SYNTHESIS, CHARACTERIZATION AND BIOLOGICAL EVALUATION OF NEW OXAZEPINE DERIVATIVES

Dissertation submitted to

CHALAPATHI INSTITUTE OF PHARMACEUTICAL SCIENCES

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

BACHELOR OF PHARMACY

Submitted by

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EVALUATION CERTIFICATE

This is to certify that dissertation work entitled ***"SYNTHESIS CHARACTERIZATION AND ANTIMICROBIAL EVALUATION OF NEW OXAZEPINE DERIVATIVES*** *is a bonafide research work done by* ***MUVVA SUJITHA(Y17BPH0560), PULI MANASA(Y17BPH0571), SHAIK SAHERA BANU(Y17BPH0577), SOMU RAMYASRI(Y17BPH0579), YARRA MANIKANTESWARI(Y17BPH0596), YERESI JYOTHSNA(Y17BPH0598)*** *and submitted in partial fulfilment of the requirement for the award of degree of* ***BACHELOR OF PHARMACY*** *is the bonafide research work carried out by the candidates in the laboratories of CHALAPATHI INSTITUTE OF PHARMACEUTICAL SCIENCES, LAM, GUNTUR and was evaluated by us during the academic year 2020-2021.*

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ABSTRACT

Schiff bases are 1st identified by Hugo Schiff in the year 1864. These are also called as imines or azomethines. Schiff bases are the compounds with imine or azomethine groups and these are formed by the condensation of primary amines with carbonyl compounds. Oxazepine derivative were 1st introduced in 1965 and it is used in the relief of the psychoneuroses which is characterized by anxiety and tension. Oxazepines were synthesized by Pericyclic cycloaddition of Schiff bases with anhydrides. Oxazepines possesses various biological activities like Anti-bacterial, anti-fungal, Anti-inflammatory, Anti-epileptic, hypnotic muscle relaxant, Anxiolytics, Telomerase inhibiter, Anti-tumor activity, TRPAI ion channel modulators and histone deacetylase inhibitor activity. Few 1,3 oxazepines are synthesized by the cyclo addition of Schiff bases with aromatic anhydrides. Schiff bases are prepared by condensation of anthranilic acid with aldehydes. The structures of the oxazepines were confirmed via elemental analysis FT-IR and ^{1}H and ^{13}C- NMR spectra . The compounds were screened for their anti bacterial activity against both gram positive (B.Subtilis) and gram negative bacteria (E.Coli). The results showed that the synthesized compounds exhibited varied anti bacterial activity in comparison with standard.

Key words: 1,3 oxazepines , cyclo addition , Schiff bases, Anti bacterial activity

FORMULATION AND EVALUATION OF CURCUMIN GEL SANITIZER

Dissertation submitted to

Chalapathi Institute of Pharmaceutical Sciences

In the partial fulfillment of the requirement

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ABSTRACT

Objective: The main intention of this research is to prepare a Curcumin based herbal gel sanitizer by minimizing the alcoholic usage and to evaluate the anti-bacterial activity of this herbal sanitizer.

Methods: Curcumin gel sanitizer was prepared from the ethanolic extract of *Curcuma longa* along with addition of gel base prepared from the combination of carbapol-940 and HPMC-E15.

Results: The curcumin gel sanitizer was formulated and evaluated for its phytochemical constituents present in curcumin, detection of active constituent of curcumin which was majorly responsible for the anti-microbial activity through HPTLC, organoleptic properties, irritancy test and the efficiency of anti-bacterial activity of curcumin was also evaluated and it is safe and effective against pathogens.

Conclusion: As a natural herb, curcumin which was a household ingredient could also be effectively formulated as a sanitizer that reduces the side effects of alcoholic sanitizer products and is a best source that acts effectively against numerous pathogens.

Keywords: Curcumin, carbapol-940, Ethanolic extract, HPMC-E15 (hydroxypropyl methyl cellulose), HPTLC, Pathogens.

EVALUATION OF ADDITIVE/SYNERGISTIC EFFECT OF *PIPER NIGRAM* AND *OCIMUM SANCTUM* EXTRACT FOR THEIR ANTIDEPRESSANT ACTIVITY

Dissertation submitted to

Chalapathi Institute of Pharmaceutical Sciences

In the partial fulfillment of the requirement

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ABSTRACT

Depression is a state of excessive sensitivity to criticism, fear of rejections, lack of self-interest, loss of pleasure. In the traditional systems of medicine, many plants and formulations have been used to treat depression for thousands of years. In recent times, research on the plants increased globally and so many plants provide the evidence to cure diseases. Ocimum sanctum, popularly known as Tulsi is one of the sacred herbs for Hindus in the Indian subcontinent. It has a versatile role in traditional medicine. The fruits of Piper nigrum are used to make black pepper. This hotly pungent spice is one of the earliest known and most widely used spices in the world today. It is used as flavouring, particularly for savoury foods, meat dishes, sauces and snack foods. It is also used as a table condiment. Wide range of animal tests for antidepressant agents are commonly used. The Forced swim test and Tail suspension test in mice were mostly used. Hence in the present study Forced swim test was used as animal model of depression. In present study immobility time in Forced swim test was significantly decreased by a combination of *Piper nigrum* fruit extract and *Ocimum sanctum* extract treated groups compared to control group. The combination of extracts (50 mg/kg each) activity was comparable to standard drug Fluoxetine. Treatment with extracts does not modify the locomotor activity of mice, which indicates that they exert antidepressant effects without modifying significantly locomotor activity. Therefore, the present study confirms the combination of alcoholic extract of piper nigrum fruit and aqueous extract of *Ocimum sanctum* possessing additive/synergistic antidepressant activity. Further studies should be conducted to explore the mechanism of synergistic/additive effect of the extracts.

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A COMPARATIVE RESEARCH BETWEEN PHARMACOLOGICAL AND NON-PHARMACOLOGICAL PROFILE OF ANTI HYPERLIPIDEMIC ACTIVITY ON RODENTS

Dissertation submitted to

CHALAPATHI INSTITUTE OF PHARMACEUTICAL SCIENCES

In the Partial Fulfillment of the Requirements

For the award of the Degree of

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A COMPARATIVE RESEARCH BETWEEN PHARMACOLOGICAL AND NON-PHARMACOLOGICAL PROFILE OF ANTI-HYPERLIPIDEMIC ACTIVITY ON RODENTS

ABSTRACT

Objective:

To carry out the comparative research between pharmacological and Non-pharmacological profile of Anti-hyperlipidemic activity on rodents.

Methodology:

The preclinical evaluation was carried out for Anti-hyperlipidemic activity on rodents by establishing In-vivo activities as followed:

1. Food induced obesity
2. Activity Wheel (Overall Body Performance)
3. Muscular Strength Maze (Cardio Performance)

Results:

The hypolipidemic effect was investigated in rats suffering from high cholesterol with diet induced hyperlipidemia. The high-cholesterol diet caused a significant increase in total lipids, total cholesterol (TC), total triglycerides (TG), low-density lipoprotein cholesterol (LDL-C), and the atherogenic index, whereas the level of high-density lipoprotein cholesterol (HDL-C) was significantly decreased. The groups with anti-hyperlipidemic medication and without medication by exposing to physical exercise are compared in one aspect and however the group treated with physical performance showed potent activity alike standard.

Key words: Hyperlipidemia, Triglycerides, low-density lipoprotein, activity wheel, Muscle strength Maze.

