"DESIGN AND DEVELOPMENT OF *N*-ACETYLCYSTINE PELLETS"

Dissertation submitted to

CHALAPATHI INSTITUTE OF PHARMACEUTICAL SCIENCES

In partial fulfillment of the requirement for the award of the degree of

BACHELOR OF PHARMACY

Submitted by

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ABSTRACT

This thesis focuses on the development of *N*-Acetyl cysteine (NAC) pellets, exploring the potential benefits of this orally active mucolytic drug. NAC acts by disrupting sulfide bonds in mucoproteins, thereby reducing mucus viscosity and promoting easier air way clearance. The global Acetyl cysteine market is expanding rapidly, with projections indicating significant growth due to NAC's versatile applications in pharmaceuticals, healthcare, and nutraceuticals. Despite its popularity, NAC is not currently available in pellet form, which offers advantages in drug absorption by facilitating dissolution in the gastrointestinal tract. In this study, *N*-acetyl cysteine pellets were designed and developed using a two-factor optimization approach with independent variables categorized into two groups. The effects of these variables on Disintegration Time, Folding Endurance, and Thickness were analyzed quantitatively using ANOVA and Design Expert® 11. Visual representations such as 3D response surface plots and contour plots were generated to elucidate the impacts of these factors on the studied responses.

The pellets were formulated through extrusion and spheronization processes, transforming wet material into granules suitable for evaluation of various parameters including average weight, uniformity, content uniformity, dissolution and stability. Analysis of formulation release models indicated that the optimized pellets exhibited first-order kinetics with strong linearity (R^2 = 0.986), supported by Higuchi's rate law. Noyes and Whitney's diffusion model contributed further insights, confirming a Fickian diffusion mechanism (Case 1) of drug release with an exponent (n) of 0.78 according to the Peppas equation. This research contributes to the understanding of NAC pellet formulation and optimization, high lighting its potential for enhanced drug delivery and therapeutic efficacy.

Keywords: Pellets, Pelletization, *N*-acetyl cysteine, Mucolyticaction

Evaluation of Antibacterial Potency of Newer Naphthalene Substituted Sulphonamide Derivatives using Computational Method

A dissertation submitted to

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ABSTRACT:

The synthetic process involved a series of steps, including Friedel-Crafts acylation of 1-Naphthol followed by bromination with N-bromo succinimide, and subsequent reaction with sulphamethoxazole and sulphadimidine to produce a newer derivative. Structural confirmation and purity assessment were carried out using advanced spectroscopic techniques, including NMR, IR, and mass spectrometry. To enhance our understanding of these compounds, molecular docking studies were employed to investigate their potential binding modes with relevant biological targets. This computational approach provided valuable insights into molecular interactions at the molecular level, offering crucial information for further studies on the relationship between the compound's structure and its biological activities.

KEY WORDS: Sulphamethoxazole, sulphadimidine, molecular docking, Autodock, antibacterial activity, disc diffusion method, spectral studies.

FORMULATION AND EVALUATION OF ORODISPERSIBLE TABLETS OF HYDRALAZINE HYDROCHLORIDE USING NATURAL SUPERDISINTEGRANT BY DIRECT COMPRESSION METHOD

A Dissertation submitted to

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ABSTRACT

Hydralazine Hydrochloride is an orally active drug and is used for the treatment of blood pressure (hypertension). The main problem for geriatric patients is dysphagia i.e, difficulty in swallowing. So to improve the patient's compliance, a novel orally disintegrating tablet (ODT) formulation of Hydralazine Hcl was developed for immmediate absorption results in rapid onset of action. In the present research work, Hydralazine Hydrochloride orodispersible tablets were prepared by direct compression method using synthetic super disintegrants (crospovidone) and natural super disintegrant (fenugreek mucilage powder) at different concentrations. The tablets were characterised for weight variation, hardness, friability, disintegration time, wetting time, water absorption ratio,dispersion time, drug content and *in-vitro* dissolution tests. The drug-excipient compatibility studies was performed by FT-IR Spectroscopy and no incompatibility was found. From *in- vitro* release studies, the formulation F6 exhibited fast release profile of about 99.98% in 30 minutes and disintegration time was found to be 39 sec when compared to other formulations. The present study reveals that natural super disintegrants show rapid disintegration and better drug release as compared to synthetic super disintegrants.

Keywords : Orodispersible tablets, Hydralazine Hydrochloride, Super disintegrants, Crospovidone, Fenugreek mucilage powder

STUDY OF MORPHOLOGICAL EFFECTS OF PLANT EXTRACTS ON HUMAN RBC

A Dissertation submitted to

ACHARYA NAGARJUNA UNIVERSITY

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ABSTRACT:

The purpose of this experiment was to ascertain how plant extracts affects human erythrocytes and how they shielded RBC from solutions that were either too hypertonic or too hypotonic. A total of 10 plants which are generally available are tested for their effects. RBC assay show that erythrocytes exposed to plant extracts exhibit haemagglutination, deformation (a change in size and shape), and the presence of echinocytes. *Amaranthus viridis, Catharanthus roseus, Citrus limetta,* and *Hibiscus sabdariffa* exposed cells exhibit cell membrane altering activity.

RP-HPLC METHOD DEVELOPMENT FOR ESTIMATION OF EMTRICITABINE AND TENOFOVIR DISOPROXIL FUMARATE IN TABLET DOSAGE FORM BY USING THE DESIGN OF EXPERIMENT APPROACH

Dissertation submitted to

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ABSTRACT

A well-designed and effective RP-HPLC method was created and verified to simultaneously determine Tenofovir disoproxil fumarate and Emtricitabine in bulk and tablet dosage forms. This method utilizes the design of experiments approach to optimize the mobile phase by considering methanol, pH, and flow rate as dependent variables, with their effects on the retention time of Tenofovir disoproxil fumarate (3.25min) and Emtricitabine (4.16min). A gradient mobile phase composition of 20mM phosphate buffer and acetonitrile in methanol in a 50:50%, v/v (pH 3.0) ratio, flow rate of 0.7 ml/min, and a Targetsil C18 – 5µm column at room temperature were used. The detection was performed at an isosbestic wavelength of 238 nm for 10 minutes. A linear response was observed over the 10–30 µg/ml and 5-25 µg/ml concentration range. The limit of detection (LOD) and limit of quantitation (LOQ) for Tenofovir Disoproxil Fumarate and Emtricitabine were found to be 1 µg/ml and 0.5µg/ml, and 3µg/ml and 1.5µg/ml, respectively. ICH guideline acceptance criteria for linearity, accuracy, precision, specificity, and robustness successfully validated the method. The analysis suggests that this method is suitable for simultaneously estimating Tenofovir Disoproxil Fumarate and Emtricitabine and can potentially be used to estimate these drugs in combined dosage forms.

Keywords: Tenofovir disoproxil fumarate, Emtricitabine, RP-HPLC, Tablets, DOE, Validation.

GREEN SYNTHESIS OF NEWER QUINAZOLINE DERIVATIVES AND THEIR PHARMACOLOGICAL EVALUATION

A dissertation submitted to

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This is to certify that the dissertation work entitled **"Green Synthesis of Newer Quinazoline Derivatives and their Pharmacological Evaluation"** submitted by B. Balaraju (Y20BPH0520), M. Maheswara chari (Y20BPH0572), N. Mukesh Reddy (Y20BPH0576), P. Bhargav (Y20BPH0582), B. Rakesh.S.N.V. Sai Tharun (L21BPH0608) in partial fulfillment of the requirement for the award of the degree of Bachelor of Pharmacy is the bonafide research work carried out by the candidates in the pharmaceutical chemistry laboratory of Chalapathi Institute of Pharmaceutical Sciences, Lam, Guntur was evaluated by us during the academic year 2023-2024

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ABSTRACT

Designing a highly effective class of innovative antimicrobial agents poses a significant challenge in the field of pharmaceutical research and development. The ongoing research focuses on discovering a new series of quinazoline and its derivatives with various substitutions. The synthetic process involves a couple of steps to prepare the quinazoline compound by reacting an amphoteric aromatic acid like anthranilic acid the desired chlorine compound benzoyl chloride in presence of highly flammable, weakly alkaline, heterocyclic organic compound pyridine, resulting in the formation of 2-phenyl-benzoxazine-4-one which is an intermediate compound which is further allowed to react with the hydrazine hydrate along with the pyridine and upon reflux for 3 hours will yield the desired quinazoline compound 3-Amino-phenyl-quinazoline-4-one. All the synthesized compounds were characterized by analytical studies.

Spectroscopy techniques such as IR spectroscopy, Proton nuclear magnetic resonance (^{1}HNMR), Carbon ^{13}C NMR, Mass spectral methods. Furthermore, these compounds are screened for their antimicrobial activity against bacterial strains such as *E. coli*, *Pseudomonas aeruginosa*, *Bacillus subtilis* and fungal strains like *Aspergillus* and *candida albicans*.

Key Words: Quinazoline derivatives, green synthesis, *Bacillus subtilis*, *Pseudomonas aeruginosa*, IR spectrum, NMR spectrum and mass spectrum, anti-bacterial activity, zone of Inhibition.

FLOATING TABLETS FOR WEIGHT REDUCTION: FORMULATION, EVALUATION AND THERAPEUTIC POTENTIAL

A dissertation submitted to

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Abstract

The aim of present work was to develop and evaluate the floating tablets of caffeine and lemon extract for weight reduction. The effect of polymer and gas releasing agent concentration were examined. The floating drug delivery system (tablets) were prepared by direct compression method using HPMC (K100M) as polymer and sodium bicarbonates as gas generating agent and and optimized using design expert software. All formulations were evaluated for the pre compression and post compression, *In vitro* buoyancy, In vitro dissolution studies, and short term stability study. Pre-compression studies revealed that there was no sign of any interaction between drug and polymers and all formulation showed good flow properties. Results of post compression parameters were found within the limits for all formulations. The optimize formulation F10 showed better buoyancy and drug release profile. The release of drug from the optimized formulation (F10) was found to follow zero order and mechanism was fickian diffusion mehnasm. Stability studies showed that there were no significant changes in the buoyancy, drug release rate and physical appearance. In vivo studies showed the levels of total cholesterol, high density lipoproteins, low density lipoproteins, very low density lipoproteins and triglycerides in treated animals decreased significantly compared to the standard treatment showing a positive potency for treatment of obesity. From the above results, it was concluded that the use of a combined caffeine and lemon extract supplement would be effective, safe, and natural option for weight loss in overweight and obese individuals.

Keywords: Caffeine, Lemon extract, floating tablets, HPMC K100M, buoyancy, *in-vitro*, *in vivo*

"THE LAXATIVE LOZENGE REVOLUTION: INNOVATIVE APPROACH TO HERBAL FORMULATIONS"

Dissertation submitted to

CHALAPATHI INSTITUTE OF PHARMACEUTICAL SCIENCES

(AUTONOMOUS)

In partial fulfillment of the requirement for the award of the degree of

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ABSTRACT

ABSTRACT

Background: India is one of the countries where most of the population use traditional system of medicine. Herbal medicines are still the mainstay of about 75 to 80% of world's population due to its acceptability, compatibility with human body, availability and minimal side effects.

Introduction: Lozenges are solid unit dosage forms that dissolve in oral cavity and enter into systemic circulation to show its pharmacological effect with increased retention time in oral cavity, thereby bypasses the first pass metabolism, reduces gastric irritation, boosts bioavailability. Constipation is epitomized by irregular and infrequent bowel movements that lasts for over a week.

Aim and objective: The primary intent of this research study is to design a herbal laxative lozenge to ameliorate constipation.

Methodology: By taking the advantage of dill, fennel, ajwain and peppermint the herbal laxative lozenge is designed by hydrosol method and respective evaluation studies are performed.

Results and conclusion: This research also includes invitro studies where rats are evaluated with the volume of feces and moisture content analysis. The formulation is optimized by employing DoE.

Key words Laxative, Constipation, Herbal lozenges, Dill, Ajwain, Fennel, Hydrosol method

PHYTOCHEMICAL, PHARMACOGNOSTICAL AND ANTI MICROBIAL STUDIES OF PHYSALIS ANGULATA

A dissertation submitted to

CHALAPATHI INSTITUTE OF PHARMACEUTICAL SCIENCES

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EVALUATION CERTIFICATE

This is to certify that the dissertation work entitled "**PHYTOCHEMICAL, PHARMACOGNOSTICAL AND ANTI MICROBIAL STUDIES OF PHYSALIS ANGULATA**" submitted by P. Sameer Khan (Y20BPH0509), P. Sasank Chandu(Y20BPH0510), S. Puneeth (Y19BPH0595), S. Vinay Kumar (Y20BPH0596), V. Varun Sai (Y20BPH0602), Y. Dhanunjaya Naidu (Y20BPH0605) in partial fulfillment of the requirement for the award of the degree of **BACHELOR OF PHARMACY** is the Bonafide research work carried out by the candidates in the pharmaceutical chemistry laboratory of **CHALAPATHI INSTITUTE OF PHARMACEUTICAL SCIENCES, LAM, GUNTUR.** Was evaluated by us during the academic year 2022-2023.

Place: Guntur

Date: 18/5/24

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ABSTRACT:

Nowadays, individuals are increasingly vulnerable to microbial infections, which are the most lethal infections for humans and can lead to fatalities. Physalis angulata is an herbaceous plant classified under the nightshade category of the Solanaceae family. *Physalis Angulata* exhibits properties such as antimicrobial, anti-inflammatory, anti-parasitic, anti-malarial, anti-leishmanial, immunosuppressive, anti-asthmatic, diuretic, and anticancer/anti-tumour activities. This current research project involves conducting phytochemical, pharmacognostical, and antimicrobial studies on physalis angulata. The plant material in powdered form was extracted using different solvents including ethanol, ethyl acetate, chloroform, and water. The solvent extracts were comprehensively characterized through a series of evaluation tests, including chemical tests, transverse section analysis of leaves, stomatal index determination, thin-layer chromatography (TLC), and physicochemical evaluations such as ash value and extractive value. The antimicrobial potential of the extracts was evaluated using cup plate and disc diffusion methods. A specially cultivated microbiological culture was used to monitor bacterial and fungal growth over a period of approximately one week. The antimicrobial activity was further assessed by determining the minimum inhibitory concentration.

KEYWORDS: Microbial infections, Herbaceous, Physalis angulata, Anti-microbial, Phyto-chemical, microbiological culture, TLC

A Design, Development and Concurrent Estimation of Anti-Retroviral Drugs by Using Different Analytical Techniques

Dissertation submitted to

CHALAPATHI INSTITUTE OF PHARMACEUTICAL SCIENCES

In the partial fulfilment of the requirements

for the award of the degree of

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EVALUATION CERTIFICATAE

This is to certify that the dissertation work entitled **"A DESIGN, DEVELOPMENT AND CONCURRENT ESTIMATION OF ANTI-RETROVIRAL DRUGS BY USING DIFFERENT ANALYTICAL TECHNIQUES"** *is a bonafide research work done by* N. PALLAVI (Y20BPH0508), A. RAMYA (Y20BPH0513), A. SRIKARI (Y20BPH0514), B. BALA THERISA (Y20BPH0519), K. JAYASRI (Y20BPH0564). *In partial fulfilment of therequirement for the award of the degree of* BACHELOR OF PHARMACY *is the bonafide research work carried out by the candidates in the laboratory of* CHALAPATHI INSTITUTE OF PHARMACEUTICAL SCIENCES, LAM, GUNTUR, *and was evaluated by us during the academic year2023-2024.*

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ABSTRACT

A recently devised procedure utilizing high performance liquid chromatography in conjunction with ultra violet detection (RPHPLC-UV) was established and verified for the concurrent determination of Lopinavir and Ritonavir which belongs to the class of protease inhibitors. Two different analytical methods UV-Spectrophotometry and RP-HPLC were simple, accurate, precise, reproducible methods that have been developed in the pure and pharmaceutical tablet dosage form. The diluent used was acetonitrile: water (50:50v/v). Based on the absorption maxima method the wavelength(λmax) of lopinavir and ritonavir was found to be 221nm and 239nm. Quantification was accomplished using UV detection at 224nm. The column used in RP-HPLC was primisil (250mm×4.6mm,5µm), the flow rate was 0.8ml/min. This approach is distinct in that it does not require the use of organophosphate buffers. The parameters Linearity, Precision, Accuracy, LOD, LOQ, Robustness are validated in accordance with the ICH guidelines.

Key words: Lopinavir, Ritonavir, UV- Spectroscopy, RP-HPLC.

