophilia and Systemic Symptoms syndrome (DRESS syndrome), Leflunomide, Drug-induced, Adverse drug reactions (ADRs).