NEWER SYNTHETIC APPROACHES AND BIOLOGICAL EVALUATION OF 2,5- Di SUBSTITUTED-1,3,4-OXADIAZOLE DERIVATIVES

Dissertation submitted to

Chalapathi Institute of Pharmaceutical Sciences

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ABSTRACT

A Series of new 2,5-disubstituted-1,3,4-oxadiazole derivatives are synthesized from hydrazone derivatives along with various aldehydes and ketones derivatives in presence of bromine water, sodium acetate and glacial acetic acid. All the newly synthesized aldehyde and ketone derived 1,3,4-oxadiazoles are characterized using elemental analysis. IR, ^{1}H NMR ^{13}C NMR spectral characterization was carried out. Purity of all compounds had been checked on thin layer chromatographic plate. All the final synthesized compounds of 1,3,4-oxadiazole derivatives are evaluated for their in-vitro anti-microbial activity against several Gm +ve bacterial strains (*Bacillus subtilis, Bacillus cereus, S. pyrogenous, S. aureus)* and Gm -ve bacterial strains (*E. coli, P. aeruginosa*) using broth dilution technique with the disc diffusion method. From the tested compounds OD-2, OD-7, OD-9 showed better activity compared to others. All the derivatives are synthesized using green synthesis.

Key Words: 1,3,4-oxadiazole, Broth dilution technique, Disc Diffusion method, Anti-microbial, Green Synthesis

PHARMACOLOGICAL EVALUATION OF HERBAL EXTRACTS OF *PHYLLANTHUS EMBLICA* AND *CAMELLIA SINENSIS* FOR ITS HEPATOPROTECTIVE ACTIVITY IN ALBINO RATS

Dissertation submitted to

Chalapathi Institute of Pharmaceutical Sciences

In the partial fulfillment of the requirement

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ABSTRACT

Objective: To evaluate the Hepatoprotective activity of *Camellia sinensis* and *Phyllanthus emblica* against paracetamol induced hepatotoxicity in rats by comparing it with standard drug silymarin.

Methods: Phytochemical analysis was carried out by using standard procedures. Animals were divided into seven groups and each group contains 3 animals out of that two groups were treated with *Camellia sinensis* (100 mg/kg and 200 mg/kg) and two groups treated with *Phyllanthus emblica* (100 mg/kg and 200 mg/kg) and silymarin (50 mg/kg) for 15 days before the damage of the liver by paracetamol. At the end of the study serum enzymes, histology of liver was evaluated

Result: The phytochemical analysis has revealed the presence of carbohydrates, glycosides, tannins, alkaloids, flavonoids, phenols, saponins. Decreasing plasma levels of SGOT, SGPT, total bilirubin animals treated with aqueous extract of *Camellia sinensis* and *Phyllanthus emblica* both were shown significant hepatoprotective effect.

Conclusion: The results support that traditional use of *Camellia sinensis* and *Phyllanthus emblica* as hepatoprotective property can be used for the treatment of liver toxicity

Keywords: *Camellia sinensis, phyllanthus emblica,* paracetamol, antioxidant activity hepatotoxicity and liver enzymes.

SYNTHESIS AND CHARACTERIZATION OF NOVEL NAPHTHALENE SUBSTITUTED SULPHONAMIDE DERIVATIVE

A dissertation submitted to

CHALAPATHI INSTITUTE OF PHARMACEUTICAL SCIENCES

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

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ABSTRACT

Most of the naphthalene substituted compounds are used as antimicrobial agents, anti-mycobacterial agents, nasal decongestants and anti-inflammatory agents. In the present work the synthesis and characterization of novel sulfonamide derivative by incorporating the naphthalene containing moiety as a substituent was carried out. Compound was synthesized initially by bromination of 1-Hydroxy acetonaphthone by using N-bromosuccinimide, followed by the reaction of obtained intermediate with Sulphanilamide at low temperature. The final compound was characterized by IR , NMR and Mass spectrometric techniques. The results have shown the presence of characteristic groups. By interpreting spectral data, we have predicted that the final product was obtained. Considering the importance of naphthalene substituted sulpha derivatives in medicine, we would like to proceed for screening of biological activities.

Key Words: 1-Hydroxy acetonaphthone, N-bromosuccinimide, Sulphanilamide , Spectral Interpretation

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DETERMINATION OF DIOSGENIN PRESENT IN THE EXTRACT OF LEAVES OF *HIBISCUS ROSA-SINENSIS* BY HPTLC AND FTIR

Dissertation submitted to

CHALAPATHI INSTITUTE OF PHARMACEUTICAL SCIENCES

In the partial fulfilment of the requirement

for the award of the degree of

BACHELOR OF PHARMACY

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ABSTRACT

Hibiscus is a topical plant which is well known for its medicinal properties. The chemical constituents responsible for those medicinal properties include Anthraquinones, Quinones, steroids, tannins, Phenols, Flavonoids, Alkaloids, Terpenoids, Saponins, Cardiac Glycosides, Proteins, Carbohydrates, Reducing sugars, Mucilage and Essential oils. Diosgenin is a phytosteroidal sapogenin. It is the main chemical constituent present in Dioscorea species and is obtained by hydrolysis of Dioscin. Diosgenin is used in the commercial synthesis of steroidal drugs like Cortisone, Pregnenolone, and Progesterone etc. Aim of the present study is to determine the presence of Diosgenin in the leaves of *Hibiscus rosa-sinensis*. Leaves of *Hibiscus rosa-sinensis* were extracted with pure isopropyl alcohol and are analyzed using UV spectrophotometer. A simple, sensitive, fast and reproducible method was developed for the isolation of Diosgenin present in the isopropyl alcohol extract of *Hibiscus rosa-sinensis* leaves using HPTLC. Pre coated Silica gel G60F254 Aluminum plates were used as stationary phase and Toluene : Isopropyl alcohol : Glacial acetic acid (5:2.5:2.5 v/v) was used as mobile phase. The retardation factor of both the standard and the extract were compared and was found to be 0.599 ± 0.1. IR interpretation of both the standard Diosgenin and the extract from the leaves was found to be similar. This is a simple method for the analysis of the Diosgenin present in various plants and plant products.

Key words: Diosgenin, *Hibiscus rosa-sinensis*, HPTLC, Retardation factor, IR interpretation

QUANTIFICATION OF THYMOQUINONE FROM KALONJI SEEDS BY DIFFERENT ANALYTICAL TECHNIQUES

Dissertation submitted to

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In the partial fulfillment of the requirement

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ABSTRACT

Kalonji seeds areused as natural home remedy and many ayurvedic formulations for immunity, hair growth, diabetes, and so for, the activities are due to presence of thymoquinone and currently the researchers are focusing on formulation issues of thymoquinone and analysis, in this paper we have focused on developing some promising analytical techniques for identification and quantification of thymoquinone. IR spectrometry to identify the structure of thymoquinone the prominent peak was observed at 1648 $cm^{-1}$for the functional group cyclohexadiene and 1661 cm^{-1} for 1,4benzoquinone from this we have confirmed for the presence of thymoquinone in both standard formulation and kalonji extract. UV spectroscopic method has been developed for quantification of thymoquinone and its identification by obtaining absorption maxima at 250 nm and checked for the parameters like linearity, precision, system suitability, specificity and robustness using methanol as solvent, linearity range was 100 to 500µg/ml and performed the regression coefficient found to be 0.999 . HPTLC method of analysis has been developed which is easy to perform and accurate results using mobile phase hexane/methanol/ethylacetate in the ratio of 7:3:1 on silica gel plates with the dimensions of 10×10cm, of 1000 to 5000ng/ml the obtained Rf value is 0.77 which is for thymoquinone standard formulation, the developed method is validated for the parameters accuracy, linearity, precision and system suitability all the obtained values are within the limits.Therefore all the above mentioned analytical methods can be used for the presence of thymoquinone in both extracts and formulations that contains thymoquinone.