FORMULATION AND EVALUATION OF ANTI - INFLAMMATORY ACTIVITY OF GUGGUL AND BOSWELLIA CREAM

A dissertation submitted to

CHALAPATHI INSTITUTE OF PHARMACEUTICAL SCIENCES

In partial fulfilment of the requirement for the award of the degree

Of

BACHELOR OF PHARMACY

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Place: Guntur

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ABSTRACT:

The primary goal of this study was to formulate and assess an anti-inflammatory cream containing Guggul and Boswellia gums.

10gm of guggul (*Commiphora wightii*) and Boswellia (Boswellia serrate) gums were separately extracted using maceration with water and two types of oils (Olive oil and Sesame oil). The resulting oil and water extracts were then used to prepare two anti-inflammatory creams, formula1 and formula2. The anti-inflammatory activity by utilizing albumin denaturation method and the physicochemical properties of the prepared creams were analysed.

Various parameters were examined to study the physicochemical properties of both creams. It was found that formula1 and exhibited superior physicochemical properties. The anti-inflammatory activity was evaluated using samples and a standard drug at concentrations of 100, 200,300, and 400 ug/ml. Interestingly, both Guggul and Boswellia shows anti-inflammatory activity equivalent to the standard drug diclofenac sodium.

The results suggest that the utilization of Guggul and Boswellia in an anti-inflammatory cream is advised for the management of different inflammatory conditions.

Commiphora Wightii, *Boswellia Serrate*, maceration, wet gum method anti-inflammatory, albumin denaturation.

FABRICATION AND CHARACTERIZATION OF *Azadirachta Indica* Oil INDUCED NANOEMULGEL USING 3^3 CENTRAL COMPOSITE DESIGN (CCD): ASSESSMENT OF ANTIBACTERIAL ACTIVITY

Dissertation submitted to

In partial fulfillment of the requirement for the award of the degree of

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EVALUATION CERTIFICATE

*This is to certify that the dissertation work entitled "**Fabrication and Characterization of Azadirachta indica oil Induced Nanoemulgel using 3^3 Central Composite Design (CCD): Assessment of Antibacterial Activity**" is a bonafide research work done by **KONDAVETI UJWALA (Y20BPH0562), NOOKALA VIMALA (Y20BPH0578), PALLA SHALINI (Y20BPH0580), PENTYALA NIKITHA (Y20BPH0585), VISHNUMOLAKALA VENKATESWARA RAO (Y20BPH0603), MEDAPATI VIKAS(L21BPH0609), MOHAMMAD BARAKATHULLA(L21BPH0610)** and submitted in partial fulfillment of the requirement for the award of the degree of **BACHELOR OF PHARMACY** by the **CHALAPATHI INSTITUTE OF PHARMACEUTICAL SCIENCES, LAM, GUNTUR** and was evaluated by us during the academic year 2023-2024.*

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ABSTRACT

Background: In this study, *neem* oil's therapeutic potential against bacterial inflammations is explored through nanoemulsion technology. Despite its historical significance in traditional medicine, *neem* oil formulations face challenges such as limited stability and poor solubility. Nanoemulsions offer a promising solution by enhancing *neem* oil's efficacy, stability, and patient acceptability. Utilizing Response Surface Methodology, specifically Central Composite Design, enables systematic optimization of nanoemulsion formulations, enhancing their therapeutic potential.

Materials & Methods: In this research, the Central Composite Design (CCD) was instrumental in fine-tuning parameters like the concentration of surfactant (A), time of homogenization (B), and speed of homogenization (C). These variables were explored across three different levels. Particle size, serving as the dependent variable, was assessed as the response to variations in these independent factors. Mathematical equations and response surface plots were used to understand the relation between the factors influencing the outcome and the resulting dependent variable.

Results: The optimized CCD model has a particle size of 97.9 nm, a zeta potential of -21.0 mV, and a PDI value of 0.512. Carbopol 934 was utilized in formulating the nanoemulgel. The observed responses closely resembled the anticipated outcomes from the optimized process. Morphological analysis and In Vitro release studies were employed to characterize the prepared nanoemulgel formulation.

Conclusion: The Response Surface Methodology (RSM) facilitates the formulation of neem oil emulsion with the smallest droplet size possible. Furthermore, the nanoemulgel exhibited significant antibacterial activity against Staphylococcus aureus (S. aureus)

Keywords: Azadirachta Indica (Neem Oil), Central Composite Design (CCD), Response Surface Methodology (RSM), Nanoemulgel.

FORMULATION AND EVALUATION OF ANTIMICROBIAL ACTIVITY OF HERBAL SYRUP

Submitted to

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ABSTARCT

Piper betel L. leaves were tested for antibacterial activity using both an aqueous extract and an ethanol extract against three Gram positive and two Gram negative bacteria, using chloramphenicol as standards for the antibacterial assays.

The two extracts demonstrated different levels of antibacterial activity against the microorganisms studied. The ethanol extract was significantly more effective than an aqueous extract at inhibiting the microbial strains studied.

Four plant extracts (44%) had action against five or more bacteria, while five plant extracts (56%) were active against three or fewer germs. None of the studied plant extracts were effective against all of the microorganisms. Asparagus racemosus had the lowest effectiveness against the investigated bacterial species.

QUANTITATIVE ESTIMATION OF ASCORBIC ACID AND QUERCETIN IN PHYLLANTHUS EMBLICA BY HPTLC

Dissertation submitted to

CHALAPATHI INSTITUTE OF PHARMACEUTICAL SCIENCES,

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ABSTRACT

For Phyllanthus emblica, an HPTLC technique was created to measure quercetin and ascorbic acid. A TLC silica gel 60 F254 plate was used as the stationary phase, and 30 µL of sample was sprayed over it at a rate of 20 µL/sec of dosing speed. This allowed for the separation of ascorbic acid and quercetin. The mobile phase used in the experiment was ethanol: water: 10% formic acid with a ratio of (3.5:6:0.5 v/v/v). The densitometric measuring mode was used to make the determination at 254nm. 0.726 and 0.662 were discovered to be the ascorbic acid and quercetin Rf values. For the quantitative analysis of ascorbic acid and quercetin in Phyllanthus emblica, the devised technique was verified in accordance with ICH requirements and demonstrated to be both convenient and reproducible. The method is linear between 750 and 1750 ng/spot, with correlations of 0.9998, 0.9998, and Rf values of 0.726 and 0.662 for quercetin and ascorbic acid, respectively. NMT 2.0% was obtained after additional parameters including area and percentage RSD were measured and computed. The process works well for routine quantitative analysis and is fast and accurate.

DESIGN DEVELOPMENT AND *IN - VITRO* DYSMENORRHEA ACTIVITY OF ORAL ACECLOFENAC MEDICATED JELLIES

A dissertation submitted to

CHALAPATHI INSTITUTE OF PHARMACEUTICAL SCIENCES

In partial fulfillment of the requirement for the award of the degree of

BACHELOR OF PHARMACY

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EVALUATION CERTIFICATE

This is to certify that dissertation work entitled "DESIGN DEVELOPMENT AND *IN - VITRO* DYSMENORRHEA ACTIVITY OF ORAL ACECLOFENAC MEDICATED JELLIES" is a bonafide research work done by A .VIJAYA LAKSHMI (Y20BPH0517), G.AKHILA (Y20BPH0544), K.THANUSHA (Y20BPH0560), M.N.V.A.S.KEERTHANA (Y20BPH0567), M.SRI VARSHITHA (Y20BPH0600)and submitted in partial fulfillment of the requirement for the award of the degree of BACHELOR OF PHARMACY by the CHALAPATHI INSTITUTE OF PHARMACEUTICAL SCIENCES, LAM, GUNTUR.and was evaluated by us during the academic year 2023-2024.

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Abstract:

An Aceclofenac jelly is a just emerging formulation which is used to relieve menstrual cramps. The main aim of study is to create and evaluate the oral medicated jellies of Aceclofenac. As prostaglandins are responsible for pain, Aceclofenac has the ability to inhibit synthesis of prostaglandins by inhibiting the cyclo-oxygenase enzyme. Over all 6 formulations (F1-F6) were prepared by Heating and congealing method. The formulated jellies were evaluated for physical appearance, viscosity, pH, drug content, weight variation , *In - vitro* dissolution studies . Based on the results F6 formulation has been found to be optimized formulation. Stability studies were carried out for F6 formulation according to ICH guidelines for 3 months and no changes were observed .

Key words: Aceclofenac, menstrual cramps, heating and congealing, medicated jelly, *In - vitro* dissolution studies , stability studies .

EVALUATION OF ANTI UROLITHIATIC ACTIVITY OF *Hemidesmus indicus* ROOTS AGAINST ETHYLENE GLYCOL INDUCED KIDNEY STONES

A dissertation submitted to

CHALAPATHI INSTITUTE OF PHARMACEUTICAL SCIENCES

In partial fulfillment of the requirement for the Award of Degree of

BACHELOR OF PHARMACY

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EVALUATION CERTIFICATE

This is to certify that dissertation work entitled "EVALUATION OF ANTI UROLITHIATIC ACTIVTY OF *Hemidesmus indicus* ROOT AGAINST ETHYLENE GLYCOL INDUCED KIDNEY STONES" ***is a bonafide research work done by*** B. KAVYA SRI (Y20BPH0504), D. KAVYA SREE (Y20BPH0536), G. HEMA SREE (Y20BPH0545), K. SRUJANA CHOWDARY(Y20BPH0561), P. VYSHNAVI (Y20BPH0583) ***and submitted in partial fulfillment if the requirement for the Award of the Degree of*** *BACHELOR OF PHARMACY* ***by the*** *CHALAPATHI INSTITUTE OF PHARMACEUTICAL SCIENCES, LAM, GUNTUR,* ***and was evaluated by us during the academic year 2023-2024.***

Place: Guntur

Date: 17/05/2024

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ABSTRACT:

Background: *Hemidesmus indicus* also known as Indian sarsaparilla used as Indian traditional medicine

Objective: The objective of the present study was to evaluate the anti urolithiatic activity of *Hemidesmus indicus* roots against ethylene glycol induced kidney stones in Wistar albino rats.

Methods: In this study 25 Wistar albino rats were randomly selected and divided in to 5 groups each group consists of 5 animals group: 1 (Control), group: 2 (negative control- ethylene glycol per oral 0.75%), group: 3 (standard- cystone 750mg) group: 4&5 (different verses of extract MEHI (40mg/kg, 80mg/kg). Kidney stones were induced with ethylene glycol at a concentration of 0.75% to the groups except control group, at 28th day estimation of body weight, serum uric acid, creatinine, urine calcium, pH and microscopical analysis were carried out.

Results: The MEHI treated groups found to improve the kidney functions by lowering the creatinine, uric acid and calcium levels similar to the cystone treated groups. The creatinine, uric acid and calcium levels were increased in ethylene glycol treated groups when compared with control group.

Conclusion: The MEHI dose of 80 mg per kg of body weight could effectively normalize the creatinine, uric acid, pH and calcium levels. It effect on the urinary concentration of the stone forming constituents and urolithiasis inducing factors, hence the MEHI could be a potential source of traditional drugs for treatment of urolithiasis.

UNLOCKING THE TRIAD OF HEALTH: INVESTIGATING THE HIGH BLOOD PRESSURE, OBESITY AND THEIR IMPACT ON PCOS IN WOMEN

A Dissertation submitted to

ACHARYA NAGARJUNA UNIVERSITY

In partial fulfillment of the Award of Degree of

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EVALUATION CERTIFICATE

This is to certify that dissertation work entitled "UNLOCKING THE TRIAD OF HEALTH: INVESTIGATING THE HIGH BLOOD PRESSURE, OBESITY AND THEIR IMPACT ON PCOS IN WOMEN" is a bonafide research work done by Isireddy Nymisha Reddy, Madala Teja Kalyani, Mekala Rikitha, Ravuri Neha Sree, Sri Harshitha Komatineni, submitted in partial fulfillment of the requirement for the award of the degree of BACHELOR OF PHARMACY *by the CHALAPATHI INSTITUTE OF PHARMACEUTICAL SCIENCES, LAM, GUNTUR.*

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ABSTRACT

BACKGROUND:

PCOS is a hormonal condition that is commonly experienced by people who have ovaries, usually in their reproductive years. A number of symptoms, such as polycystic ovaries (many tiny follicles present in ovaries), high androgen (male hormone) levels, and irregular menstrual periods are what define it. Numerous consequences, including obesity, hypertension, insulin resistance, type 2 diabetes, heart disease, depression, anxiety and infertility can result from PCOS. Between **3.7%** and **22.5%** of Indian women who are of reproductive age have PCOS.

AIM:

To comprehensively investigate the Interplay between Obesity, Hypertension and their Impact on PCOS in women & its implications for their health

METHODOLOGY:

Inclusion criteria:

All samples aged 13 years and above were eligible for the study after informed consent. Samples were taken both from medical, non-medical and general women adults. Participants with a confirmed diagnosis of Polycystic Ovary Syndrome (PCOD) based on established diagnostic criteria, such as the Rotterdam criteria. Participants with a Body Mass Index (BMI) greater than or equal to 30 kg/m^2, indicating obesity. Participants with diagnosed hypertension, defined as systolic blood pressure (SBP) of 140 mm Hg or higher and/or diastolic blood pressure (DBP) of 90 mm Hg or higher, or currently taking antihypertensive medication.

Exclusion criteria:

Samples who were too unwell to respond to the questionnaires and those whose mental state made them incapable to participate in the study were omitted.

STUDY PROCEDURE:

- This study was cohort, questionnaire-based research conducted in Guntur regional area
- The period of this study was from September 2023 to February 2024
- A total of 1246 questionnaires were randomly distributed to the participants. Out of which, 118 samples were diagnosed with PCOS.
- The questionnaire was made up of 8 sections and comprised a total of thirty-five structured questions.
- At the end of the study, all the data obtained was analyzed by using statistical methods. Mean, Standard deviation was calculated and reported.

RESULTS:

- A month-by-month evaluation of samples identified as having PCOS was conducted between October 2023 and March 2024. It was discovered that the t-value was **-3.523** and the p-value was **0.024.**
- From October 2023 to March 2024, a month-by-month evaluation of samples with HTN diagnosis was conducted. The t-value was computed to be **-3.389** and the p-value was determined to be **0.027.**
- Samples identified with obesity were evaluated month-by-month from October 2023 to March 2024. A p-value of **0.004** was discovered. **-5.715** was determined to be the t-value.
- Samples diagnosed with PCOS plus HTN were evaluated month-by-month from October 2023 to March 2024. After computation, the t-value came out to be **-9.797** and the p-value was discovered to be **0.0006.**
- Samples identified with PCOS+OBESITY were evaluated month-by-month from October 2023 to March 2024. The t-value was discovered to be **-9.797** and the p-value to be **0.0006.**

- A month-by-month evaluation of samples identified with PCOS+OBESITY+HTN was conducted between October 2023 and March 2024. A t-value of **-5.879** and a p-value of **0.004** were discovered.
- Examining samples with OBESITY+HTN on a month-by-month basis was done between October 2023 and March 2024. It was discovered that the t-value was **-5.099** and the p-value was **0.006.**

DISCUSSION:

Our study began with a comprehensive survey conducted in Guntur on both physical and virtual platforms to investigate the prevalence and underlying causes of PCOS. With validated surveys similar to those used in research on the Jordanian populace, we collected a solid dataset with 1246 answers. The fact that 14.53% of the individuals in this dataset had a PCOS diagnosis highlights the seriousness of this illness in our society. By the end of the study, 112 individuals are diagnosed with PCOS.

CONCLUSION:

We have started a number of educational programs and counseling sessions to increase public knowledge of PCOS and the hazards that are linked with it in response to our findings. Our goal is to provide people with the information and tools they need to make wise health decisions by distributing pamphlets in both the local language and English. By amalgamating data from local and online platforms, we garnered a nuanced understanding of PCOS prevalence and risk factors, with 14.53% of our sample diagnosed with this condition.

KEYWORDS: Quality of life, Menstrual irregularity, body hair, weight, emotion, polycystic ovary syndrome.

"DEVELOPMENT AND CHARACTERIZATION OF *IXORA COCCINEA* LINIMENT TO ALLEVIATE NOCICEPTIVE ACTIVITY"

Dissertation submitted to

CHALAPATHI INSTITUTE OF PHARMACEUTICAL SCIENCES

In partial fulfillment of the requirement for the award of the degree of

BACHELOR OF PHARMACY

Submitted by

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DEVINENI KRISHNA TULASI	(Y20BPH0538)
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May - 2024

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EVALUATION CERTIFICATE

This is to certify that the dissertation work entitled "DEVELOPMENT AND CHARACTERIZATION OF *IXORA COCCINEA* LINIMENT TO ALLEVIATE NOCICEPTIVE ACTIVITY" ***is a bonafide research workdone by*** *in partial fulfillment of the requirement for the award of the degree of* BACHELOROF PHARMACY *is the bonafide research work carried out by the candidates* ANNA CHARUNYA (Y20BPH0515), DEVINENI KRISHNA TULASI (Y20BPH0538), JAMPANI MANASWINI (Y20BPH0551), KAMBHAMPATI YAMUNA (Y20BPH0557), SHAIK SABRIN (Y20BPH0591) *in the laboratory of* ***CHALAPATHI INSTITUTE OF PHARMACEUTICAL SCIENCES, LAM, GUNTUR****, and was evaluated by us during the academic year 2023-2024.*

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ABSTRACT

This research work is undertaken with the aim to formulate and evaluate Ixora coccinea liniment. Five different formulations were prepared and observed the physical characteristics like color, odor, pH. The pH of the prepared formulations was found in between 5.24 to 5.54 which lies in normal pH range of the skin. The spectra of API and prepared formulations were determined by ATR-FTIR model. The particle size was also determined by microscopic method and the average particle size in the formulated liniment was 3.5µm It concludes that final product is safe and compatible with excipients and also without causing any adverse effects. In-vitro drug release studies was performed and evaluated using Franz diffusion cell. From all the formulations F4 was concluded as optimized formulation as it showed higher drug release.

KEY WORDS: Ixora coccinea, Liniment, pH, ATR-FTIR, Microscopic method, Franz diffusion cell

"EVALUATION OF ANTI-EPILEPTIC ACTIVITY OF ETHANOLIC SEED EXTRACT *OF HYPTIS SUAVEOLENS* IN MICE"

Submitted to

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"EVALUATION OF ANTI-EPILEPTIC ACTIVITY OF ETHANOLC SEED EXTRACT OF *Hyptis Suaveolens. L* SEEDS IN MICE"

ABSTRACT

Objective:

Evaluation of anti-epileptic activity of ethanolic seed extract of *Hyptis suaveolens* in mice using strychnine.

Methods:

The experiment was carried out for 14 days, first 7 days for acclimatization of animals to animal house conditions and next 7 days for animal experimentation. Twenty-five animals were separated into five equal groups. Group I was allotted for distilled water (10mL/kg), group II remains without any intervention, group III was administered standard drug (diazepam 1mg/kg) and group IV and V are allotted for EEHS extract (100 and 200mg/kg). On 14th day, strychnine was administered to all treatment groups (except the control group) after extract and diazepam treatments respectively. Animals were observed for onset of convulsions, duration of convulsions and mortality rate of each group.

Results:

The ethanolic seed extract of *Hyptis suaveolens* contains significant anti-convulsant activity against the strychnine induced convulsions, when compared with disease control and the standard group. The activity increases with an increase in the dose concentration.

Conclusions:

The flavonoids in *Hyptis suaveolens* is responsible for its anticonvulsant effect, and its antiepileptic efficacy rises in a dose-dependent way.

Key words:

Hyptis suaveolens, maceration, ethanolic extract, anti-epileptic activity, HPTLC, IR and strychnine.

A CROSS SECTIONAL INVESTIGATION OF THE SOCIOECONOMIC IMPACT ON THE QUALITY-OF-LIFE OF PEOPLE SUFFERING WITH CHRONIC DISORDERS IN GUNTUR

A Dissertation submitted to

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ABSTRACT

Aim: Our study aims to assess the impact of socio-economic variables on the Quality of Life (QoL) of individuals suffering with chronic diseases in Guntur district. This study investigates socioeconomic status, and quality of life, and identifies significant factors that may influence individuals' health outcomes. Additionally, this survey highlights challenges faced by individuals that may influence their healthcare decisions and assess the impact of patient counselling recommendations on the individual's ability to enhance the overall quality of life.

Methodology: Conducted from August 2023 to February 2024, the study involved 994 individuals, with 820 having chronic diseases. The cross-sectional study employed clustered random sampling from different areas in Guntur. Data on socio-economic status were collected through validated surveys, and QoL was assessed using the WHOQOL-BREF questionnaire.

Results: Most individuals with chronic diseases were in the upper lowerclass. Statistical analysis using the Chi square test revealed a significant relationship between socio-economic status and QoL. Participants in lower classes preferred generic medications and self-medicated more, while higher classes favored branded medications and had more regular health checkups. Despite socio-economic challenges, the upperlowerclass reported higher QoL scores. Patient counselling interventions significantly improved medication adherence, awareness of chronic disease risk factors, and health management skills.

Conclusion: The study highlights the complex relationship between socio-economic variables and QoL in individuals with chronic diseases in Guntur district, emphasizing the need for targeted interventions to raise socio-economic standards, enhance healthcare access, and bolster social support systems.

Key words: Chronic diseases, Socioeconomic class, Quality of Life, WHOQOL-BREF, Kuppuswamy Socioeconomic Scale.

A CROSS-SECTIONAL STUDY ON EPIDEMIOLOGICAL FEATURES OF HEALTH WITH TOBACCO USERS IN RURAL AREAS OF GUNTUR

A Dissertation submitted to

CHALAPTHI INSTITUTE OF PHARMACEUTICAL SCIENCES

In partial fulfillment of the Award of Degree of

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ABSTRACT

Background: Tobacco is a psychoactive substance with the property of producing dependence. Excess use of tobacco causes a high burden of disease and has significant social and economic consequences. Its consumption is a causal factor for more than 200diseases and injuries and other health conditions. Heavy tobacco drinking is a major preventable cause of many disorders like hypertension, diabetes, pancreatitis, liver cirrhosis, etc.

Aim: A Cross-sectional study on epidemiological features of health with tobacco consumption in rural areas of Guntur.

Methodology: A cross-sectional study was conducted in Guntur area for a period of 5months i.e., from October 2022 to March 2023. Data was collected from 605 subjects.The study method involves all subjects who will be selected based on inclusion and exclusion criteria. The data will be tabulated and analyzed using suitable statistical tools.

Results: On reviewing the demographic data among 605 subjects it was found that Regarding the demographics 19-30yrs (35%) age group, schooling subjects (29%), goods workers (39%) & middle class (44%) subjects were found to be common tobaccoconsumers. The association between the medical conditions and age group (p=0.000039)***, occupation (0.0000021)***, economic status (9.59), post-marital status (0.0000073)***, Consanguineous marriages (0.102), dietary pattern (0.018)*, smoking (0.0000010)***, daily tobacco consumers (0.00009)***, twice weekly (0.00094)***, thrice weekly (0.2603), occasional tobacco consumers (0.0039)*** & family history (0.0001)***.

Conclusion: In conclusion, the present study found that among the demographics age, and occupation are having positive associations with disease occurrence. The economic status does not show any significant association between diseases. The habit of smoking is significantly associated with disease occurrence and the habit of drinking tobacco daily is significantly associated with diseases like gastroenterological, endocrinological, cardiological, pulmonological problems, and family history also.

Keywords: Tobacco, Epidemiological features, Health, smoking, consanguineous marriage.

HEALTH RELATED QUALITY OF LIFE [HRQOL] AND IT'S CLINICAL MANIFESTATIONS, ETIOLOGY IN END STAGE RENAL DISEASE[ESRD] ON HEMODIALYSIS PATIENTS: A CROSS SECTIONAL STUDY

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ABSTRACT

BACKGROUND: Haemodialysis, a common treatment for ESRD, can significantly impact patients' quality of life and risk of complications, necessitating an understanding of its causes to enhance patient outcomes. Health-related quality of Life is significantly impacted by hemodialysis patients with ESRD due to treatment side effects, dietary restrictions, and daily activity limitations. The objective of this study was to evaluate the health-related quality of life (HRQOL) of patients with end-stage renal failure who underwent maintenance hemodialysis treatment along with the underlying causes and complications related to advanced renal disease.

METHODS: A 6-month cross-sectional study was conducted in a tertiary care hospital, involving 204 patients on hemodialysis. Data was collected using the KDQOL -36 scale with five subscales including physical and mental health, symptoms, burden, and effect of kidneys.

RESULTS: The study found that most patients with ESRD reported facial puffiness, fatigue, and decreased urine output. Major etiological factors included hypertension (42%), diabetes mellitus, thyroid dysfunction, hypotension, and hypertension with diabetes mellitus. Most people were non-alcoholics and non-smokers. Hemodialysis frequency could improve HRQOL, but it could impact PCS ratings. Working subjects showed better PCS ratings and improved HRQOL.

CONCLUSION: Patients with kidney failure undergoing hemodialysis in a tertiary care hospital have lower HRQOL due to unemployment, low income, and longer dialysis duration. Over half have co-morbidity conditions, and low quality of life is more common in men. Continuous moral support and counseling are needed to improve medication adherence and patient care. Further research is recommended for further analysis.

KEYWORDS: End-stage renal failure, hemodialysis, Health-Related Quality of life

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UNRAVELING THE THREAD: AN OBSERVATIONAL STUDY ON SUBSTANCE USE AND ITS IMPACT ON COGNITION AND PSYCHIATRIC SYMPTOMS AMONG A DIVERSE AGE GROUP

Dissertation submitted to

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This is to certify that dissertation work entitled "UNRAVELING THE THREAD: AN OBSERVATIONAL STUDY ON SUBSTANCE USE AND ITS IMPACT ON COGNITION AND PSYCHIATRIC DISORDERS AMONG A DIVERSE AGE GROUP" is a bonafide research work done by ***MALLAMPATI VARSHINI (Y19PHD0118), NOMULA KUMUDAVALLI (Y19PHD0121), NANDURI NAGA SWETHA (Y19PHD0119), KAVURI PRUDHVI (Y19PHD0125)*** submitted in partial fulfillment of the requirement for the Award of Degree of *DOCTOR OF PHARMACY* by the *CHALAPATHI INSTITUTE OF PHARMACEUTICAL SCIENCES, LAM, GUNTUR.*

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ABSTRACT

Background: Substances that alter brain function and have the potential to produce long-lasting behavioral and cognitive deficits include alcohol, nicotine, caffeine, cannabis, stimulants, and opioids. One in seventeen people worldwide reported using drugs in 2022, a 23% rise from a decade earlier. The incidence of drug use worldwide remains high, Andhra Pradesh has the highest rate of substance use prevalence, with opiate use at 4.46%, cannabis at 2.08%, sedatives at 3.3%, and alcohol at 17.10%The main purpose of the study is to assess the relationship between drug abuse and how it affects mental health and cognitive function in a range of age groupings.

Aim: The study aims to investigate the intricate connections and temporal sequences among Substance Use, and its Impact on Cognition and Psychiatric Disorders among a Diverse Age Group.

Objectives: To identify prevalent substances and usage patterns across diverse age groups, investigate potential age-related vulnerabilities or resilience concerning substance-induced impacts on cognitive abilities, investigate the correlation between substance use and the occurrence or exacerbation of psychiatric disorders and suggest strategies or counselling to diverse age groups for minimizing adverse cognitive effects and psychiatric disorders related to substance use.

Methodology: An observational study was carried out for a period of 6 months where the patients were screened based on inclusion and exclusion criteria. Following the issuance of informed permission, patients who meet the study's eligibility requirements were included. The pre-designed Montreal Cognitive Assessment (MoCA), Brief Psychiatric Rating Scale (BPRS) Assessment were used to gather the data. Each of this information was gathered from educational institutes and inpatient and outpatient departments of psychiatry at tertiary care hospital. Upon applying statistical methods to evaluate and tabulate the data, results were generated.

Results: A total of 628 subjects were included in the study based on the inclusion criteria. Statistical analysis was done and proved the substance use impact on cognition and psychiatric disorders among diverse age groups. Most of the subjects were under the age group of 26-35(n=189, 30.09%). Majority of the subjects were males (n=460, 73.24%) than females (n=168,26.75%).

The prevalence of substance uses among all age groups (alcohol- 71.33%, Tobacco- 67.51%, Pan masala- 38.05%, opiates- 13.21%, cannabis- 27.22%, caffeine- 72.61%, and sleeping pills/pain killers- 60.35%). Substance use impact on cognition impairment (alcohol- 50.62%, Tobacco- 47.77%, pan masala- 26.59%, opiates- 13.21%, cannabis- 24.36%, Caffeine- 37.57%, and sleeping pills/pain killers- 40.44%). Substance use impact on psychiatric disorders (alcohol influences more in psychiatric disorders (anxiety- 61.94%, depression- 47.13%, sleep disturbances- 58.12%, Hallucinations- 26.91%, Disorientation- 27.07%).

Conclusion: This study emphasizes the pervasiveness of substance use across diverse age groups including the detrimental impacts of alcohol, tobacco, pan masala/gutka, opiates, cannabis, caffeine, and sleeping pills/pain killers medications on mental health and cognitive function. It demonstrates alarmingly high prevalence rates, indicating a pressing public health concern. The effects of substance-related harm can be minimized by addressing these concerns through focused education programs and awareness efforts.

Key words: Substance Use (SU), Alcohol, Tobacco, Pan Masala/gutka, Opiates, Cannabis, Caffeine, Sleeping pills/ Pain killers, Cognition, Anxiety, Depression, Sleep Disturbances, Hallucinations, Disorientation.

HYPERTENSION CARE ASSESSMENT: UNVEILING ADHERENCE, DIET AND LIFESTYLE IMPACT A-COHORT INVESTIGATION

Dissertation submitted to

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(AUTONOMOUS)

'Accredited by NAAC with A' Grade'

In partial fulfillment of the requirements for the Award of Degree of

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ABSTRACT

Aim: The primary aim of this cohort study is to assess the potential impact of medication adherence, dietary restrictions, and lifestyle modifications in the management of Hypertension (HTN) and prevention of its complications.

Objectives:

Primary Objectives:

1. To determine whether medication adherence, dietary restrictions, and lifestyle modifications contribute to optimal therapeutic outcomes.

Secondary Objectives:

1. To assess the effect of patient counseling in improving quality of life (QOL) in hypertensive individuals.
2. To explore the potential impact of patient counseling in preventingcomplications.

Methodology: A Cohort observational study was carried out for 6 months where the patients were screened based on inclusion and exclusion criteria. Patients who satisfied the inclusion criteria were included in the study after obtaining informed consent. The data was collected in the pre-designed data collection forms. All this data was collected from the hypertensive patients dwelling in rural areas ofGuntur. Results were obtained and statistical tools were used to analyze and tabulate the data.

Results:

200 subjects met the inclusion criteria and were included in the study. The following results are tabulated and analyzed using specific statistical tools. Descriptive data were expressed as percentage, mean, and standard deviation, and the ANOVA test was used for continuous data. Two-way ANOVA was used, and the significance level was set at $p<0.05$ with a 95% confidence interval.

The results of the present study include the demographic distribution of patients, therole of clinical pharmacists in lifestyle modification, and disease outcomes. Statistical analysis proved the influence of the clinical pharmacist's role on disease outcome and reducing the complications associated with uncontrolled blood pressure.

Conclusion:

Based on the results obtained, our study concludes that 51-60 years age group subjects are more diagnosed with hypertension and the disease can occur in both males and females. Effective management of the disease requires both pharmacological and non-pharmacological management. The majority of the subjects in our study are middle-aged adults and their BP values lie within the normal range of prehypertension with strict follow-up of non-pharmacological management. Our study aims to prioritize the role of the clinical pharmacist in the effective management of Hypertension through patient counseling and patient educationabout the disease, medication use, lifestyle, dietary changes, and salt restriction. With this, we conclude that regular physical activity, good medication adherence, dietary (DASH), and salt restrictions can effectively contribute to the management of Hypertension (HTN).

A PROSPECTIVE OBSERVATIONAL STUDY ON THE CLINICAL SPECTRUM OF ACUTE PANCREATITIS IN DEPARTMENT OF GENERAL MEDICINE IN A TERTIARY CARE TEACHING HOSPITAL

Dissertation submitted to

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ABSTRACT

Background

Acute pancreatitis (AP) is a potentially life-threatening inflammatory disorder of the pancreas, characterized by sudden onset abdominal pain, elevated pancreatic enzymes, and potential multi-organ involvement. The clinical course of acute pancreatitis can vary significantly between individuals, making its management a complex and demanding task for healthcare providers. Understanding the diverse clinical spectrum of this disease is essential for optimizing patient care and outcomes. Severe acute pancreatitis (SAP) remains a significant public health concern globally, with an increasing incidence in recent years. It imposes a substantial burden on healthcare systems due to its potential for rapid progression to severe forms of the disease, leading to prolonged hospitalizations, increased healthcare costs, and a higher risk of mortality.