Key words: kalonji seeds,extract, thymoquinone, UV Spectrometry, HPTLC, Validation, accuracy, linearity, precision, system suitability.

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BIOAVAILABILITY ENHANCEMENT OF RITONAVIR BY SOLID DISPERSION TECHNIQUE

Dissertation submitted to

CHALAPATHI INSTITUTE OF PHARMACEUTICAL SCIENCES

In the partial fulfillment of the requirement

for the award of the degree of

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ABSTRACT

Ritonavir is an antiretroviral agent used in the treatment of HIV-infection. It is a BCS class IV drug having poor aqueous solubility leading to poor bioavailability. In order to improve bioavailability, many techniques like solid dispersions, nano particles, liposomes, encapsulation methods were present. The main aim of this study is to improve the bioavailability of ritonavir with the help of PVP K-30 by using solid dispersion technique. Different formulations were made with varied concentrations of polymer. Characterization of solid dispersion was done by phase solubility, drug content, FT-IR, DSC and *invitro* dissolution studies. from phase solubility studies that apparent solubility constant was found to be $42.227M^{-1}$. The drug content of the binary system of ritonavir and PVP was found to be ranging from 99.17% to 103.06%. %. FT-IR studies revealed that there was no drastic change in the wave number indicating polymer compatibility with drug. Invitro dissolution studies proved that there was an increase in drug release of ritonavir with incremental ratios of polymer and F5 formulation has shown almost 95% of drug release.

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PHYSICOCHEMICAL INCOMPATIBILITY STUDIES AND OPTIMIZATION OF DISSOLUTION MEDIUM FOR RIVAROXABAN

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ABSTRACT

Incompatibility is the inactivation of active pharmaceutical ingredient (API) through either decomposition or loss of drug by its conversion to a less favorable physical or chemical form. When two or more API and excipient with each other and if they are antagonistic and affect adversely the safety, therapeutic efficacy, appearance or elegance then they are said to be incompatible. Physico- chemical compatibility studies are performed to check the effect of different excipients on API and it is the prerequisite in the preformulation studies. Rivaroxaban is a drug which is an oral anti-coagulant which mainly acts by blocking clotting factor Xa. Optimization of dissolution medium was done by taking multiple concentrations of sodium lauryl sulphate(SLS) ranging from 0.1% to 2.0% in 0.1N HCl. Incompatibility studies are performed for rivaroxaban with hydroxy propyl methyl cellulose, lactose, magnesium stearate, sodium lauryl sulphate, microcrystalline cellulose, croscarmellose sodium and hydroxy propyl cellulose was done using the Scanning electron microscopy, X-ray powder diffraction, Differential scanning calorimetry. 1:1 physical mixture of rivaroxaban and selected excipients were taken and sent for analysis using differential scanning calorimeter. Rivaroxaban showed the transition at 231.79 ^{0}C and the specific heat of fusion was found out to be 114.2 J/g. Slight change in the transition temperature was seen with the combination of rivaroxaban and excipients which lies in acceptable limits. The 2θ values of the standard drug are compared with the spectrum obtained from the XRD study. This comparison showed no evidence regarding the incompatibility of drug with excipients. The pictographs obtained by SEM were evidence for the absence of any interaction between rivaroxaban and the excipients, providing visual support for the results. There were no interactions of drug with selected excipients and found to be compatible. Therefore, it is a mandatory clause for the compound compatibility with various excipients in the formulation which affect the stability and efficacy of the formulation. The results obtained from the dissolution media suggests that none of the medium is showing 85 percent of drug release, so 0.1N HCl with varied concentrations of SLS may not be suitable as dissolution medium for rivaroxaban.

Keywords: Rivaroxaban, Incompatibility, Preformulation, DSC, XRD and SEM, Dissolution.

DEVELOPMENT AND EVALUATION OF FAST DISSOLVING TABLETS OF ALLOPURINOL BY SUBLIMATION METHOD

A DISSERTATION SUBMITTED TO

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

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ABSTRACT

Allopurinol is a xanthine oxidase enzyme inhibitor that is one of the most effective drugs used to decrease urate levels and is frequently used in the treatment of chronic gout, belongs to Biopharmaceutical Classification System Class II. The current research was to develop and evaluate fast dissolving tablets of allopurinol solid dispersion using sublimation method. Fast dissolving tablets of allopurinol were formulated and prepared using subliming agents such as camphor and ammonium bicarbonate and various concentrations of sodium starch glycolate and cross povidone by direct compression technique. The method is to enhance the porosity of prepared tablets whereby subliming agent was sublimed from tablets by exposing the tablets to vacuum. The drug and excipients were characterized using FT-IR technique. The blend was analyzed for pre-compression characteristics - angle of repose, bulk density, tapped density, compressibility index and Hausner's ratio. The porous tablets were then evaluated for post-compression parameters - hardness, friability, *in vitro* disintegration time, and *in vitro* dissolution studies. The fast-dissolving tablets prepared with higher concentrations of subliming agents have exhibited rapid disintegrating features which is characteristics feature of melt in mouth tablets. The *in vitro* drug release study shown that F8 formulation was able to hasten the release of allopurinol within 30 minutes. In conclusion, the results obtained suggested that sublimation method is useful to enhance solubility as well as dissolution rate of poorly aqueous soluble drug such as allopurinol.

Keywords: Fast dissolving tablet, direct compression, aliopurinol, Subliming agent, super disintegrant.

SYNTHESIS AND SPECTRAL CHARACTERISATION OF 1,7-*BIS*(13-CHLORO-9-ETHYL COUMARIN -8*YL*) -5-HYDROXY-3-OXOHEPTA-1,4,6-TRIENE

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ABSTRACT

Curcumin is an active component derived from turmeric, a common Indian spice and colouring agent which is a dried rhizome of the plant Curcuma longa belonging to the family Zingiberaceae. Curcumin is an important nutraceutical and also known that it has also been used traditionally as a medicine in countries like India, China, Thailand for approximately 2000 years without any knowledge of its mechanism. Curcumin is widely studied in food and medicine field as it has various activities. It is considered as "Magic molecule" because it plays an important role with pharmacological activities like anti-inflammatory, anti-oxidant, skin diseases, intestinal worms, constipation, wound healing, anti-infective, anti-viral, anti-atherosclerosis, hepatic disorder, rheumatism etc. Curcumin also provides positive outcomes in life-threatening diseases like cancer, diabetes, and other auto-immune and neurodegenerative diseases. Curcumin shows anti-tumorigenic activity by controlling Reactive Oxygen Species (ROS) levels by competitive binding to ROS metabolic enzymes and inhibiting their activity. Though it has wide range of activities, the built-in physicochemical characteristics like poor water solubility, low bioavailability, chemical instability, photo degradation and short half-life limits the pharmaceutical significance. These pharmaceutical issues were improved using the advanced techniques like nanoparticles, nanofibres, nanovesicles, nanocomposite hydrogels, nanoemulsions, polymeric micelles etc. Incorporation of curcumin in these delivery systems improved solubility, half-life, stability etc.

Keywords: Curcumin, Magic molecule, Reactive Oxygen Species (ROS), Nutraceutical, Anti-tumorigenic, Polymeric micelles.

DETERMINATION OF ANTI MICROBIAL ACTIVITY OF ACALYPHA INDICA AND AZARDIRACHTA INDICA ON SELECTED PATHOGENS

Dissertation submitted to

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EVALUATION CERTIFICATE

This is to certify that dissertation work entitled ***"Determination of Antimicrobial Activity of Acalypha indica and Azardirachta indica on selected pathogens"*** *is a bonafide research work done in the laboratories of* ***Chalapathi Institute Of Pharmaceutical Sciences. Lam. Guntur*** *by* ***PUSHADA PURNA CHANDU (Y17BPH0509), GOLLAMUDIJOHN ASTEEN (Y17BPH0530),KATURI GANESH (Y17BPH0544)*** *and submitted in partial fulfilment of the requirement for the award of degree of* ***BACHELOR OF PHARMACY by Chalapathi Institute of Pharmaceutical Sciences, Lam, Guntur*** *and was evaluated by us during the academic year 2020-2021.*

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STUDY OF MICROBIAL LOAD ON DIFFERENT MASKS

Dissertation submitted to

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FORMULATION AND EVALUATION OF POLYHERBAL OINTMENT AND CREAM IN WOUND HEALING

Dissertation submitted to

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ABSTRACT

Wound-It is a circumscribed injury which is caused by external force and it can involve any tissue and organ. A wound is a break in the skin's or tissues integrity, which is typically accompanied with structural and functional disturbance. Healing is the body's response to injury in an attempt to restore normal structure and function. The process of healing involves two distinct processes which includes regeneration and repair. Several herbs and floras were utilised in Ayurvedic cosmetics that actually functioned, thanks to the knowledge of Ayurveda. Ayurvedic cosmetics not only improved the appearance of the skin, but also protected the body from environmental influences. oily components are taken in a beaker and aqueous components in another beaker and to the oily components aqueous ingredients are added slowly by vigorous trituration in mortar. The process employed for the formulation of the ointment here is fusion method. 4 groups of animals were taken and small cut was made on the surface of the skin and the cut was made as deep over an area of 20mm. Group-I received control, group-II received herbal cream, group - III received herbal ointment and group IV received standard drug (saffromycin). Animals were treated with ointment and cream daily at same time as it received on day 0. Animals were checked for depth of the wound regularly with a span of 7 days. polyherbal cream shown good wound healing nature within first 7 days. Both polyherbal ointment and cream tend to show complete wound healing nut in comparison to the two polyherbal cream is acting rapidly on the site if action.

Key words: Wound, Polyherbal cream, Polyherbal ointment, Ayurveda, Ayurvedic cosmetics.

FORMULATION AND EVALUATION OF FERMENTED RICE WATER HERBAL SHAMPOO

Dissertation submitted to

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ABSTRACT

Ayurvedic therapy is the best way for the treatment of various conditions, as it has minimal side effects. Now-a-days, the most occurring problem is hair fall, so the main aim of the study is to reduce hair fall and promote hair growth. The main ingredient in this study is fermented rice water [*Oryza sativa*] which contains many antioxidants when compared to the plain rice water. Inositol is the major constituent which helps in decreasing hair fall. A herbal shampoo was formulated using some traditional herbs like *Hibiscus-rosa-sinensis, Phyllanthus emblica, Aloe barbedensis*, *Trigonella foenum graceum* along with fermented rice water in different proportions. The prepared herbal shampoo was evaluated for physico chemical parameters like pH, foam formation, dirt dispersion, surface tension, viscosity and wetting test. The evaluation of the herbal shampoo indicated that it is ideal to use, safe and effective in the treatment of hair fall.

Key words: Herbal shampoo, Oryza sativa, hair fall, hair growth, evaluation.

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Certified that this is a bonafide record of the **Clerkship** done by *"ATMAKURI GOPAL"* of **Regd. No: Y16PHD0109** in the V/VI Pharm D during the year 2020-2021 in the Department of Pharmacy Practice, Government General Hospital, A Unit of Chalapathi Institute of Pharmaceutical Sciences, Lam, Guntur.

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Examiners:

1.External

2.Internal 16/04/2021

PRINCIPAL
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CLERKSHIP REPORT

May 2020 to February 2021

V/VI Pharm D

DOCTOR OF PHARMACY

Submitted by

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Certified that this is a bonafide record of the Clerkship done by *"CHEREDDY THANMAI CHOWDARY"* of Regd. No: Y16PHD0110 in the V/VI Pharm D during the year 2020-2021 in the Department of Pharmacy Practice, Government General Hospital, A Unit of Chalapathi Institute of Pharmaceutical Sciences, Lam, Guntur.

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Examiners:

1. External

2. Internal

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CLERKSHIP REPORT

May 2020 to February 2021

V/VI Pharm D

DOCTOR OF PHARMACY

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Examiners:

1.External 16/04/2021

2.Internal 16/4/2021

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CLERKSHIP REPORT

May 2020 to February2021

V/VI Pharm.D

DOCTOR OF PHARMACY

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CLERKSHIP REPORT

May 2020 to February 2021

V/VI Pharm D

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2. Internal 16/04/21

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CLERKSHIP REPORT

May 2020 to February 2021

V/VI Pharm D

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2. Internal 16/04/2021

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CLERKSHIP REPORT

May 2020 to February 2021

V/VI Pharm D

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CLERKSHIP REPORT

May 2020 to February 2021

V/VI Pharm D

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Examiners:

1.External

2.Internal

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CLERKSHIP REPORT

May 2020 to February 2021

V/VI Pharm D

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Examiners:

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2.Internal

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CLERKSHIP REPORT

May 2020 to February 2021

V/VI Pharm D

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CLERKSHIP REPORT

May 2020 to February 2021

V/VI Pharm D

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Examiners:

1. External

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PRINCIPAL
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CLERKSHIP REPORT

May 2020 to February 2021

V/VI Pharm D

DOCTOR OF PHARMACY

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CLERKSHIP REPORT

May 2020 to February 2021

V/VI Pharm D

DOCTOR OF PHARMACY

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CLERKSHIP REPORT

May 2020 to Feburary 2021

V/VI Pharm.D

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INSTITUTE OF PHARMACEUTICAL SCIENCES

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(Affiliated to AcharyaNagarjuna 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 REMINISETTY SAI MANASA , Regd. No: Y16PHD0123 in the V/VI Pharm D during the year 2019 - 2020 in the Department of Pharmacy Practice, Govt. General Hospital, A Unit of Chalapathi Institute of Pharmaceutical Sciences, Lam, Guntur.

Preceptor
(Dr.Y.Sravani)

Staff in charge:-

(Dr.RaviNagalekhini)
Department of Pharmacy Practice
B-Class IInd Floor, Inpatient Block
Govt. General Hospital
GUNTUR-522 001

Head Of the Department :-
(Dr.N.V.Ramarao)

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

2.Internal

PRINCIPAL
Chalapathi Institute of Pharmaceutical Sciences
(Autonomous)
Chalapathi Nagar LAM, GUNTUR-2

CLERKSHIP REPORT

May 2020 to Feburary2021

V/VI Pharm.D

DOCTOR OF PHARMACY

Submitted by

Mr.SRIKANTH.BANDARUPALLI

REG. NO: Y16PHD0124

DEPARTMENT OF PHARMACY PRACTICE,

GOVT. GENERAL HOSPITAL,

CHALAPATHI INSTITUTE OF PHARMACEUTICAL SCIENCES,

(AUTONOMOUS)

Accredited by NAAC with "A" Grade

CHALAPATHI NAGAR, LAM, GUNTUR.

CHALAPATHI INSTITUTE OF PHARMACEUTICAL SCIENCES (Autonomous) LAM, GUNTUR-34.

PRINCIPAL

Chalapathi Institute of Pharmaceutical Sciences

(Autonomous)

Chalapathi Nagar LAM, GUNTUR-34.