Aim:

This study aims to shed light on the clinical spectrum of the multifaceted nature of acute pancreatitis by systematically documenting and analyzing its clinical presentation, severity, etiological factors, complications, and treatment outcomes within the context of a tertiary care teaching hospital in the general medicine department.

Objectives:

To describe the demographic and clinical characteristics of patients with acute pancreatitis, to identify the common etiological factors leading to acute pancreatitis, to assess the severity of acute pancreatitis using established scoring systems, to observe the treatment outcomes in acute pancreatitis patients, to analyze the factors associated with disease progression and complications, and to contribute valuable insights to the existing body of knowledge.

Methodology:

A prospective observational study was carried out for 6 months where the patients were screened based on inclusion and exclusion criteria. Patients who satisfied the inclusion criteria were included in the study after obtaining informed consent. The data was collected in the pre-designed data collection forms. Results were obtained and statistical tools were used to analyze and tabulate the data.

Results: A total of 121 subjects, 116 males (95.87%) and 5 females (4.13%), were included in the study based on the inclusion criteria. Most of the subjects were under the age group of 26-35 (36.36%). Alcohol was found to be a major etiological factor with 101 cases (83.4%), gallstone pancreatitis (1.65%), and idiopathic cases 18(14.95%). Most of the patients developed complications mainly acute fluid collection (43.13%), and ascites (33.33%) during the first four weeks of admission. Abdominal pain was found to be the most common clinical manifestation in all the age groups followed by vomiting, fever, and epigastric pain. A severity assessment was done using the BISAP scoring scale, and RANSON scoring scale, found to be at mild risk. Most of the subjects were included under the score 0(59.5%), followed by score 1(28.9%), and score 2 (11.57%) with BISAP assessment criteria. Most of the subjects were included under the score 0-2(71.9%), followed by a score of 3-5(28.09%), a score with RANSON assessment criteria. The treatment outcome of getting relief from abdominal pain when the subjects were prescribed pancreatin was found to be non-significant($p>0.05$) as the patients who have not prescribed pancreatin (32 out of 68 i.e., 47%) were also relieved from abdominal pain.

Conclusion: The study found that males were more prevalent in India due to alcohol consumption, and the age group of 26-35 is highly prone to acute pancreatitis. Abdominal pain and vomiting were more common clinical presentations. The study found that serum lipase is a more accurate biomarker in diagnosing acute pancreatitis than serum amylase. We also observed that pancreatin alone is not the only way to relieve abdominal pain. The study suggests enhancing nutritional status and educating patients on pain management techniques can lower the risk of acute pancreatitis.

Keywords: Acute pancreatitis (AP), bedside index of severity of acute pancreatitis (BISAP), Severe acute pancreatitis (SAP)

A RETROSPECTIVE ANALYSIS OF CARDIOTOXICITY WITH DOXORUBICINAND TRASTUZUMAB IN BREAST CANCER HER-2 POSITIVE PATIENTS

Dissertation submitted to

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This is to certify that the dissertation work entitled "A RETROSPECTIVE ANALYSIS OFCARDIOTOXICITY WITH DOXORUBICIN AND TRASTUZUMAB IN BREAST CANCER HER-2 POSITIVE PATIENTS" is a bonafide research work done by ***DASARI RAHUL PRAMODH KUMAR, BODEMPUDI NAGA VENKATA SAI, KOMMINENI SAITEJA, YASAM SHREE*** *submitted in partial fulfillment of the requirement for the Award of Degree of DOCTOR OF PHARMACY by the CHALAPATHI INSTITUTE OF PHARMACEUTICAL SCIENCES, LAM, GUNTUR.*

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ABSTRACT

Background: Breast cancer is the most prevalent cause of mortality for women worldwide, and its prevalence is rising in emerging countries. The widespread availability of numerous drugs that target the HER2 receptor has led to improvements in survival rates for patients with Human Epidermal Growth Factor Receptor-2-positive (HER2+) breast cancer over the past few decades.

Aim: To study the cardiotoxicity associated with the use of doxorubicin and trastuzumab in HER-2 positive breast cancer patients, a retrospective analysis.

Methodology: A retrospective analysis. Patients were screened based on inclusion and exclusion criteria. The self-designed and validated questionnaire was used to assess the cardiotoxicity with doxorubicin and trastuzumab in breast cancer HER-2 positive patients. Collected data was tabulated and interpreted using statistical software.

Results: Upon reviewing demographic data from 117 subjects, it was noted that breast cancer is most prevalent among individuals over 65 years old, with 51 (40.51%) subjects, significant at p=0.03436. All subjects in the study were female except one male. A higher proportion of subjects with a BMI of 30-34 kg/m2 were reported, with 53 (45.20%) subjects, significant at p=0.04131. Additionally, individuals from low socioeconomic backgrounds comprised a larger portion, with 47 (38%) subjects, significant at p=0.03386. Service workers had a higher incidence of breast cancer, with 56 (45%) subjects, significant at p=0.03376. Among social habits, regular smokers were found to be at a higher risk of breast cancer, significant at p=0.02115. Late menopause was associated with increased risk, with 54 (48%) subjects, significant at p=0.03887. The assessment of cardiotoxicity with doxorubicin pre- and post-therapy using ejection fraction (EF) was statistically analyzed with a p-value of 0.000017. Trastuzumab at a dose of 2mg/kg showed an EF assessment of 0.2035, statistically insignificant for cardiotoxicity. However, at a dose of 8mg/kg, trastuzumab showed a statistically significant EF assessment of 0.000018. Regarding follow-up, 99 (85%) subjects were alive, 7 (6%) were discharged against medical advice (LAMA), and 11 (9%) subjects had expired.

Conclusion: This study found that breast cancer is common among older individuals, those with higher BMI, lower socioeconomic status, service workers, late menopause, and regular tobacco users. Trastuzumab at 2mg/kg showed no cardiotoxicity, while both trastuzumab at 8mg/kg and doxorubicin exhibited similar cardiotoxicity effects, with more deaths associated with doxorubicin. Therefore, trastuzumab at a lower dose appears to be effective and safe.

Keywords: Trastuzumab, Doxorubicin, Cardiotoxicity, Breast cancer, Prevalence, ejection fraction.

AN AMBISPECTIVE STUDY ON ATAXIA PATIENTS ADMITTED IN NEUROLOGY DEPARTMENT OF TERTIARY CARE HOSPITAL

Dissertation submitted to

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ABSTRACT

Background: Ataxia is a lack of coordination. Ataxia is the term used to characterize inadequate motor control leading to trouble moving. Walking, balance, hand-eye coordination, speaking, swallowing, and eye movements can all be impacted. Damage to the cerebellum, a region of the brain that regulates muscular coordination, or its connections can lead to ataxia. This study's primary goal is to assess the relationship between various forms of ataxias and their origin, risk factors, comorbid disorders, and other variables.

Aim: To study etiology, risk factors and various factors associated with ataxia in the department of neurology in the tertiary care teaching hospital.

Objectives: To evaluate the etiology, evaluate comorbidities associated with ataxia, evaluate proportion of hereditary and acquired ataxia.

Methodology: An Ambispective observational study was carried out for a period of 6 months where the patients were screened based on inclusion and exclusion criteria. Patients who satisfy inclusion criteria were included in the study after obtaining informed consent. The data was collected in the pre designed data collection forms. All this data was collected from Neurology outpatient and inpatient department. Results were obtained and statistical tools were used to analyze and tabulate the data.

Results: A total of 48 subjects were included in the study based on the inclusion criteria. Most of the subjects were under the age group of 31-45 (n=16, 33%). Majority of the subjects were males (n=30, 62.5%). Most of the subjects fall into underweight category (P=0.000096). Most of the subjects chief complaints were unsteady gait (n=44,91.6%), difficulty incoordination (n=30, 62.5%). Majority of subjects were from consanguineous marriage (P=0.009375). Some other clinical parameters like alcohol (P=0.009375), tobacco usage (P=0.000667) and blood pressure (P=0.002329) showed significant association with ataxia.

A CROSS-SECTIONAL STUDY ON THE FACTORS AFFECTING BREASTFEEDING TIMELINE AND ITS IMPACT ON CHILD DEVELOPMENT

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CERTIFICATE

This is to certify that dissertation work entitled "*A CROSS SECTIONAL STUDY ON THE FACTORS AFFECTING BREASTFEEDING TIMELINE AND ITS IMPACT ON CHILD DEVELOPMENT*" is a bonafide research work done by *DASARI PREM KUMAR (Y19PHD0107), TANINKI SHANMUK ABHINAY (Y19PHD0130), NIMMAGADDA MANISHA (Y19PHD0120), KANCHARLA SHYNI (Y19PHD0113)* submitted in partial fulfillment of the requirement for the Award of Degree of *DOCTOR OF PHARMACY* by the *CHALAPATHI INSTITUTE OF PHARMACEUTICAL SCEINCES, LAM, GUNTUR.*

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ABSTRACT

BACKGROUND:

Earlier studies in various countries have shown that Exclusive Breastfeeding (EBF) practice has a lot of variability which can be associated with various socioeconomic, demographic, obstetric, and healthcare factors related to child and mother (i.e., size of child at birth, sex of child, age of child, birth order, preceding birth interval, place of delivery, and mode of delivery, etc). Breastfeeding is associated with long-term well-being of a child. This includes as low risk of both infectious and non-infectious diseases (like asthma, cancer, autoimmune diseases, and obesity) during childhood. In recent years, important advances have been made in understanding the human breast milk (HBM) composition. Breast milk components such as, non-immune and immune cells, bio-active molecules, namely, cytokines/chemokines, lipids, hormones, and enzymes reportedly play many roles in breastfed newborns and in mothers. HBM is reportedly said to provide disease protection and shapee the immune system of the newborn. Bio-active components of HBM are also involved in tolerance and appropriate inflammatory response in breastfed infants. Our study focuses on exploring the factors aaffecting the breastfeeding timeline and its impact on development of the child. We will also shed some light on the relationship between mother and her infant through breast milk with regard to disease protection and the child development.

AIM:

To study the factors affecting breastfeeding time line and its impact on child development.

OBJECTIVES:

Primary Objectives:

To assess the factors that may influence the breast-feeding time line, to assess the impact of breast feeding on child growth and development, to assess the feeding patterns and its impact on child's immunity.

Secondary Objectives:

To assess the pattern of drugs, use in breastfeeding mothers, to promote awareness about benefits and risks associated with breastfeeding among new mothers.

METHODOLOGY:

A cross sectional study was carried out in department of pediatrics, government general hospital, for a period of 6 months i.e., 2023 to 2024 after obtaining approval from institutional

EFFICACY AND IMPACT OF L-ARGININE IN SECOND TRIMESTER PATIENTS WITH OLIGOHYDRAMNIOS IN TERTIARY CARE HOSPITAL – AN AMBISPECTIVE OBSERVATIONAL STUDY

Dissertation submitted to

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ABSTRACT

BACKGROUND:

Oligohydramnios leads to feto-maternal morbidity and mortality remains a significant public ealth concern globally, with an increasing incidence in recent years. Use of L-Arginine in ligohydramnios elevates the amniotic fluid to normal range. It promotes placental perfusion, induces asodilatation, and ultimately raises amniotic fluid since it is a nitric oxide donor. Amniotic sac consists f fluid known as Amniotic fluid, rich in presence of water in the early stages of pregnancy. Nutrients, ormones, antibodies, and the baby's urine gradually start to appear in later stages .It serves as the main ource of nutrition for the developing foetus and guards against infection having bacteriostatic nature. relieves pressure, cushions, and keeps things from drying out. For normal growth, the foetal fluid ust be sufficient. The normal amniotic fluid range is 5-25cm. Any deviations from the normal value auses harmful effects on the foetus. The main purpose of this study is to evaluate the efficacy and mpact of L-Arginine at various AFI ranges in 2nd trimester pregnant women.

AIM:

This study aims to assess the impact of L-Arginine in various values of AFI [Amniotic fluid index] in 2nd trimester of Oligohydramnios patients.

OBJECTIVES:

PRIMARY OBJECTIVES:

- To assess the efficacy of L-Arginine at specific ranges of AFI.
- To identify the risk factors of Oligohydramnios.
- To assess the impact of Stress in Oligohydramnios.

SECONDARY OBJECTIVES:

- To analyze the range of amniotic fluid index in 2nd trimester pregnant women.
- To assess the importance of hydration in Oligohydramnios.

METHODOLOGY:

An Ambispective observational study was carried out for a period of 6 months where the subjects were screened based on inclusion and exclusion criteria. Subjects who satisfy

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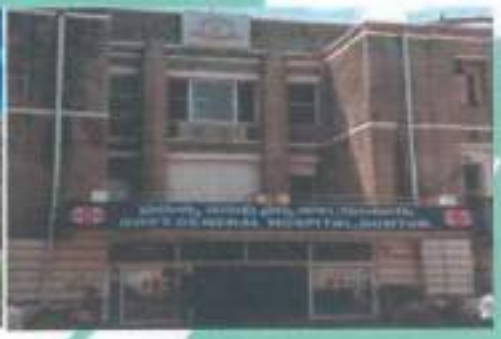

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Academic year JUNE 2022 to APRIL 2023

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DOCTOR OF PHARMACY

Submitted by

Ms. KORLAGUNTA. BHAVANADEVI

REG. NO: Y18PHD0112

DEPARTMENT OF PHARMACY PRACTICE,

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CHALAPATHI INSTITUTE OF PHARMACEUTICAL SCIENCES,

(AUTONOMOUS)

Accredited by NAAC with "A" Grade

CHALAPATHI NAGAR, LAM, GUNTUR.

CHALAPATHI

INSTITUTE OF PHARMACEUTICAL SCIENCES

(AUTONOMOUS)
(Affiliated to Acharya Nagarjuna University, Guntur, Approved by A.I.C.T.E., & PCI, New Delhi)
Accredited by NAAC with "A" Grade
I.S.O. 9001: 2008 CERTIFIED INSTITUTION

CERTIFICATE

Certified that this is the bonafide record of the Clerkship done by KorlagantaBhavanadevi Regd.No: Y18PHD0112 in the V/VI Pharm.D during the year 2022-2023 in the Department of Pharmacy Practice, Govt. General Hospital, Chalapathi Institute of Pharmaceutical Sciences, Lam, Guntur.

14/03/23
Department of Pharmacy Practice
IInd Floor, Out Patient Block
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Preceptor:- GUNTUR (Dt).

H.O.D: 14/03/2023

Head of the Department
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B-Class, IInd Floor, Inpatient Block
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GUNTUR-522 001

Examiners:-

1. External 9.5.2023

2. Internal 09/05/2023

CLERKSHIP REPORT

June 2022 to April 2023

V/VI Pharm.D

DOCTOR OF PHARMACY

Submitted by

Mr. KUMBHA ESWAR NARENDRA BABU

REG. NO: Y18PHD0113

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I.S.O. 9001: 2008 CERTIFIED INSTITUTION

CERTIFICATE

Certified that this is the bonafide record of the Clerkship done by KUMBHA.ESWARNARENDRA BABU Regd.No:Y18PHD0113 in the V/VI Pharm.D during the year 2022-23 in the Department of Pharmacy Practice, Govt. General Hospital, Chalapathi Institute of Pharmaceutical Sciences, Lam, Guntur.

Preceptor:-

Department of Pharmacy Practice
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HOD:

Examiners:-

1. External

2. Internal

Medicine Department
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CLERKSHIP REPORT

June 2022 to April 2023

V/VI Pharm.D

DOCTOR OF PHARMACY

Submitted by

Ms. MANNAVA. MITHRAVINDHYA SAI MEGHANA

REG. NO: Y18PHD0114

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CHALAPATHI NAGAR, LAM, GUNTUR.

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INSTITUTE OF PHARMACEUTICAL SCIENCES

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CERTIFICATE

Certified that this is the bonafide record of the Clerkship done by MANNAVA.MITHRAVINDHYASAIMEGHANA Regd .No:Y18PHD0114 in the V/VI Pharm.D during the year 2022-23 in the Department of Pharmacy Practice, Govt. General Hospital, Chalapathi Institute of Pharmaceutical Sciences, Lam,Guntur.

Preceptor:-

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HOD:

Examiners:-

1. External 9.05.2023

2. Internal 09/05/2023

11/03/2023

Head of the Department
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GUNTUR-522 001

CLERKSHIP REPORT

June 2022 to April 2023

V/VI Pharm.D

DOCTOR OF PHARMACY

Submitted by

Ms. MUNAGALA. TARANI

REG. NO: Y18PHD0115

DEPARTMENT OF PHARMACY PRACTICE,

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CERTIFICATE

Certified that this is the bonafide record of the Clerkship done by MUNAGALA TARANI Regd.No: Y18PHD0115 in the V/VI Pharm.D during the year 2022-2023 in the Department of Pharmacy Practice, Govt. General Hospital, Chalapathi Institute of Pharmaceutical Sciences, Lam, Guntur.