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 *SRIKANTH.BANDARUPALLI* **Regd.No:** *Y16PHD0124* **in the V/VI PharmD during the year 2020 - 2021 in the Department of Pharmacy Practice, Govt. General Hospital, A Unit of Chalapathi Institute of Pharmaceutical Sciences, Lam, Guntur.**

Preceptor: -
(Dr. Y. Sravani)

Staff In charge:
(Dr. Ravi Nagalekhini)
Department of Pharmacy Practice
B-Class IInd Floor, Inpatient Block
Govt. General Hospital
GUNTUR-522 001

Signature of HOD
(Dr. N. V. Ramarao)
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

2. Internal 14/04/21

PRINCIPAL
Chalapathi Institute of Pharmaceutical Sciences
(Autonomous)
Chalapathi Nagar, LAM, GUNTUR-22

CLERKSHIP REPORT

May 2020 to February 2021

V/VI Pharm.D

DOCTOR OF PHARMACY

Submitted by

Mr. Tamma Hemanth Kumar Reddy

Regd. No: Y16PHD0125

DEPARTMENT OF PHARMACY PRACTICE,

GOVT. GENERAL HOSPITAL,

CHALAPATHI INSTITUTE OF PHARMACEUTICAL SCIENCES.

(AUTONOMOUS)

Accredited with "A" Grade by NAAC

CHALAPATHI NAGAR, LAM, GUNTUR- 522034.

CHALAPATHI INSTITUTE OF PHARMACEUTICAL SCIENCES (Autonomous) LAM, GUNTUR-34.

PRINCIPAL
Chalapathi Institute of Pharmaceutical Sciences
(Autonomous)
Chalapathi Nagar, LAM, GUNTUR-34

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 "TAMMA HEMANTH KUMAR REDDY" Regd.No: Y16PHD0125, in the V/VI PHARM.D during the year 2020-2021 in the Department of pharmacy practice, Govt.General Hospital, A unit of Chalapathi Institute of Pharmaceutical Sciences, Lam, Guntur.

Preceptor: -
Dr. Y.SRAVANI

Examiners: -

Staff In- charge: -
Dr.R.NAGA LEKHINI
Department of Pharmacy Practice
B-Class, IInd Floor, Inpatient Block
Govt. General Hospital
GUNTUR-522 001

1. External: -

HOD: -
Dr. N.V. RAMA RAO
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

2. Internal: -

PRINCIPAL
Chalapathi Institute of Pharmaceutical Sciences
(Autonomous)
Chalapathi Nagar, LAM, GUNTUR-2.

CLERKSHIP REPORT

May 2020 to February2021

V/VI Pharm.D

DOCTOR OF PHARMACY

Submitted by

Mr.Tanniru Vamsi Narayana

REG. NO: Y16PHDO126

DEPARTMENT OF PHARMACY PRACTICE,

GOVT. GENERAL HOSPITAL,

CHALAPATHI INSTITUTE OF PHARMACEUTICAL SCIENCES,

(AUTONOMOUS)

Accredited by NAAC with "A" Grade

CHALAPATHI NAGAR, LAM, GUNTUR.

CHALAPATHI INSTITUTE OF PHARMACEUTICAL SCIENCES (Autonomous) LAM, GUNTUR-34.

PRINCIPAL
Chalapathi Institute of Pharmaceutical Sciences
(Autonomous)
Chalapathi Nagar LAM, GUNTUR-34

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 *TANNIRU.VAMSI NARAYANA* Regd. No: Y16PHD0126 in the V/VI Pharm D during the year 2020 - 2021 in the Department of Pharmacy Practice, Govt. General Hospital, A Unit of Chalapathi Institute of Pharmaceutical Sciences, Lam, Guntur.

Preceptor :-
(Dr.Y.Sravani)

Staff In charge:
(Dr.Ravi Nagalekhini)
Department of Pharmacy Practice
B-Class IInd Floor, Inpatient Block
Govt. General Hospital
GUNTUR-522 001

Head Of the Department :
(Dr.N.V.Ramarao)

Head of the Department
Department of Pharmacy Practice
B-Class, IInd Floor, Inpatient Block
Govt. General Hospital
Chalapathi Institute of Pharmaceutical Sciences
GUNTUR-522 0

Examiners :-

1. External 16/04/2021

2.Internal 16/04/2021

PRINCIPAL
Chalapathi Institute of Pharmaceutical Sciences
(Autonomous)
Chalapathi Nagar LAM, GUNTUR-34.

CLERKSHIP REPORT

May 2020 to Feburary 2021

V/VI Pharm.D

DOCTOR OF PHARMACY

Submitted by

Ms. TANUJA. SUGGUNA

REG. NO: Y16PHD0127

DEPARTMENT OF PHARMACY PRACTICE,
GOVT. GENERAL HOSPITAL,
CHALAPATHI INSTITUTE OF PHARMACEUTICAL SCIENCES,
(AUTONOMOUS)
Accredited by NAAC with "A" Grade
CHALAPATHI NAGAR, LAM, GUNTUR.

CHALAPATHI INSTITUTE OF PHARMACEUTICAL SCIENCES (Autonomous) LAM, GUNTUR-34.

PRINCIPAL
Chalapathi Institute of Pharmaceutical Sciences
(Autonomous)
Chalapathi Nagar LAM, GUNTUR-34.

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 *TANUJA.SUGGUNA*, Regd.No: Y16PHD0127 in the V/VI Pharm.D during the year 2020 - 2021 in the Department of Pharmacy Practice, Govt. General Hospital, A Unit of Chalapathi Institute of Pharmaceutical Sciences, Lam, Guntur.

Preceptor: -
(Dr. Y. Sravani)

Examiners:-

Staff in charge:
(Dr. Ravi Nagalekhini)
Department of Pharmacy Practice
B-Class IInd Floor, Inpatient Block
Govt. General Hospital
GUNTUR-522 001

1. External 16/04/2021

2. Internal 16/04/2021

Signature of HOD
(Dr. N.V. Ramarao)
Head of the Department
Department of Pharmacy Practice
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GUNTUR-522 001

CHALAPATHI INSTITUTE OF PHARMACEUTICAL SCIENCES (Autonomous) LAM, GUNTUR-34

PRINCIPAL
Chalapathi Institute of Pharmaceutical Sciences
(Autonomous)
Chalapathi Nagar LAM, GUNTUR-34

CLERKSHIP REPORT

May 2020 to February 2021

V/VI Pharm.D

DOCTOR OF PHARMACY

Submitted by

Mr.SRIHARSHA. RAVIPATI,

REG. NO: Y16PHD0128

DEPARTMENT OF PHARMACY PRACTICE,

GOVT. GENERAL HOSPITAL,

CHALAPATHI INSTITUTE OF PHARMACEUTICAL SCIENCES,

(AUTONOMOUS)

Accredited by NAAC with "A" Grade

CHALAPATHI NAGAR, LAM, GUNTUR.

CHALAPATHI INSTITUTE OF PHARMACEUTICAL SCIENCES (Autonomous) LAM, GUNTUR-34.

PRINCIPAL
Chalapathi Institute of Pharmaceutical Sciences
(Autonomous)
Chalapathi Nagar LAM, GUNTUR-34

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 *SRIHARSHA.RAVIPATI* Regd.No: *Y16PHD0128* in the V/VI PharmD during the year 2020 - 2021 in the Department of Pharmacy Practice, Govt. General Hospital, A Unit of Chalapathi Institute of Pharmaceutical Sciences, Lam, Guntur.