Preceptor:-

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GUNTUR

Head Of The Department:

17/03/2023

Head of the Department
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B-Class, IInd Floor, Inpatient Block
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Chalapathi Institute of Pharmaceutical Sciences
GUNTUR-522 001

Examiners:-

1. External

9-5-2023

2. Internal 9/5/2023

CLERKSHIP REPORT

June 2022 to April 2023

V/VI Pharm.D

DOCTOR OF PHARMACY

Submitted by

Ms. NALLAMEKALA. KEERTHI

REG. NO: Y18PHD0116

DEPARTMENT OF PHARMACY PRACTICE,

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INSTITUTE OF PHARMACEUTICAL SCIENCES

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CERTIFICATE

Certified that this is the bonafide record of the Clerkship done NALLAMEKALA.KEERTHI

Regd.No:Y18PHD0116 in the V/VI Pharm.D

during the year 2022-23 in the Department of Pharmacy Practice, Govt. General Hospital, Chalapathi Institute of Pharmaceutical Sciences, Lam, Guntur.

14/03/23

Preceptor:-

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Head of the Department:

Head of the Department
Department of Pharmacy Practice
B-Class, IInd Floor, Inpatient Block
Govt. General Hospital
Chalapathi Institute of Pharmaceutical Sciences
GUNTUR-522 001

Examiners :

1. External

9.5.2023

2. Internal

9/05/2023

CLERKSHIP REPORT

June 2022 to April 2023

V/VI Pharm.D

DOCTOR OF PHARMACY

Submitted by

Ms. NIZAMPATNAM MANJUSHA

REG. NO: Y18PHD0118

DEPARTMENT OF PHARMACY PRACTICE,

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Certified that this is the bonafide record of the Clerkship done by NIZAMPATNAM. MANJUSHA Regd.No:Y18PHD0118in the V/VIPharm.D during the y year 2022-23 in the Department of Pharmacy Practice, Govt. General Hospital, Chalapathi Institute of Pharmaceutical Sciences, Lam, Guntur.

Preceptor:-

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Head of the Department:

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GUNTUR-522 001

Examiners:-

9.5.2023.

1. External

9/5/2023

2. Internal

CLERKSHIP REPORT

June 2022 to April 2023

V/VI Pharm.D

DOCTOR OF PHARMACY

Submitted by

Ms. THRIVENI PAMISETTY

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DEPARTMENT OF PHARMACY PRACTICE,

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CERTIFICATE

Certified that this is the bonafide record of the Clerkship done by PAMISETTY.THRIVENI Regd.No: Y18PHD0119 in the V/VI Pharm.D during year 2022-23 in the Department of Pharmacy Practice, Govt. General Hospital, Chalapathi Institute of Pharmaceutical Sciences, Lam, Guntur.

Preceptor:

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GUNTUR-522 001

Examiners:-

1. External 9.5.2023.

2. Internal 09/05/2023

CLERKSHIP REPORT

June 2022 to April 2023

V/VI Pharm.D

DOCTOR OF PHARMACY

Submitted by

Mr. PENTELA TARUN SAI

REG. NO: Y18PHD0120

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GUNTUR-522 001

Examiners:-

8.5.2023

1. External

09/05/2023

2. Internal

CLERKSHIP REPORT

June 2022 to April 2023

V/VI Pharm.D

DOCTOR OF PHARMACY

Submitted by

Mr. PULI RAJ KUMAR

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INSTITUTE OF PHARMACEUTICAL SCIENCES

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CERTIFICATE

Certified that this is the bonafide record of the lerkship done by PULI.RAJKUMAR

egd.No:Y18PHD0121 in the V/VIPharm.D during the ear 2022-23 in the Department of Pharmacy Practice, Govt. eneral Hospital, Chalapathi Institute of Pharmaceutical iences, Lam, Guntur.

eceptor:-

Department of Pharmacy Practice
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ad of the Department:

Head of the Department
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GUNTUR-522 001

Examiners:-

1. External

9.5.2023

2. Internal

09/05/2023

CLERKSHIP REPORT

June 2022 to April 2023

V/VI Pharm.D

DOCTOR OF PHARMACY

Submitted by

Ms. RUDRAPOGU.PRIYANKA

REG. NO: Y18PHD0122

DEPARTMENT OF PHARMACY PRACTICE,

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INSTITUTE OF PHARMACEUTICAL SCIENCES

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I.S.O. 9001: 2008 CERTIFIED INSTITUTION

CERTIFICATE

Certified that this is the bonafide record of the Clerkship done by Rudrapogu. Priyanka Regd.No: Y18PHD0122 in the V/VI Pharm.D during the year 2022-2023 in the Department of Pharmacy Practice, Govt. General Hospital, Chalapathi Institute of Pharmaceutical Sciences, Lam,Guntur.

Preceptor:-

Department of Pharmacy Practice
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HOD:

14/03/2023

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GUNTUR-522 001

Examiners:-

1. External

9.5.2023.

2. Internal

09/05/2023

CLERKSHIP REPORT

June 2022 to April 2023

V/VI Pharm.D

DOCTOR OF PHARMACY

Submitted by

Ms. SHAIK.AMEENA AYESHA

REG. NO: Y18PHD0123

DEPARTMENT OF PHARMACY PRACTICE,

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Certified that this is the bonafide record of the Clerkship done by SHAIK.AMEENAAYESHA Regd. No:Y18PHD0123 in the V/VI Pharm.D during the year 2022-23 in the Department of Pharmacy Practice, Govt. General Hospital, Chalapathi Institute of Pharmaceutical Sciences, Lam, Guntur.

14/03/2023

Department of Pharmacy Practice
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Preceptor:-

14/03/2023

Head of the Department
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GUNTUR-522 001

HOD:

Examiners:-

9.5.2023.

1. External

09/05/2023

2. Internal

CLERKSHIP REPORT

June 2022 to April 2023

V/VI Pharm.D

DOCTOR OF PHARMACY

Submitted by

Mr. SHAIK BAJI RAHAMTULLA

REG. NO: Y18PHD0124

DEPARTMENT OF PHARMACY PRACTICE,

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CHALAPATHI INSTITUTE OF PHARMACEUTICAL SCIENCES,

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CHALAPATHI

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(Affiliated to Acharya Nagarjuna University, Guntur, Approved by A.I.C.T.E., & PCI, New Delhi)

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I.S.O. 9001: 2008 CERTIFIED INSTITUTION

CERTIFICATE

Certified that this is the bonafide record of the Clerkship done by ***SHAIK.BAJIRAHAMTULLA*** *Regd. No:Y18PHD0124 in the V/VI Pharm.D during the year 2022-23 in the Department of Pharmacy Practice, Govt. General Hospital, Chalapathi Institute of Pharmaceutical Sciences, Lam, Guntur.*

Preceptor:- 15/3/23

Department of Pharmacy Practice
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HOD:- 14/03/2023

Head of the Department
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GUNTUR-522 001

Examiners:-

1. External 9.5.2023

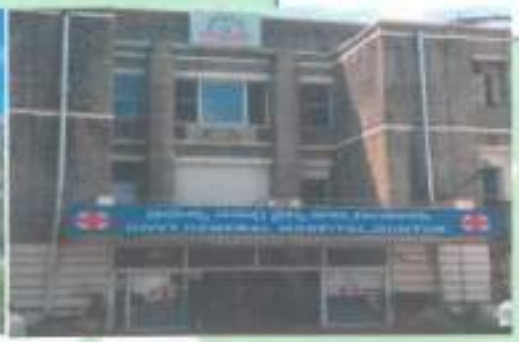
2. Internal 09/05/2023

CLERKSHIP REPORT

June 2022 to April 2023

V/VI Pharm.D

DOCTOR OF PHARMACY



Submitted by

Ms. THAMANAMPALLI PRATHYUSHA

REG. NO: Y18PHD0126

DEPARTMENT OF PHARMACY PRACTICE,

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CHALAPATHI NAGAR, LAM, GUNTUR.

CHALAPATHI

INSTITUTE OF PHARMACEUTICAL SCIENCES

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I.S.O. 9001: 2008 CERTIFIED INSTITUTION

CERTIFICATE

Certified that this is the bonafide record of the Clerkship donebyTHAMANAMPALLIPRATHYUSHA Regd.No:Y18PHD0106 in the V/VI Pharm.D during the year 2022-2023 in the Department of Pharmacy Practice, Govt. General Hospital, Chalapathi Institute of Pharmaceutical Sciences, Lam, Guntur.

Preceptor:-

Department of Pharmacy Practice
IInd Floor, Out Patient Block
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GUNTUR

Head of the Department :

14/03/2023

Head of the Department
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B-Class, IInd Floor, Inpatient Block
Govt. General Hospital
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GUNTUR-522 001

Examiners:-

9.5.2023

1. External

2. Internal

CLERKSHIP REPORT

June 2022 to April 2023

V/VI Pharm.D

DOCTOR OF PHARMACY

Submitted by

Mr. THOTA PRUDVI

REG. NO: Y18PHD0127

DEPARTMENT OF PHARMACY PRACTICE,

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CHALAPATHI INSTITUTE OF PHARMACEUTICAL SCIENCES,

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INSTITUTE OF PHARMACEUTICAL SCIENCES

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I.S.O. 9001: 2008 CERTIFIED INSTITUTION

CERTIFICATE

Certified that this is the bonafide record of the Clerkship done by THOTA.PRUDVI Regd.No:Y18PHD 0127 in the V/VI Pharm.D during the year 2022-23 in the Department of Pharmacy Practice, Govt. General Hospital, Chalapathi Institute of Pharmaceutical Sciences, Lam,Guntur.

Preceptor:- 15/5/23

Department of Pharmacy Practice
2nd Floor, Out Patient Block
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GUNTUR - 522 001.

HOD: 11/05/2023

Head of the Department
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GUNTUR-522 001

Examiners:-

1. External 9.5.2023

2. Internal 9/5/2023

CLERKSHIP REPORT

June 2022 to April 2023

V/VI Pharm.D

DOCTOR OF PHARMACY

Submitted by

Mr. TIRUPATIMAHANTI VENKATESH

REG. NO: Y18PHD0128

DEPARTMENT OF PHARMACY PRACTICE,

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CHALAPATHI INSTITUTE OF PHARMACEUTICAL SCIENCES,

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CHALAPATHI NAGAR, LAM, GUNTUR.

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INSTITUTE OF PHARMACEUTICAL SCIENCES

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CERTIFICATE

Certified that this is the bonafide record of the Clerkship done by TIRUPATIMAHANTI. VENKATESH Regd.No:Y18PHD0128 in the V/VI Pharm.D during the year 2022-23 in the Department of Pharmacy Practice, Govt. General Hospital, Chalapathi Institute of Pharmaceutical Sciences, Lam, Guntur.

14/05/23

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14/03/2023

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GUNTUR-522 001

Examiners:-

9.05.2023

1. External

09/05/2023

2. Internal

CLERKSHIP REPORT

June 2022 to April 2023

V/VI Pharm.D

DOCTOR OF PHARMACY

Submitted by

Ms. VAJINEPALLI ALEKHYA

REG. NO: Y18PHD0129

DEPARTMENT OF PHARMACY PRACTICE,

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CHALAPATHI NAGAR, LAM, GUNTUR.

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14/03/2023

Department of Pharmacy Practice
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Preceptor:-

HOD:

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GUNTUR-522 001

Examiners:-

9.5.2023

1. External

10/05/2023

2. Internal

CLERKSHIP REPORT

June 2022 to April 2023

V/VI Pharm.D

DOCTOR OF PHARMACY

Submitted by

Ms. YARRAMREDDY KRISHNAVENI

REG. NO: Y18PHD0130

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CERTIFICATE

Certified that this is the bonafide record of the Clerkship done by YARRAMREDDY.KRISHNAVENI Regd.No: Y18PHDO130 in the V/VI Pharm.D during the year 2022-23 in the Department of Pharmacy Practice, Govt. General Hospital, Chalapathi Institute of Pharmaceutical Sciences, Lam, Guntur.

Preceptor:- 5/3/23

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GUNTUR-522 001

Examiners:-

1. External 9.05.2023

2. Internal 09/05/2023

FORMULATION AND EVALUATION OF FAST DISOLVING FILM OF ANTI HYPERTENSIVE DRUG

Thesis submitted to

CHALAPATHI INSTITUTE OF PHARMACEUTICAL SCIENCES, LAM, GUNTUR

In partial fulfillment of the Requirements for the award of the degree of

MASTER OF PHARMACY

(PHARMACEUTICS)

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Under the guidance of

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Abstract

Atenolol is a beta-blocker drug predominantly utilized for the management of hypertension and angina pectoris. This research aimed to develop a fast-dissolving film containing Atenolol for hypertension treatment, utilizing varying amounts of polymers such as Polyvinyl Alcohol (PVA) and Ethyl Cellulose (EC). Films of Atenolol were fabricated by the solvent casting method utilizing polymers such as PVA and ethyl cellulose in various proportions. Glycerin was utilized as a plasticizer. Films underwent physicochemical characterization, including assessments of thickness, weight uniformity, folding durability, drug content, surface pH, *in vitro* drug release, and stability investigations. Films were deemed satisfactory based on assessments of thickness, weight uniformity, *in vitro* drug release, folding durability, drug content, and disintegration time. The surface pH of all the films was determined to be neutral. The *in vitro* drug release in the optimized formulation F8 was determined to be 78.62% within 4 minutes. The optimized formulation F8 demonstrated an acceptable pH, drug content (97.12%), disintegration time of 24 seconds, effective in vitro drug release (98.99% in 10 minutes), and satisfactory stability.

Keywords: Anti-hypertensive drug, FDF, Solvent casting technique, *in vitro* drug release

FORMULATION AND EVALUATION OF MICROSPONGE GEL FOR TOPICAL DELIVERY

Thesis submitted to

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Abstract

The aim of this study is to develop metronidazole microsponges and incorporate them into a gel formulation. Metronidazole is a highly recommended antibiotic for treating anaerobic infections. The microsponges were developed, evaluated, and optimized using a 3^2 factorial design. The optimized formulation, F10 had a drug release rate of 93.77%. The gel formulation for topical treatment was developed by incorporating optimized microsponge formulation F10 into a gel formulation. The gel formulation was created and assessed for physical parameters such as pH, spreadability, viscosity, drug content, and *in vitro* diffusion testing. The results indicated that the microsponge gel formulation exhibited a continuous and controlled release of metronidazole for a period of 12 hours. The drug release data was assessed using various kinetic models, revealing that the drug release from the gel formulation adheres to a zero-order release pattern. The devloped microsponge gel is expected to have a longer duration of action on the skin compared to existing formulations. It will release its contents gradually over time. Hence, the metronidazole microsponges and microsponge gel devised in this study exhibit great potential in surpassing conventional formulations for the management of bacterial infections.

Keywords: microsponges, factorial design, controlled release, bacterial infections

DEVELOPEMENT OF AN ANNONA SQUAMOSA BASED TOPICAL GEL FOR THE TREATMENT OF PSORIASIS

Thesis submitted to

CHALAPATHI INSTITUTE OF PHARMACEUTICAL SCIENCES, LAM, GUNTUR

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ABSTRACT:

Aim: This study set out to develop and asses a topical gel that would be used to treat psoriasis, using *Annona squamosa* extract as the active component for the treatment of psoriasis.

Method: Annona *squamosa* as the active ingredient, while Carbopol 940 was served as the basis. The produced gel was characterized by physical-chemical properties, *in-vitro* diffusion experiments, quantitative analysis, spreadability, pH, viscosity, and preliminary phytochemical analysis. Studies on the healing of wounds were conducted using the improved formulation (F10). The Soxhlet extraction method was used to get *Annona squamosa* extract, which was then added to the gel formulation. The gel's spreadability, viscosity, and *in-vitro* diffusion were all found to be within acceptable bounds by the results. When compared to a gel that is currently on the market, the improved formulation F10 proved to be more effective. The results of this investigation point to the possibility of topical Annona squamosa gel as a potentially effective therapy option for psoriasis.

Conclusion: The results of this investigation point to the possibility of topical Annona squamosa gel as a potentially effective therapy option for psoriasis.

Key points: Annona squamosa, Carbapol-940, Viscosity, Spreadability.