Preceptor: -
(Dr. Y. Sravani)

Staff In charge:
(Dr. Ravi Nagalekhini)
Department of Pharmacy Practice
B-Class IInd Floor, Inpatient Block
Govt. General Hospital
GUNTUR-522 001

Signature of HOD
(Dr. N. V. Ramarao)

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

2. Internal

PRINCIPAL
Chalapathi Institute of Pharmaceutical Sciences
(Autonomous)
Chalapathi Nagar LAM, GUNTUR-34

CLERKSHIP REPORT

May 2020 to February2021

V/VI Pharm.D

DOCTOR OF PHARMACY

Submitted by

Mr.VUSURUMARTHI BOLA SHANKAR

REG. NO: Y16PHD0129

DEPARTMENT OF PHARMACY PRACTICE,

GOVT. GENERAL HOSPITAL,

CHALAPATHI INSTITUTE OF PHARMACEUTICAL SCIENCES,

(AUTONOMOUS)

Accredited by NAAC with "A" Grade

CHALAPATHI NAGAR, LAM, GUNTUR.

CHALAPATHI INSTITUTE OF PHARMACEUTICAL SCIENCES (Autonomous) LAM, GUNTUR-34

PRINCIPAL
Chalapathi Institute of Pharmaceutical Sciences
(Autonomous)
Chalapathi Nagar LAM, GUNTUR-34.

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 "VUSURUMARTHI BOLA SHANKAR", Regd.No: Y16PHD0129, in the V/VI PHARM.D during the year 2020-2021 in the Department of pharmacy practice, Govt.General hospital, A unit of Chalapathi Institute of Pharmaceutical Sciences, Lam, Guntur.

Preceptor: -
(Dr.Y. Sravani)

Staff Incharge: -
(Dr.R. Naga Lekhini)
Department of Pharmacy Practice
B-Class. IInd Floor, Inpatient Block
Govt. General Hospital
GUNTUR-522 001

HOD: -
(Dr.N.V. Rama Rao)
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: - 16/04/2021

2.Internal: - 16/04/2021

PRINCIPAL
Chalapathi Institute of Pharmaceutical Sciences
(Autonomous)
Chalapathi Nagar, LAM, GUNTUR-3

CLERKSHIP REPORT

May 2020 to February2021

V/VI Pharm.D

DOCTOR OF PHARMACY

Submitted by

Ms.VUSURUMURTHYDURGA DEVI

REG. NO: Y16PHD0130

DEPARTMENT OF PHARMACY PRACTICE,
GOVT. GENERAL HOSPITAL,
CHALAPATHI INSTITUTE OF PHARMACEUTICAL SCIENCES,
(AUTONOMOUS)
Accredited by NAAC with "A" Grade
CHALAPATHI NAGAR, LAM, GUNTUR.

CHALAPATHI INSTITUTE OF PHARMACEUTICAL SCIENCES (Autonomous) LAM, GUNTUR-34

PRINCIPAL
Chalapathi Institute of Pharmaceutical Sciences
(Autonomous)
Chalapathi Nagar LAM, GUNTUR-34.

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 "VUSURUMURTHY DURGADEVI," Regd.No: Y16PHD0130, in the V/VI PHARM.D during the year 2020-2021 in the Department of Pharmacy Practice, Govt.General hospital, A Unit of Chalapathi Institute of Pharmaceutical Sciences, Lam, Guntur.

Preceptor: -
(Dr.Y. Sravani)

Examiners: -

Staff Incharge: -
(Dr.R. Naga Lekhini)
Department of Pharmacy Practice
B-Class IInd Floor, Inpatient Block
Govt. General Hospital
GUNTUR-522 001

1. External: -

HOD: -
(Dr.N.V. Rama Rao)
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

2. Internal: -
16/04/2021

CHALAPATHI INSTITUTE OF PHARMACEUTICAL SCIENCES (Autonomous) LAM, GUNTUR-34.

PRINCIPAL
Chalapathi Institute of Pharmaceutical Sciences
(Autonomous)

CLERKSHIP REPORT

May 2020 to February 2021

V/VI Pharm.D (PB)

DOCTOR OF PHARMACY

Submitted by

ANISETTY.NOMITHA

Redg. NO: L19PHD0131

DEPARTMENT OF PHARMACY PRACTICE,
GOVT. GENERAL HOSPITAL,
CHALAPATHI INSTITUTE OF PHARMACEUTICAL SCIENCES,
(AUTONOMOUS)
Accredited by NAAC with "A" Grade
CHALAPATHI NAGAR, LAM, GUNTUR.

CHALAPATHI INSTITUTE OF PHARMACEUTICAL SCIENCES (Autonomous) LAM, GUNTUR-34.

PRINCIPAL
Chalapathi Institute of Pharmaceutical Sciences
(Autonomous)
Chalapathi Nagar LAM, GUNTUR-34

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

ANISETTY NOMITHA, Regd. No: L19PHD0131 in the V/VI Pharm D during the year 2020 - 2021 in the Department of Pharmacy Practice, Govt. General Hospital, A Unit of Chalapathi Institute of Pharmaceutical Sciences, Lam, Guntur.

Preceptor :-
(Dr.Y.Sravani)

Staff in charge :-
(Dr. Ravi NagaLekhini)
Department of Pharmacy Practice
B-Class IInd Floor, Inpatient Block
Govt. General Hospital
GUNTUR-522 001

HOD :-
(Dr.N.V.Ramarao)
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 16/04/2021

2. Internal 16/04/2021

PRINCIPAL
Chalapathi Institute of Pharmaceutical Sciences
(Autonomous)
Chalapathi Nagar LAM, GUNTUR-34.

CLERKSHIP REPORT

May 2020 to February 2021

V/VI Pharm D (P.B)

DOCTOR OF PHARMACY

Submitted by

Ms. Dandibhotla. Parvathi

Regd.No: L19PHD0132

DEPARTMENT OF PHARMACY PRACTICE,

GOVT. GENERAL HOSPITAL,

CHALAPATHI INSTITUTE OF PHARMACEUTICAL SCIENCES.

(AUTONOMOUS)

Accredited with "A" Gradeby NAAC

CHALAPATHI NAGAR, LAM, GUNTUR- 522034.

(Autonomous) LAM, GUNTUR-34

PRINCIPAL
Chalapathi Institute of Pharmaceutical Sciences
(Autonomous)
Chalapathi Nagar, LAM, GUNTUR-34

CHALAPATHI

INSTITUTE OF PHARMACEUTICAL SCIENCES

(AUTONOMOUS)

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

Accredited with "A" Grade by NAAC

I.S.O. 9001: 2008 CERTIFIED INSTITUTION

CERTIFICATE

Certified that this is a bonafide record of the Clerkship done by *"DANDIBHOTLA.PARVATHI"* of **Regd. No: L19PHD0132** in the V/VI Pharm D during the year 2020-2021 in the Department of Pharmacy Practice, Government General Hospital, A Unit of Chalapathi Institute of Pharmaceutical Sciences, Lam, Guntur.

Preceptor:
(Dr. Y. Sravani)

Staff In charge:
(Dr. Ravi NagaLekhini)
Department of Pharmacy Practice
B-Class, IInd Floor, Inpatient Block
Govt. General Hospital
GUNTUR-522 001

HOD:
(Dr. N. V. Rama Rao)
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 16/04/2021

2.Internal 16/04/2021

CHALAPATHI INSTITUTE OF PHARMACEUTICAL SCIENCES (Autonomous) LAM, GUNTUR-34

PRINCIPAL
Chalapathi Institute of Pharmaceutical Sciences
(Autonomous)
Chalapathi Nagar LAM, GUNTUR-522

CHALAPATHI INSTITUTE OF PHARMACEUTICAL SCIENCES

DEPARTMENT OF PHARMACY PRACTICE
GOVERNMENT GENERAL HOSPITAL, GUNTUR

<>NIRF-All India 54th Rank-2020<>

INTERNSHIP CERTIFICATE

This is to certify that **Mr. KONIDANA DILEEPCHAND**, Regd. No.: Y15PHD0101, S/o. KONIDANA NAGAMALLESWARA RAO has successfully completed his **INTERNSHIP** as per the Academic curriculum of **DOCTOR OF PHARMACY (PHARM.D)** prescribed by Pharmacy Council of India (Under Regulation 16 and Appendix C of Doctor of Pharmacy Council Regulation 2008), New Delhi and the Acharya Nagarjuna University, Nagarjuna Nagar, Guntur in Govt. General Hospital, Guntur, Andhra Pradesh, India from **May-2020 To April-2021.**

Department	Under Doctor	Period	Duration
GENERAL MEDICINE	Dr. Y. V. L. NARASIMHAM	01-05-2020 To 31-10-2020	06 Months
PEDIATRICS	Dr. C. N. MOHAN CHANDRAN	01-11-2020 To 31-12-2020	02 Months
OBSTETRICS & GYNECOLOGY	Dr. P. CHANDRA SEKHAR RAO	01-03-2021 To 30-04-2021	02 Months
PSYCHIATRY	Dr. P. LOKESWARA REDDY	01-01-2021 To 28-02-2021	02 Months

He is eligible for award of the Doctor of Pharmacy (Pharm.D) Degree of the Acharya Nagarjuna University, Guntur, A.P. During this period his work has been Satisfactory.

Dr. N. Prabhavathi
Medical Superintendent,
Govt. General Hospital,
Guntur, A.P., India
Superintendent
Govt. General Hospital
GUNTUR

CHALAPATHI INSTITUTE OF PHARMACEUTICAL SCIENCES
Dt. 15/06/2021
LAM, GUNTUR-34.

15/06/2021
Prof. Rama Rao Nadendla
Principal,
Chalapathi Inst. of Pharma.
Sciences, Lam, Guntur, A.P.
PRINCIPAL
Chalapathi Institute of Pharmaceutical Sciences
Chalapathi Nagar, LAM, GUNTUR-34.

CHALAPATHI INSTITUTE OF PHARMACEUTICAL SCIENCES (Autonomous) LAM, GUNTUR-34.

PRINCIPAL
Chalapathi Institute of Pharmaceutical Sciences
(Autonomous)
Chalapathi Nagar LAM, GUNTUR-34

CHALAPATHI INSTITUTE OF PHARMACEUTICAL SCIENCES

DEPARTMENT OF PHARMACY PRACTICE
GOVERNMENT GENERAL HOSPITAL, GUNTUR

<>NIRF-All India 54th Rank-2020<>

INTERNSHIP CERTIFICATE

This is to certify that **Mr. MALEMPATI PRAVEEN**, Regd. No.: Y15PHD0102, S/o. MALEMPATI VENKATA SUBBA RAO has successfully completed his **INTERNSHIP** as per the Academic curriculum of **DOCTOR OF PHARMACY (PHARM.D)** prescribed by Pharmacy Council of India (Under Regulation 16 and Appendix C of Doctor of Pharmacy Council Regulation 2008), New Delhi and the Acharya Nagarjuna University, Nagarjuna Nagar, Guntur in Govt. General Hospital, Guntur, Andhra Pradesh, India from **May-2020 To April-2021.**

Department	Under Doctor	Period	Duration
GENERAL MEDICINE	Dr. Y. V. L. NARASIMHAM	01-07-2020 To 31-12-2020	06 Months
PEDIATRICS	Dr. C. N. MOHAN CHANDRAN	01-01-2021 To 28-02-2021	02 Months
OBSTETRICS & GYNECOLOGY	Dr. P. CHANDRA SEKHAR RAO	01-05-2020 To 30-06-2020	02 Months
PSYCHIATRY	Dr. P. LOKESWARA REDDY	01-03-2021 To 30-04-2021	02 Months

He is eligible for award of the Doctor of Pharmacy (Pharm.D) Degree of the Acharya Nagarjuna University, Guntur, A.P. During this period his work has been Satisfactory.

Dr. N. Prabhavathi
Medical Superintendent,
Govt. General Hospital,
Guntur, A.P., India

Superintendent
Govt. General Hospital
GUNTUR

CHALAPATHI INSTITUTE OF PHARMACEUTICAL SCIENCES ★ LAM, GUNTUR-34.

15/06/2021

Prof. Rama Rao Nadendla
Principal,
Chalapathi Inst. of Pharma.
Sciences, Lam, Guntur, A.P.

PRINCIPAL
Chalapathi Institute of Pharmaceutical Sciences
Chalapathi Nagar, LAM, GUNTUR-34.

CHALAPATHI INSTITUTE OF PHARMACEUTICAL SCIENCES (Autonomous) LAM, GUNTUR-34.

PRINCIPAL
Chalapathi Institute of Pharmaceutical Sciences
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Chalapathi Nagar LAM, GUNTUR-34

CHALAPATHI INSTITUTE OF PHARMACEUTICAL SCIENCES

DEPARTMENT OF PHARMACY PRACTICE

GOVERNMENT GENERAL HOSPITAL, GUNTUR

<>NIRF-All India 54th Rank-2020<>

INTERNSHIP CERTIFICATE

This is to certify that **Miss. SRUJANA BIRUDU**, Regd. No.: Y15PHD0103, D/o. SANKARAIAH has successfully completed her **INTERNSHIP** as per the Academic curriculum of **DOCTOR OF PHARMACY (PHARM.D)** prescribed by Pharmacy Council of India (Under Regulation 16 and Appendix C of Doctor of Pharmacy Council Regulation 2008), New Delhi and the Acharya Nagarjuna University, Nagarjuna Nagar, Guntur in Govt. General Hospital, Guntur, Andhra Pradesh, India from **May-2020 To April-2021.**

Department	Under Doctor	Period	Duration
GENERAL MEDICINE	Dr. Y. V. L. NARASIMHAM	01-09-2020 To 28-02-2021	06 Months
PEDIATRICS	Dr. C. N. MOHAN CHANDRAN	01-03-2021 To 30-04-2021	02 Months
OBSTETRICS & GYNECOLOGY	Dr. P. CHANDRA SEKHAR RAO	01-07-2020 To 31-08-2020	02 Months
PSYCHIATRY	Dr. P. LOKESWARA REDDY	01-05-2020 To 30-06-2020	02 Months

She is eligible for award of the Doctor of Pharmacy (Pharm.D) Degree of the Acharya Nagarjuna University, Guntur, A.P. During this period her work has been Satisfactory.

Dr. N. Prabhavathi
Medical Superintendent,
Govt. General Hospital,
Guntur, A.P., India
Superintendent
Govt. General Hospital
GUNTUR

CHALAPATHI INSTITUTE OF PHARMACEUTICAL SCIENCES ★ Dt. 15/06/2021 LAM, GUNTUR-34

15/06/2021
Prof. Rama Rao Nadendla
Principal,
Chalapathi Inst. of Pharma.
Sciences, Lam, Guntur, A.P.
PRINCIPAL
Chalapathi Institute of Pharmaceutical Sciences
Chalapathi Nagar, LAM, GUNTUR-34.