FORMULATION AND EVALUATION OF NIOSOMAL GEL CONTAINING ACYCLOVIR BY USING DoE

Thesis submitted to

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ABSTRACT

The aim of present research work is to formulate, optimize and assess the niosomal gel containing acyclovir for topical application. Compatibility analysis was conducted to evaluate potential interactions, using techniques such as FT-IR spectroscopy and DSC thermal analysis. Acyclovir niosomal suspension was prepared by thin film hydration method using 3^2 factorial design. Nine distinct formulations were formulated using varied non-ionic surfactant (tween 80) and lipid (cholesterol) concentrations as the two primary independent variables. particle size, Zeta potential and *in vitro* drug release are the dependent variables. All the nine formulations were assessed for particle size, zeta potential and *in vitro* drug release. According to overlay plot F3 formulation was optimized with tween 80 and cholesterol ratio of 300:20 resulting in a particle size of 110.8, zeta potential of -24.2, entrapment efficiency of 81.53% and *in vitro* drug release of 83.94% after 24 hours. The optimized niosomal suspension was incorporated in to carbopol base gel. pH, viscosity, spreadability and *in vitro* drug release of the acyclovir niosomal gel (F3) were assessed. Acyclovir niosomal gel with a pH value 5.6, viscosity and spreadability of 3721cps &7.4g.cm/sec respectively. drug content was found to be 80.56% and % drug release of 82.73% for F3. stability studies were performed and the results demonstrated good stability of the niosomal gel.

Keywords: Acyclovir, Tween 80, Cholesterol, factorial design, *in vitro* drug release.

OPTIMIZATION AND EVALUATION OF TOPICAL GEL CONTAINING SOLID LIPID NANOPARTICLES LOADED WITH LULICONAZOLE

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Abstract:

New topical pharmaceutical options are critically needed for the treatment of fungal infections for prolonged therapeutic action. Luliconazole is a topical antifungal medicine for the treatment of fungal infection but bioavailability barriers of luliconazole approached to develop effective topical luliconazole solid lipid nanoparticles (SLN) gel formulation with prolonged therapeutic potential against tropical fungal infection.SLN of luliconazole was prepared by the solvent diffusion method using stearic acid & poloxamer 188. The preformulation studies were conducted for the authenticity of the leading moiety. Thereafter, the prepared SLN followed by gel formulations were subjected to physicochemical evaluation, *in-vitro* release profile of drug with kinetics studies. Thereafter, FTIR spectroscopy and scanning electron microscopy of the optimized formulation was done successfully. The results reveal that SLN F6 shows a significant entrapment efficacy with the highest entrapment of 92.13%±0.975. In particle size, size distribution and zeta potential analysis, SLN exhibit a mean particle diameter of ~344.3 nm, with unimodal size distribution, a polydispersity index of 0.168, intercept value 0.98 with 92% peak intensity and zeta potential -18.8 mV. Further, G3 gel shows a higher entrapment efficacy with 91.39%±0.187 as compared to other formulation. The *in-vitro* drug release profile of the G3 gel with 1.5 % carbopol 934 w/v shows a sustained release profile with 79.57%±0.213 of the drug release even after 24 hrs of the time. It is concluded that the Luliconazole loaded SLN based gel formulation containing carbopol 934 1.5% w/v is suitable for topical application and may show a much better result of anti-fungal activity.

Key words: Solid lipid nanoparticles loaded Gel, Drug Content, pH of the Gel, In-vitro drug release study

DEVELOPMENT OF INTRANASAL NANOCERIA FORMULATION FOR THE MANAGEMENT OF ALZHEIMER'S DISEASE

Thesis submitted to

CHALAPATHI INSTITUTE OF PHARMACEUTICAL SCIENCES, LAM, GUNTUR

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ABSTRACT

Cerium oxide nanoparticles (CNPs), owing to their antioxidant property, have recently emerged as therapeutic candidate for Alzheimer's disease (AD). However, intravenous CNPs is limited due to its poor physico-chemical properties, rapid blood clearance and poor blood brain penetration. Intranasal CNPs were developed and evaluated for its potential in experimental AD. CNPs were synthesized by homogenous precipitation method and optimized through Box–Behnken Design. The formation of CNPs was confirmed by UV spectroscopy and FTIR. The optimized CNP were spherical, small (134.0±3.35nm), uniform (PDI, 0.158±0.0019) and stable (ZP, -21.8± 4.94 mV). The presence of Ce in CNPs was confirmed by energy-dispersive X-ray analysis. Further, the X-ray diffraction spectra revealed that the CNPs were Nano-crystalline. The DPPH assay showed that at concentration of 50 µg/mL, the percentage radical scavenging was 95.40±0.006%. Results of the *in-vivo* behavioral studies in scopolamine-induced Alzheimer rat model showed that intranasal CNPs dose dependently reversed the cognitive ability. At a dose of 6 mg/kg the Morris water maze results (escape latency, path length and dwell time) and passive avoidance results (retention latency) were significantly different from untreated group but not significantly different from positive control group (Rivastigmine patch, 13.3 mg/24h). Further, biochemical estimation showed that intranasal CNP up regulated the levels of SOD (Superoxide dismutase) and GSH (Glutathione) in brain. In conclusion, intranasal CNPs, through its antioxidant effect, could be a prospective therapeutics for the treatment of cognitive impairment in AD.

Keywords: Biochemical estimation, Morris water maze test, Nose to brain, Passive avoidance test, Rivastigmine.

FORMULATION AND EVALUATION OF SUBLINGUAL TABLETS USING FENUGREEK SEED POWDER AS A SUPERDISINTEGRANT

Thesis submitted to

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Abstract

Objective: The aim of the study is to formulate and evaluate hydralazine fast dissolving sublingual tablets using fenugreek seed powder as super disintegrants by direct compression method. Design of experiment was used to optimize the formulation. The tablets that were manufactured exhibited mechanical strength and good flow characteristics. A design expert presented the optimized formulation F10 for sublingual tablets containing 65 mg of fenugreek seed powder and 25 mg of sodium starch glycolate. It was discovered that the formulation F10 complied with the IP standards in terms of weight variation with crown diameter of 8 mm. The hardness and percentage friability was 4.34±0.38 kg/cm^2 and 0.77% respectively. The wetting time for formulation F10 was 28±1.0 seconds. The percentage drug content of formulation F10 was found to 95.51±0.57%w/w. The *in-vitro* disintegration time for the formulation F10 was 57±0.58 seconds. The amount of drug released from formulation F10 at end of 14 min was 94.12±0.13%. Peppas model was the best fit model for formulation F10, with n = 0.37 and indicating a fickian diffusion drug release mechanism. The results of hydralazine sublingual tablets showed it as a potential candidate for usage as a substitute for parenteral treatment in the fast control of hypertension.

Keywords: Fenugreek seed powder, sublingual tablet, design expert, fickian diffusion

Formulation And Evaluation of Fast Dissolving Tablets (FDT's) Containing Methanolic Leaf Extract of *Psidium guajava Linn.* Evincing Anti Hyperglycemic Activity

Dissertation submitted to

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(Autonomous)

In the partial fulfillment of the requirements for the award of the degree in

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This is to certify that the dissertation work entitled "Formulation and Evaluation of Fast Dissolving Tablets (FDT's) Containing Methanolic Leaf Extract of *Psidium guajava Linn.* Evincing Anti Hyperglycemic Activity" *is a bonafied research work done by* ***P.SUDHEER KUMAR(Y22MPHPC408)*** *and submitted in partial fulfillment of the requirements for the award of the degree of MASTER OF PHARMACY in* **Pharmaceutics** *was carried out by the candidate in the laboratories of CHALAPATHI INSTITUTE OF PHARMACEUTICAL SCIENCES, LAM, GUNTUR and was evaluated by us during the academic year 2023-2024.*

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ABSTRACT

Psidium guajava Linn., a medicinal plant familiar with Ayurvedic medicine and found worldwide, has leaves rich in phytochemicals. These compounds have demonstrated various beneficial effects, including anticancer, antioxidant, anti-diarrhea, antimicrobial, anti-obesity, lipid-lowering, hepatoprotective, and anti-hyperglycaemic properties. This research aimed to create fast-dissolving tablets using methanolic leaf extracts of Psidium guajava, which have demonstrated anti-hyperglycaemic activity by inhibiting enzymes for instance α-Amylase and α-glucosidase. The tests for identification and in vitro anti-hyperglycaemic activity were positive. FTIR and DSC analyses confirmed the compatibility of the leaf extract and excipients. Fast-dissolving tablets were chosen as the formulation method to improve the bioactivity of the extract, given the typically low bioavailability of herbal formulations. The formulas were optimized using Design Expert 10.0 software and 3^2 factorial designs. This design aimed to study the effects of the independent variables Crospovidone (X1) and Micro Crystalline Cellulose (X2), in combination. Three responses - disintegration time (Y1), % drug release (Y2), and friability (Y3) - were evaluated in this design, and experimental trials were conducted for all nine formulations. All formulations underwent pre-compression and post-compression studies. The optimal formulation, C1, was identified by the model, with characteristics of 0.52±0.010 seconds for friability, 93.8±0.014 % for drug release, and 38±1.0 seconds for disintegration time.

Key words: Psidium guajava Linn., Fast dissolving Tablets, Anti-Hyperglycemic Activity, Crospovidone, Microcrystalline cellulose, Disintegration time.

PREPARATION AND EVALUATION OF MORINDA CITRIFOLIA EXTRACT PELLETS BY EXTRUSION AND SPHERONIZATION

Thesis submitted to

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ABSTRACT

ABSTRACT

The present study aims to formulate hygroscopic dry powder of *Morinda Citrifolia* extract in to pellets by extrusion and spheronization method using DoE software 2^3 factorial design. Nine different formulations were prepared by varying the concentration of PVP, MCC, and Lactose. PVP, MCC, lactose are the independent variables. The independent variable shows effect on formation of pellets were evaluated to develop an optimized formula. The effect of three independent variables on the drug content, friability, and invitro drug release was evaluated to develop an optimized formulation. All formulations were evaluated by pre-formulation, post-formulation parameters and dissolution studies. The F8 formulation with polymers and binder in the ratio of 5:1:0.25with 91.29drug release showed better results. From overlay plot the f8 formulation was optimized and developed in to F9. F9 formulation was found to be best with drug content of 96.73mg, friability of 0.2, and %drug release of 74.1% respectively. Stability studies were performed and showed good stability study.

Key words: Hygroscopic, *Morinda Citrifolia*, factorial design, *in vitro* dissolution, DOE, extrusion and spheronization.

OPTIMIZING TRANSDERMAL PATCH FORMULATION FOR ENHANCED DELIVERY OF RIVAROXABAN: A COMPREHENSIVE DESIGN OF EXPERIMENTS APPROACH

Thesis submitted to

CHALAPATHI INSTITUTE OF PHARMACEUTICAL SCIENCES, LAM, GUNTUR

In partial fulfillment of the requirements

for theaward of the degree of

MASTER OF PHARMACY IN PHARMACEUTICS

Submitted by

P.V.L.N.Priyanka

(Y22MPHPC410)

Under the guidance of

Prof. Rama Rao Nadendla, M. Pharm.,Ph.D.,F.I.C.,

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This is to certify that the dissertation work entitled "OPTIMIZING TRANSDERMAL PATCH FORMULATION FOR ENHANCED DELIVERY OF RIVAROXABAN: A COMPREHENSIVE DESIGN OF EXPERIMENTS APPROACH" a bonafide research work done by ***P.V.L.N.PRIYANKA (Y22MPHPC410)*** *and submitted in partial 4ulfillment of the requirements for the award of the degree of MASTER OF PHARMACY in* ***Pharmaceutics*** *was carried out by the candidate in the laboratories of CHALAPATHI INSTITUTE OF PHARMACEUTICAL SCIENCES, LAM, GUNTUR and was evaluated by us during the academic year 2023-2024.*

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ABSTRACT

The current research project endeavors to innovate by developing and assessing Rivaroxaban transdermal patches. These patches were meticulously crafted in the study using a combination of HPMC E50, PVP K30, and Propylene glycol across eight distinct formulations. Through comprehensive analysis including FTIR and DSC, it was confirmed the absence of any incompatibilities within the drug and physical mixtures. Employing a 2^3 factorial design to the formulations, it was discerned that the F9 formulation, identified through Design Expert software, emerged as the optimized configuration. Subsequent evaluation encompassed critical parameters such as thickness, folding endurance, *in vitro* diffusion studies, kinetics, percentage drug content, percentage moisture uptake and percentage moisture loss. The optimized formulation exhibited a thickness of 0.2913mm, folding endurance of 91, percentage drug content of 94.26%, percentage moisture uptake of 22.31% and percentage moisture loss of 1.04%. Notably, *in vitro* diffusion studies showcased an impressive 94.58% drug release at the 24th hour. In summation, the study underscores the enhanced efficacy of transdermal patch formulation, characterized by substantial improvements in *in vitro* drug release kinetics, predominantly driven by Fickian diffusion mechanisms.

Keywords: Rivaroxaban, Transdermal patches, Factorial design, *in vitro* drug release.

Inhibitory Effect of Lozenges Containing Xylitol Against Streptococcus mutans

Thesis submitted to

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ABSTRACT:

Streptococcus mutans is considered a major contributor to the development of dental caries and increased risk of developing dental caries later in life. The principal objective of this research is to design and develop xylitol lozenges that treat dental caries. Xylitol plays a major role in treating dental caries that act against Streptococcus mutans at different stages. The compatibility studies were performed using FT-IR and determining the MICs using the broth dilution method aids in the selection of the best formulation to reduce dental caries recurrence. In MIC 2% concentration of xylitol shows 66 % reduction of streptococcus mutans. Lozenges of varying concentrations were developed using corn syrup and tests were performed on the developed formulations. An anti-microbial assay was performed on the optimized formulation, and the largest inhibitory zone against microorganisms was observed. Based on the findings of this study, it can be hypothesized that the developed formulation was active at lower concentrations and prolonged release by *in-vitro* drug release studies which reduce dental carics.

KEYWORDS: Xylitol, Lozenges, Streptococcus mutans, MIC, *In vitro* drug release.

METHOD DEVELOPMENT AND SIMULTANEOUS ESTIMATION OF TRANEXAMIC ACID AND ETHAMSYLATE IN BULK AND PHARMACEUTICAL DOSAGE FORMS USING RP-HPLC METHOD

Dissertation submitted to

CHALAPATHI INSTITUTE OF PHARMACEUTICAL SCIENCES, LAM, GUNTUR

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ABSTARCT

A reversed-phase high-performance liquid chromatography method is developed and validated for the determination of tranexamic acid Ethamsylate in bulk drug and marketed dosage forms. The chromatographic determination was performed on Shimadzu Lab solutions with a variable wavelength detector. The separation was conducted using thermoscientific Hypersil BDS (150 mm x 5 mm) with a mobile phase consisting of phosphate buffer: acetonitrile (80:20, %v/v) ratio. The mobile phase was delivered at a flow rate of 1.0 mL/min. The eluents were monitored at wavelength 280 nm and found sharp and symmetrical peaks with retention times of 3.27 and 4.27 min. The method was validated for linearity, accuracy, precision, and system suitability. The method was found to be linear over the concentration range 10-30µg/mL, 10-30µg/ml, with regression 0.999. The percentage recoveries for Tranexamic acid and Ethamsylate were found to be in the range of 100.41% and100.31 %, respectively. The developed HPLC technique is precise, specific, accurate, and stable. Hence, this study proves that the method is reproducible, selective, and suitable to be applied for the analysis of tranexamic acid Ethamsylate in commercial pharmaceutical dosage form for quality control applications.

Keywords: Tranexamic acid, Ethamsylate RP-HPLC,

METHOD DEVELOPMENT AND SIMULTANEOUS ESTIMATION OF SIMETHICONE AND LOPERAMIDE IN BULK AND PHARMACEUTICALDOSAGE FORMS INRP-HPLCMETHOD

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ABSTRACT

A simple, sensitive, specific, and accurate RP-HPLC method was developed for the simultaneous estimation of Simethicone and Loperamide HCl in a pharmaceutical dosage form. The RP-HPLC separation was achieved on a primisil C_{18} (250 mm x 4.6 mm, 5µm) column and isocratic elution. The mobile phase was composed of phosphate buffer: methanol (80:20 v/v) at a flow rate of 1 ml/min. The chromatographic determination was performed on Shimadzu LC solution software with a PDA detector with a wavelength of 230 nm. The run time is 7 minutes. The retention times of Simethicone and Loperamide HCl were found to be 4.663 min and 5.987 mins respectively. Linearity was established for Simethicone and Loperamide HCl in the range of 80 ng/ml and 400 ng/ml, respectively. System precision and method precision were found to be within the limits of the acceptance criteria. The relative standard deviation of Loperamide HCl and Simethicone for system precision was found to be and respectively, and method precision was found to be validated respectively. The percentage recoveries for Simethicone and Loperamide HCl were found to be in the range of 99.80% and 99.71%, respectively.

Keywords: TFA, RP-HPLC, LOD, LOQ, Method validation

INTRODUCTION

A VALIDATED RP-HPLC METHOD FOR SIMULTANEOUSESTIMATION OF REPAGLINIDE AND VOGLIBOSE INPHARMACEUTICALAPPLICATION

Dissertation submitted to

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ABSTRACT

A validated RP-HPLC method was developed and validated for the simultaneous estimation of Repaglinide and Voglibose HPLC method was developed in reverse phase mode using Acetonitrile, methanol and Phosphate buffer as mobile phase in the ratio of 40:20:40 (v/v/v) over HYPERSIL BDS column (250×4.6mm, 5µm) at a volumetric rate1mL/min and Quantitation was achieved with PDA detector at 219nm and elution time was identified to be 3.522 min and 4.066 min for Repaglinideand Voglibose respectively. According to ICH guidelines the developed method was validated. The linearity was considered to be in the range of 1-5 µg/mL and 1 – 5 µg/mL with correlation coefficient of 0.9999 and 1 for REP and VOG respectively. The developed method is validated and the peaks were more resolved when compared to the previous literatures with reduced run time. The %RSD of REP and VOG were 1.30and1.06. There gression coefficient of Repaglinide and Voglibose were y = 193560x + 812.43andy = 282738x + 985.1 respectively. The mean recovery was considered to be 99.80 and 100.54% of REP and VOG respectively. Method was precise and robust with a % RSD NMT 2. Hence the developed RP-HPLC method was assessed to be specific and can be used for convention an analysis and academics also this expedite as an analogous method for synchronous estimation of drugs Repaglinide and Voglibose in marketed formulation since there was no co-elution of peak with the drug.

KEY WORDS: Anti-diabetic, Repaglinide, Voglibose, RP-HPLC, ICH

METHOD DEVELOPMENT AND SIMULTANEOUS ESTIMATION OF CADMIUM CONTENT IN OLOPATADINE HYDROCHLORIDE OPHTHALMIC SOLUTION USP 0.1% V/W PHARMACEUTICAL DOSAGE FORM BY USING ICP-MS METHOD

Dissertation submitted to

CHALAPATHI INSTITUTE OF PHARMACEUTICAL SCIENCES, LAM, GUNTUR

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for the award of the degree of

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ABSTRACT

A simple, sensitive, specific, and accurate ICPMS method was developed for the simultaneous estimation of cadmium content in Olopatadine Hydrochloride Ophthalmic solution USP 0.1% w/v in a pharmaceutical dosage form. This was achieved on ICP-MS Agilent -7800. The analytical determination was performed on Agilent Technologies mass hunter software with a Electron multiplier (EM) detector. Linearity was established for cadmium element correlation coefficient (r) of calibration curve ≥0.99. System precision and method precision were found to be within the limits of the acceptance criteria. The relative standard deviation of Olopatadine Hydrochloride Ophthalmic solution USP 0.1% w/v for system precision was found to be and respectively, and method precision was found to be validated respectively. The mean percentage recoveries values for Olopatadine Hydrochloride Ophthalmic solution USP 0.1% w/v were found to be in the range of 70.0% and 150.0%.

Keywords: EM, ICPMS, LOD, LOQ, Method validation

EVALUATION OF NOOTROPIC ACTIVITY OF METHANOLIC EXTRACT OF *LEPIDIUM MEYENII* LEAVES ON MICE

Dissertation submitted to

CHALAPATHI INSTISTUTE OF PHARMACEUTICAL SCIENCES

(Autonomous)

In the partial fulfillment of the requirements for the award of the degree of

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ABSTRACT

The present study aimed to evaluate the nootropic activity of *Lepidium meyenii* using its aqueous and methanolic extracts. The cognitive effects of these extracts were assessed using the Y-Maze, Morris Water Maze, and Hebb-Williams Maze, focusing on memory enhancement. Latency scores were used as evaluation parameters in the Y-Maze and Hebb-Williams Maze, while the time taken to reach the hidden platform was measured in the Morris Water Maze. Scopolamine was used to induce dementia in experimental animals, and Donepezil served as the standard drug for comparison.

The results indicated that the test treatment groups receiving *Lepidium meyenii* extracts significantly improved cognitive performance, with latency scores and time to reach the platform comparable to the Donepezil group. The memory enhancement observed is attributed to the inhibition of the acetylcholinesterase enzyme, resulting in increased acetylcholine levels, similar to the action of Donepezil. These findings suggest that *Lepidium meyenii* may have potential as a natural alternative for improving memory and managing cognitive impairments.

Keywords: Scopolamine induced dementia, hebbs William Maze, Y maze, Cognitive impairment, *Lepedium meyenii*, Donepezil.

EVALUATION OF ANTI DEPRESSANT ACTIVITY OF ETHANOLIC EXTRACT OF *ANNONA RETICULATA* SEEDS ON ALBINO MOUSE

Dissertation submitted to

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EVALUATION OF ANTI DEPRESSANT ACTIVITY OF ETHANOLIC EXTRACT OF *ANNONA RETICULATA* SEEDS IN ALBINO MOUSE

ABSTRACT

Objective:

- The objective of the present study is to prepare ethanolic seed extraction of *Annona Reticulate linn* by maceration technique and analyze them for the presence of phytochemicals.
- To evaluate the anti- depressant activity of Ethanolic seed extract of *Annona Reticulata Linn* in mouce by using Forced swim test and Open field test and Marble burying test.

Methodology:

The following animal models were used in the preclinical testing of the standardized ethanolic extract of seeds of *Annona Reticulata Linn* for antidepressant activity:

- Open Field TEST(OFT)
- Forced Swim Test (FST)
- Marble burying Test (MBT)

Results:

Using OFT, FST, MBT the ethanolic extract of *Annona Reticulata Linn* seeds demonstrated notable antidepressant action in mice. The time spent and the number of entries in the central compartment (OFT) and the immobility time (FST) and number of marbles buried (MBT) are among the numerous factors that have been drastically changed.

Keywords:

Antidepressant activity, *Annona Reticulata Linn*, Open filed test (OFT), Forced swim test (FST) and Marble Burying Test (MBT)

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FIRST LINE ANTI-TUBERCULOSIS TREATMENT INDUCED JAUNDICE AND ASSOCIATED LIVER DISEASE- A CLINICAL STUDY

Dissertation submitted to

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This is to certify that dissertation work entitled **"FIRST LINE ANTI-TUBERCULOSIS TREATMENT INDUCED JAUNDICE AND ASSOCIATED LIVER DISEASE: A CLINICAL STUDY"** was carried out by **BALLA HEMA SAI NAGA SUDHEESHNA (Y22MPHPY443)** is a bonafide work done in Department of Pharmacology, Chalapathi institute of pharmaceutical sciences, Guntur, for the award of degree in **MASTER OF PHARMACY in PHARMACOLOGY** and was evaluated by us during the academic year 2023-24.

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ABSTRACT:

Aim: To study the jaundice and associated liver disease among patients treated with first-line anti-tuberculosis treatment.

Objective: To determine the incidence of jaundice and liver disease in TB patients treated with first-line anti-TB drugs.

Methodology: Between February 2024 and July 2024, 138 TB patients aged 18 to 80 were screened, and 72 met the study criteria. Socio-demographic data were collected via a semi-structured questionnaire before starting anti-TB treatment. Patients were followed up regularly, with bi-weekly blood samples analysed for liver function markers such as AST, ALT, APT, and bilirubin levels. Management of hepatotoxicity involved discontinuing the offending drugs, initiating liver-protective medications, and monitoring recovery. Statistical analysis, performed using Excel, included calculating means, standard deviations, and percentages, with the chi-square test used to assess the significance of risk factors associated with hepatotoxicity.

Discussion: In this study, 11.11% of the 72 TB patients developed drug-induced hepatotoxicity, underscoring a significant challenge in treatment management. The most frequent symptoms were nausea and fatigue (87.5%), abdominal pain (75%), and vomiting (62.5%), with jaundice and loss of appetite being less common (12.5% and 50%, respectively). Hepatotoxicity severity ranged from mild in six patients, moderate in two, to severe in one. Age and gender showed no significant correlation with hepatotoxicity. Management involved discontinuing the offending drugs and rechallenging patients with the full anti-TB regimen for patients diagnosed with grade 1 and grade 2 hepatotoxicity and for grade 3 grade 4 hepatotoxicity safer individual drugs are used. This highlights the necessity for improved strategies to prevent and manage hepatotoxicity, emphasizing continuous monitoring and personalized treatment adjustments to ensure patient safety and effective therapy.

Key words: Drug induced liver injury Chi-square test, Means, Standard deviation, Percentage.

EVALUATION OF NOOTROPIC ACTIVITY OF ETHANOLIC EXTRACT OF *EUPHORBIA CYATHOPHORA* STEMS ON MICE.

Dissertation submitted to

CHALAPATHI INSTITUTE OF PHARMACEUTICAL SCIENCES
LAM, GUNTUR

In the partial fulfillment of the requirements for the award of the degree of

MASTER OF PHARMACY

(Pharmacology)

Submitted by

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EVALUATION OF NOOTROPIC ACTIVITY OF ETHANOLIC EXTRACT OF *EUPHORBIA CYATHOPHORA* STEMS ON MICE

ABSTRACT

Objective:

To evaluate the nootropic activity of ethanolic extract of stems of *Euphorbia Cyathophora* on mice.

Methodology:

The preclinical evaluation of standardization memory enhancement activity of ECEE was carried out by using the following models:

a) Hebb's William Maze
b) Labyrinth Maze
c) Morris Water Maze

Results:

Behavioral models that affect the cognitive processes was standardized and evaluated by using ECEE. The extract has shown significant memory enhancement activity due to the presence of flavonoids. Latency time and Escape latency was considered for the evaluation parameters. From the observed results latency scores and escape latency showed significant values byusing statistical analysis.

Key words:

Learning and Memory, *Euphorbia Cyathophora*

SALVIA ROSMARINUS WITH *EUCALYPTUS GLOBULUS* ALLEVIATES STRESS INDUCED INSOMNIA IN MICE THROUGH BRIGHTNESS DISCRIMINATION TO PROLONG SLEEP ONSET LATENCY

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ABSTRACT

Title: *Salvia rosmarinus* with *Eucalyptus globulus* alleviates Stress-Induced Insomnia in mice through brightness discrimination to prolong sleep onset latency.

Background: Insomnia is a common sleep disorder characterized by difficulty in falling asleep, often aggravated by stress and environmental factors such as disturbed continuous lighting. This study investigates the potential of *Salvia rosmarinus* (rosemary) and *Eucalyptus* essential oils to alleviate stress-induced insomnia by prolonging sleep onset latency in an animal model.

Methods: The study involved exposing a group of subjects to disturbed continuous lighting conditions inside a cage, designed to induce insomnia. To explore the therapeutic effects, essential oils of *Salvia rosmarinus* and *Eucalyptus* were applied to cotton swabs and placed inside the cage throughout the night. The sleeping onset latency time, defined as the time taken to fall asleep, was recorded using video tracking technology analyzed with Kdenlive software.

Results: Preliminary findings suggest that exposure to *Salvia rosmarinus* and *Eucalyptus* essential oils significantly reduced sleep onset latency compared to the control group, which was not exposed to the essential oils. The results indicate that the calming and stress-reducing properties of these essential oils may have contributed to a faster onset of sleep despite the continuous disturbed lighting conditions.

Conclusion: The study demonstrates that *Salvia rosmarinus* and *Eucalyptus* essential oils may have a positive effect on reducing sleep onset latency in an environment of stress-induced insomnia. These findings support the use of these essential oils as a complementary approach for managing insomnia, particularly in conditions involving environmental stressors. Further studies are needed to elucidate the mechanisms behind their effects and to explore their potential application in clinical settings.

Key words: *Salvia Rosmarinus, Eucalyptus globulus,* Insomnia, Sleep onset latency, Stress.

NEUROPHARMACOLOGICAL EVALUATION OF *OCIMUM SANCTUM* WITH *COLEUS AMBOINICUS* FOR ANTI DEPRESSANT ACTIVITY ON MICE

Dissertation submitted to

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ABSTRACT

Objective: This study aimed to evaluate the antidepressant activity of a combination of leaf extracts from *Coleus amboinicus* and *Ocimum sanctum* in comparison to the standard antidepressant drug amitriptyline using the tail suspension test (TST) and forced swim test (FST) in mice.

Background: Depression is a prevalent mental health disorder characterized by persistent sadness, loss of interest, and impaired functioning. Current antidepressant medications, like amitriptyline, are effective but often associated with side effects. Thus, exploring natural alternatives with fewer adverse effects is of considerable interest. *Coleus amboinicus* and *Ocimum sanctum* have been traditionally used for their therapeutic properties, including potential antidepressant effects.

Methods: The study used male mice, randomly divided into groups receiving either the combination of leaf extracts of *Coleus amboinicus* and *Ocimum sanctum* at various doses, amitriptyline, or a control solution. The antidepressant activity was evaluated using the TST and FST, which are widely accepted behavioral assays for screening antidepressant activity in rodents. Immobility time was recorded, with decreased immobility indicating antidepressant-like activity.

Results: The combination of leaf extracts of *Coleus amboinicus* and *Ocimum sanctum* significantly reduced immobility time in both the TST and FST, demonstrating a dose-dependent antidepressant-like effect. The combination was found to be comparable to the standard drug amitriptyline at higher doses. The reduction in immobility suggests that the combination extract exerts antidepressant effects, likely mediated through interactions with monoaminergic systems in the brain.

Conclusion: The combination of leaf extracts from *Coleus amboinicus* and *Ocimum sanctum* exhibits significant antidepressant activity in preclinical models, comparable to amitriptyline. These findings support the potential use of these herbal extracts as an alternative or complementary therapy for depression. Further research, including clinical trials, is recommended to confirm the efficacy and safety of this combination in humans.

Keywords: Antidepressant, *Coleus amboinicus*, Monoaminergic system, *Ocimum sanctum*.

Intervention Of Benzodiazepine-GABAergic, Serotonergic And Adrenergic Systems To Show Anxiolytic And Anti-Depressant Activity Of Fraction Of Medicinal Herbs In Alcohol Withdrawal Mice.

Dissertation submitted to

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Intervention of Benzodiazepine-GABAergic, Serotonergic And Adrenergic Systems To Show Anxiolytic And Anti-Depressant Activity of Fraction of Medicinal Herbs in Alcohol Withdrawal Mice.

ABSTRACT:

Aim: To Elucidate therapeutic potential anxiolytic and depression activity of fraction of medicinal plants

Objectives: Future aspects of these medicinal plants compared with marketed formulation to minimize the side effects

Methodology: 30 mice were divided into six groups, each consisting of five animals. These groups included a Saline group receiving saline solution, a Alcohol withdrawal group receiving alcohol, a Standard group receiving Diazepam, and three Test groups receiving extracts from *Psidium guajava, Piper betle, and Morinda citrifolia*. All groups, except the Control and Test groups, were subjected to alcohol administration Throughout the course of three days, following which the Standard medicine, Diazepam, was administered to Standard groups, and the animals were evaluated for anti-depressant and anti-anxiety activity after one hour. Anti-depressant activity was assessed through the Sucrose Preference Test (SPT), while anti-anxiety activity was evaluated using the Elevated Plus Maze (EPM), Open Field Test (OFT), and Marble Burying Test (MBT). Animals were weighed, and the appropriate dose of each drug was administered orally to the respective groups.

Discussion: They under go GABAergic and Serotonergic Mechanism In behavioral tests, Piper betle extract (MPB) administered at 50mg/kg orally demonstrated superior efficacy in reducing anxiety in mice undergoing alcohol withdrawal compared to *Psidium guajava* (MPG) and *Morinda citrifolia* (MMC) extracts in the same amount. Specifically, MPB showed stronger anxiolytic effects than MPG and MMC in the Open Field Test and Elevated Plus Maze, indicating its potential as a therapeutic agent for alcohol withdrawal-induced anxiety. Additionally, in the Marble Burying Test, MPB exhibited notable anxiolytic effects in the alcohol withdrawal group, suggesting its effectiveness in reducing anxiety-related behaviours.

Key Words: Open field test , Elevated plus maze, Marble burying test , Sucrose preference test Methanolic extract from Piper betle (MPB) , Methanolic extract of Morinda citrifolia (MMC) , Methanolic extract of Psidium guajava (MPG) ,Diazepam

ANTIPSYCHOTIC EVALUATION OF FRUIT EXTRACTS OF *FICUS CARICA* BY AMPHETAMINE INDUCED PSYCHOSIS IN RATS

Dissertation submitted to

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ABSTRACT

Objective: The study aims to investigate the potential antipsychotic activity of *Ficus carica* fruit extract, traditionally used in herbal medicine for its various therapeutic properties.

Background: Psychotic disorders, such as schizophrenia, are characterized by a range of symptoms, including delusions, hallucinations, and cognitive impairments. Conventional antipsychotic medications often have side effects that limit their long-term use. Therefore, there is a growing interest in identifying natural compounds with antipsychotic properties and fewer side effects.

Methods: The study utilized animal models of psychosis to assess the antipsychotic effects of *Ficus carica* fruit extract. Behavioral tests, including the amphetamine-induced climbing test, Continuous avoidance response, haloperidol induced catatonia were employed to evaluate the extract's efficacy. The extract was administered orally and intraperitoneally at varying doses to determine its dose-dependent effects.

Results: The results demonstrated that *Ficus carica* fruit extract significantly reduced psychotic symptoms in animal models. The extract showed a dose-dependent reduction in amphetamine-induced climbing test, Continuous avoidance response, haloperidol induced catatonia.

Conclusion: *Ficus carica* fruit extract exhibits promising antipsychotic activity in preclinical models, likely mediated through its effects on dopamine and serotonin pathways. These findings support the potential use of *Ficus carica* as a natural alternative or adjunctive therapy for managing psychotic disorders. Further studies, including clinical trials, are warranted to confirm these effects in humans and to explore the safety and efficacy of long-term use.

INVESTIGATE THE EFFECT OF ETHANOLIC ROOT EXTRACT OF MANGIFERA INDICA ON ALLOXAN INDUCED DIABETES IN WISTAR RATS

Dissertation submitted to

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ABSTRACT

Title *To investigate the effect of ethanolic root extract of Mangifera Indica on ALLOXAN induced diabetes in wistar rats*

Background Diabetes is a leading metabolic disorder characterized by hyperglycemia associated with impairment in insulin secretion. Long term dm is associated with damage to various organs such as eyes, kidneys, nerves, and heart. Roughly 5% of all cases of diabetes are type 1 dm and type 2 dm usually effects adults older than 45 years

Methods

1. Plant collection
2. Extraction using Soxhlet apparatus
3. Phytochemical screening
4. Pharmacological studies - acute toxicity studies and induction and assessment of diabetes

Results The present study is an attempt to investigate the effect of EEMI root on alloxan induced diabetes in wister albino rats. The phytochemical screening showed the presence of tannins, carbohydrates, flavanoids, alkaloids, phenols, sugar and amino acids. The findings of the present investigation suggest that EEMI root extract has potential for its evaluation as a protective agent against toxicity induced by alloxan.

Key words: Diabetes, EEMI, Alloxan, Mangifera indica, Acute toxicity studies

"APPLICATIONS AND PRINCIPLES OF *QUALITY BY DESIGN (QbD)* IN EUROPEAN UNION REGULATORY DOSSIERS FOR MEDICINAL PRODUCTS FROM 2020 TO 2023"

A Dissertation submitted to

CHALAPATHI INSTITUTE OF PHARMACEUTICAL SCIENCESLAM, GUNTUR

In partial fulfillment of the requirement for the award of degree of

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ABSTRACT

Dr. Joseph M. Juran, an early influencer in quality management, conceptualized Quality by Design (QbD) in the early 1970s, as a comprehensive risk-based strategy for drug development, involving ongoing risk management across a product's lifecycle and predefined objectives. The International Council of Harmonization (ICH) standards Q8 – 11 provide detailed guidance on implementing QbD. The European Medicines Agency adopted QbD principles for the EU's pharmaceutical regulatory system a decade ago. Despite recognizing its importance in 2014, the integration of QbD into European marketing authorization applications (MAA) remains limited and is not yet standard practice. A recent four-year investigation (2020–2023) aimed to assess the implementation of QbD concepts in all EU-approved marketing applications, using data from EPARs. Among 335 pharmaceuticals, only 33.13% (111) were developed with QbD principles, and 37.01% of total authorized products (77 out of 208 with full dossiers under article 8(3)) employed QbD. Interestingly, 30-40% of authorized products submitted as stand-alone documents over four years embraced QbD. Notably, a majority (71% in 2020 and 100% from 2021 to 2023) of authorized fixed-dose combination products were developed using a QbD approach. Additionally, the EMA rejected four market authorization applications with QbD principles in the dossier. In conclusion, according to EPARs, regulatory dossiers often lack complete QbD implementation, but the modest use of QbD components suggests a growing interest among businesses, potentially indicating a shift towards accepted development standards. Effective communication between regulatory bodies and companies is crucial for addressing challenges in QbD application.

KEY WORDS: QbD, EMA, EPAR's, Marketing Authorizations (MAs), Drug Development, Critical Quality Attributes.

"Traversing the Regulatory Environment: Approvals and Retrievals of Medical Devices through USFDA (2019 – 2023)"

A Dissertation submitted to

CHALAPATHI INSTITUTE OF PHARMACEUTICAL SCIENCESLAM, GUNTUR

In partial fulfillment of the requirement for the award of degree of

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IN

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ABSTRACT

Medical Devices play a vital role in various aspects of healthcare, and advances in science & technology of medical industry is coming up with innovations. The role of AI in medical devices where the large tech companies have been accelerating in developing smart products, such as smart wearables. Many of them are using AI and developing new AI applications to bring new, innovative, patient friendly functionalities. This study examines the approvals and recalls of medical devices with their assigned classes during the span of 2019-2023. About 99% of approvals of Class-3 devices whereas the recalls of Class-1(7.04%), Class-2 (78.8%) and Class-3 (14.09%) and these carry great dangers, show different patterns of clearance. All Classes show an increasing trend in recalls, and common causes include defects in production, poor quality control, malfunctioning software, and incorrect labelling. Ultimately this research highlights the crucial importance of continuous post-market surveillance, flexible regulations, and thorough studies to improve safety practices and foster creative breakthroughs in medical device technology.

KEY WORDS: Medical Devices, Food and Drug Administration, Approvals, Recalls, Center of Disease Radiological Health (CDRH)

"TRENDS IN THE INDIAN PATENT SCENARIO: A META-ANALYSIS"

A Dissertation Submitted to

CHALAPATHI INSTITUTE OF PHARMACEUTICAL SCIENCES
LAM, GUNTUR

In partial fulfillment for the requirements for the award of the Degree of

MASTER OF PHARMACY

IN

REGULATORY AFFAIRS

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ABSTRACT

This trend analysis delves into the landscape of Indian patents from 2012 to 2022, aiming to identify and evaluate significant trends and changes in innovation. The primary objectives of this research include discerning patenting patterns, exploring innovative domains, assessing the impacts of legislative modifications, and projecting future developments. Through a comprehensive analysis of patent data, it seeks to ascertain prevalent technological domains, key influencing factors, and India's competitive standing within the global innovation landscape. The report underscores sector-specific patenting trends, placing emphasis on the emergence of new industries such as artificial intelligence, renewable energy, pharmaceuticals, and telecommunications. It illuminates India's evolving research and development objectives by scrutinizing patent filing rates, trends in technical collaborations, and the country's participation in the global arena. Additionally, it considers how changes in policy frameworks and regulations may influence patent activities. Our findings reveal a substantial increase in patent applications across various industries, with notable surges observed in technology, pharmaceuticals, and renewable energy sectors. Notably, this analysis underscores the necessity for continual policy support and increased investments in research and development to harness the full potential of Indian innovation. This comprehensive analysis provides strategic insights into future innovation trajectories, contributing to a nuanced understanding of India's patent landscape over the past decade.

Key words: Indian patents, innovation trends, patenting patterns

"NAVIGATING THE REGULATORY LANDSCAPE: UNRAVELINGTHE RULES ON MISLEADING ADVERTISEMNENTS IN USA"

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ABSTRACT

FDA mandates pre-approval scrutiny for pharmaceutical products, assessing various production sites. After approval, risk-based surveillance inspections occur. A study examines warning letters from FDA's FTC (federal trade commission) and OPDP (office of prescription drug promotion) to drug firms' post-approval, delving into reasons behind such regulatory actions for enhanced pharmaceutical industry compliance and public safety. Advertisements are vital in a community where all companies fight for development and economic success. Drug development is a time-consuming and risky business. Marketing has a huge positive impact on the introduction of new products to the market. However, several pharmaceutical goods marketing specifically branded products are disputed and in violation of advertising regulations. Over a decade, advertising has been a crucial tool for any industry in reaching out to new clients while preserving confidence with existing ones. Pharmaceutical advertising, from a regulatory standpoint, is far more than just advertising in the traditional sense. Each country has its own legislative framework in place to protect the interests of consumers and corporations. Administrative bodies and lawmakers limit advertising opportunities for better results. This study emphasizes the overall regulatory consequences of misleading advertisements of drugs with respect to warning letters issued by both FTC and OPDP in USA from 2017 to 2023.

Key words: Federal trade commission, office of prescription drug promotion, warning letters food drug administration.

"REGULATIONS AND QUALITY CONSIDERATIONS OF DRUG DEVICE COMBINATION PRODUCTS IN USA"

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ABSTRACT

The emergence of drug-device combo products has had a tremendous impact on the healthcare environment in the United States. A new trend in medical product growth, regulatory acceptability, and business involvement was sparked by drug-device combo products. Combination products, or design innovations, maintain a fundamental idea and strengthen it through sophisticated links between core technology and updated complementing pieces. Depending on whether the FDA classifies the combined product as a medication, device, or biologic, these can differ significantly. Finally, the concerns that applicants and the FDA are addressing along the process of FDA action plans to address these intricate concerns provide some insight into how regulation of new technologies is evolving and changing. This research offers a thorough analysis of the advantages and disadvantages brought about by combination medications, setting them apart from traditional medication or drug delivery methods of earlier generations. It does this by analyzing case studies that concentrate on drug-device stents and trans-dermal patches. In addition to highlighting the critical role that architectural innovations play in market rivalry and compliance with regulations, the study also identifies a new high-value area within the combination product industry.

Key words: drug-device, Regulations, pre-market approval, combination products, market dynamics

"The Comparative Trend Analysis of Good Clinical Practice Inspection Processes for Marketing Applications between the European Medicines Agency and the US Food and Drug Administration (2016-2023)"

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ABSTRACT

Since 2009, the EMA and FDA have jointly conducted GCP inspections for marketing applications, yet no prior thorough assessment of their procedures exists. This study, the first of its kind, analyses GCP inspection processes, emphasizing geographic distribution, inspection types, and the timeline from 2016 to 2023 marketing applications. The investigation meticulously examines the dynamic landscape of GCP inspections by the FDA and EMA from 2016 to 2023, emphasizing collaborative initiatives initiated in 2009. Findings reveal distinctive trends, including a substantial decline in European Union (EU) inspections in 2020 and 2021 due to the global impact of the COVID-19 pandemic. In contrast, varied patterns are observed in the United States during the same period. Notably, 2022 witnesses an increase in U.S. inspections, while EU inspections maintain stability. Joint inspections between the EU and USA decline from 2016 to 2019, with a complete absence from 2020 to 2023, raising considerations about the pandemic's impact and regulatory prioritization. The discussion underscores broader implications, highlighting the pandemic's influence, potential regulatory shifts, and the need for transparent reporting. The lack of EU inspections in 2023 and the absence of joint inspections in subsequent years prompt inquiries about data completeness and reporting timelines. This study provides nuanced insights into the regulatory dynamics of GCP inspections, laying a foundation for informed discourse among regulatory bodies, industry stakeholders, and researchers in the domain of clinical trials and drug development.

Key words: Good Clinical Practice, European Medicines Agency, United States of Food and Drug Administration, Inspections.

TREND ANALYSIS OF ANTI-VIRAL DRUGS APPROVED BY USFDA DURING 2019-2023

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Abstract

Abstract: Both the treatment of patients and pharmaceutical research and development depend on the identification of innovative medications. A viable approach to achieving this crucial objective is the repurposing of current medications that can have expected side effects. Thorough examination and systematic research of licensed medications may yield insightful information about patterns in the development and may help methodically with the ongoing development of novel medications. Drug Evaluation and Research Center of the Food and Drug Administration (FDA) Novel medications, some of which are really unique and aid in the advancement of clinical treatment, are summarized annually by Research (CDER). As such, an analysis of drug approval trends by the FDA during the last 5 decades was carried out. From 2019-2023 we just collected the how many new drugs are formed and in that how many are the anti-viral drugs I just given the graphs and also collected the for what reason the drugs are rejected finally given the conclusion

Key words: Antiviral drugs, USFDA, Viral infection, Drug development

"INSIGHTS AND COMPLIANCE CHALLENGES FOR NUTRACEUTICAL REGULATIONS IN INDIAN MARKET"

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ABSTRACT

Nutraceuticals, comprising supplements, herbal medicines, vitamins, and minerals, claim therapeutic benefits in addressing disease causes. Coined in 1989, the term denotes compounds promoting health. Projections suggest India's nutraceutical business will reach USD 18 billion by 2025, necessitating robust oversight. The Food Safety and Standards Authority of India (FSSAI), established under the Food Safety and Standards Act of 2006, governs approvals. This study aimed to collate data on approved, refused, and withdrawn nutraceutical products and ingredients in India from 2020 to 2023. During this period, 58 out of 110 applications, constituting 52.7%, gained approval. Notably, 20–40% of applications related to nutraceuticals faced refusal or withdrawal within the preceding four years. Factors contributing to rejections and withdrawals include the sorting of S-adenosyl-L-methionine (SAMe) as a pharmaceutical compound, non-compliance with recommended dietary intake, potential drug-like properties, misleading labelling, and insufficient evidence of product efficacy. Withdrawals often result from issues like adulteration, substandard ingredients, and noncompliance with Good Manufacturing Practices (GMP) regulations. To surmount these challenges, FSSAI must establish rigorous regulations and guidelines for nutraceutical promotion, including public notifications for any modifications, with a concurrent expectation for industries to adhere to these guidelines in promoting public health. The collaboration of applicants/nutraceutical industry, and FSSAI would foster stable expansion, as evident in the CAGR for nutraceutical products and ingredients in India.

KEY WORDS: Nutraceuticals, Dietary Supplements, FSSAI, FoSCoS, CAGR, Covid – 19, India.

"ORPHAN DRUG MARKET: TRENDS IN APPROVED AND INSIGHT OF PRODUCT FAILURES IN US (2019-2023)"

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ABSTRACT

The quest for medications addressing rare or orphan diseases has been a focal point since the inception of the Orphan Drug Act in 1983. Analyzing data gleaned from the USFDA's Orphan Drug Approving and Designating database, along with insights from the USFDA Warning Letters database detailing rejected orphan pharmaceuticals spanning 2019 to 2023, this study offers a comprehensive examination. During this timeframe, 421 orphan medications received authorization, underscoring concerted efforts to advance treatments for rare diseases. However, this progress is accompanied by challenges, as evidenced by the rejection of seven orphan drugs. The delicate balance between approvals and rejections provides a nuanced perspective on the landscape of orphan medications, showcasing the dynamic nature of the market. The year 2020 marked a significant milestone with the approval of 90 orphan pharmaceuticals, reflecting substantial progress in addressing unmet medical needs for rare diseases. This positive trend continued in 2021, with 93 orphan drug approvals, affirming a commitment to therapeutic advancements. However, 2022 saw a deviation, witnessing a decrease to 73 approvals, prompting scrutiny into potential contributing factors. The subsequent rebound in 2023, with 90 approvals, echoes the successes observed in 2020. Among the approvals, seven orphan drugs faced rejection over the five-year period, offering insights into regulatory challenges and criteria. Understanding these instances provides valuable knowledge for refining drug development strategies for rare diseases. This study, encapsulating quantitative aspects of approvals and rejections in the orphan medication landscape, emphasizes the dynamic regulatory processes and challenges inherent in drug development for rare diseases. As the orphan medication market evolves, this analysis serves as a foundational resource for optimizing the regulatory pathway in the ongoing pursuit of innovative treatments for uncommon and orphan diseases.

KEY WORDS: Orphan Drug Act, USFDA, Designation of Orphan Drug and Approval database, USFDA Warning Letters database, rare disease, New Drug Application.