CHALAPATHI INSTITUTE OF PHARMACEUTICAL SCIENCES (Autonomous) LAM, GUNTUR-34

PRINCIPAL
Chalapathi Institute of Pharmaceutical Sciences
(Autonomous)
Chalapathi Nagar LAM, GUNTUR-34

CHALAPATHI INSTITUTE OF PHARMACEUTICAL SCIENCES

DEPARTMENT OF PHARMACY PRACTICE
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<>NIRF-All India 54th Rank-2020<>

INTERNSHIP CERTIFICATE

This is to certify that **Mr. VUDUTHURI MAHESHWARA REDDY**, Regd. No.: Y15PHD0104, S/o. VUDUTHURI OM PRAKASH REDDY has successfully completed his **INTERNSHIP** as per the Academic curriculum of **DOCTOR OF PHARMACY (PHARM.D)** prescribed by Pharmacy Council of India (Under Regulation 16 and Appendix C of Doctor of Pharmacy Council Regulation 2008), New Delhi and the Acharya Nagarjuna University, Nagarjuna Nagar, Guntur in Govt. General Hospital, Guntur, Andhra Pradesh, India from **May-2020 To April-2021.**

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OBSTETRICS & GYNECOLOGY	Dr. P. CHANDRA SEKHAR RAO	01-09-2020 To 31-10-2020	02 Months
PSYCHIATRY	Dr. P. LOKESWARA REDDY	01-07-2020 To 31-08-2020	02 Months

He is eligible for award of the Doctor of Pharmacy (Pharm.D) Degree of the Acharya Nagarjuna University, Guntur, A.P. During this period his work has been Satisfactory.

Dr. N. Prabhavathi
Medical Superintendent,
Govt. General Hospital,
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CHALAPATHI INSTITUTE OF PHARMACEUTICAL SCIENCES
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INTERNSHIP CERTIFICATE

This is to certify that **Mr. ACHYUTHA VENKATA NAGANJANEYULU**, Regd. No.: Y15PHD0105, S/o. ACHYUTHA SIVA KONDALU has successfully completed his **INTERNSHIP** as per the Academic curriculum of **DOCTOR OF PHARMACY (PHARM.D)** prescribed by Pharmacy Council of India (Under Regulation 16 and Appendix C of Doctor of Pharmacy Council Regulation 2008), New Delhi and the Acharya Nagarjuna University, Nagarjuna Nagar, Guntur in Govt. General Hospital, Guntur, Andhra Pradesh, India from **May-2020 To April-2021.**

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INTERNSHIP CERTIFICATE

This is to certify that **Miss. AMUDALAPALLI SURYA RACHANA**, Regd. No.: Y15PHD0106, D/o. AMUDALAPALLI V DURGA PRASAD has successfully completed her **INTERNSHIP** as per the Academic curriculum of **DOCTOR OF PHARMACY (PHARM.D)** prescribed by Pharmacy Council of India (Under Regulation 16 and Appendix C of Doctor of Pharmacy Council Regulation 2008), New Delhi and the Acharya Nagarjuna University, Nagarjuna Nagar, Guntur in Govt. General Hospital, Guntur, Andhra Pradesh, India from **May-2020 To April-2021.**

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INTERNSHIP CERTIFICATE

This is to certify that **Miss. BANDLA RUPASREE**, Regd. No.: Y15PHD0107, D/o. BANDLA SADA SIVA RAO has successfully completed her **INTERNSHIP** as per the Academic curriculum of **DOCTOR OF PHARMACY (PHARM.D)** prescribed by Pharmacy Council of India (Under Regulation 16 and Appendix C of Doctor of Pharmacy Council Regulation 2008), New Delhi and the Acharya Nagarjuna University, Nagarjuna Nagar, Guntur in Govt. General Hospital, Guntur, Andhra Pradesh, India from **May-2020 To April-2021.**

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INTERNSHIP CERTIFICATE

This is to certify that **Miss. BHASHYAM NAGA NEELIMA**, Regd. No.: Y15PHD0108, D/o. BHASHYAM SAMBASIVA RAO has successfully completed her **INTERNSHIP** as per the Academic curriculum of **DOCTOR OF PHARMACY (PHARM.D)** prescribed by Pharmacy Council of India (Under Regulation 16 and Appendix C of Doctor of Pharmacy Council Regulation 2008), New Delhi and the Acharya Nagarjuna University, Nagarjuna Nagar, Guntur in Govt. General Hospital, Guntur, Andhra Pradesh, India from **May-2020 To April-2021.**

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This is to certify that **Mr. DHANEKULA GOPI ABHISHEK**, Regd. No.: Y15PHD0109, S/o. DHANEKULA SIVA PRASAD has successfully completed his **INTERNSHIP** as per the Academic curriculum of **DOCTOR OF PHARMACY (PHARM.D)** prescribed by Pharmacy Council of India (Under Regulation 16 and Appendix C of Doctor of Pharmacy Council Regulation 2008), New Delhi and the Acharya Nagarjuna University, Nagarjuna Nagar, Guntur in Govt. General Hospital, Guntur, Andhra Pradesh, India from **May-2020 To April-2021.**

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INTERNSHIP CERTIFICATE

This is to certify that **Miss. GURRAM GAYATHRI**, Regd. No.: Y15PHD0110, D/o. GURRAM SATYAMA REDDY has successfully completed her **INTERNSHIP** as per the Academic curriculum of **DOCTOR OF PHARMACY (PHARM.D)** prescribed by Pharmacy Council of India (Under Regulation 16 and Appendix C of Doctor of Pharmacy Council Regulation 2008), New Delhi and the Acharya Nagarjuna University, Nagarjuna Nagar, Guntur in Govt. General Hospital, Guntur, Andhra Pradesh, India from **May-2020 To April-2021.**

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Dr. N. Prabhavathi
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INTERNSHIP CERTIFICATE

This is to certify that **Miss. JANGA ALAN ROSE**, Regd. No.: Y15PHD0111, D/o. JANGA MOHANA RAO has successfully completed her **INTERNSHIP** as per the Academic curriculum of **DOCTOR OF PHARMACY (PHARM.D)** prescribed by Pharmacy Council of India (Under Regulation 16 and Appendix C of Doctor of Pharmacy Council Regulation 2008), New Delhi and the Acharya Nagarjuna University, Nagarjuna Nagar, Guntur in Govt. General Hospital, Guntur, Andhra Pradesh, India from **May-2020 To April-2021.**

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Govt. General Hospital
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INTERNSHIP CERTIFICATE

This is to certify that **Miss. KAMMELA NAGA MOUNIKA**, Regd. No.: Y15PHD0112, D/o. KAMMELA SRINIVASA RAO has successfully completed her **INTERNSHIP** as per the Academic curriculum of **DOCTOR OF PHARMACY (PHARM.D)** prescribed by Pharmacy Council of India (Under Regulation 16 and Appendix C of Doctor of Pharmacy Council Regulation 2008), New Delhi and the Acharya Nagarjuna University, Nagarjuna Nagar, Guntur in Govt. General Hospital, Guntur, Andhra Pradesh, India from **May-2020 To April-2021.**

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INTERNSHIP CERTIFICATE

This is to certify that **Miss.** KANUMURI TEJASWINI, Regd. No.: Y15PHD0113, D/o. KANUMURI KOTESWARA RAO has successfully completed her **INTERNSHIP** as per the Academic curriculum of **DOCTOR OF PHARMACY (PHARM.D)** prescribed by Pharmacy Council of India (Under Regulation 16 and Appendix C of Doctor of Pharmacy Council Regulation 2008), New Delhi and the Acharya Nagarjuna University, Nagarjuna Nagar, Guntur in Govt. General Hospital, Guntur, Andhra Pradesh, India from **May-2020 To April-2021.**

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This is to certify that **Miss. KATTA ROJA,** Regd. No.: Y15PHD0114, D/o. KATTA PITCHAIAH has successfully completed her **INTERNSHIP** as per the Academic curriculum of **DOCTOR OF PHARMACY (PHARM.D)** prescribed by Pharmacy Council of India (Under Regulation 16 and Appendix C of Doctor of Pharmacy Council Regulation 2008), New Delhi and the Acharya Nagarjuna University, Nagarjuna Nagar, Guntur in Govt. General Hospital, Guntur, Andhra Pradesh, India from **May-2020 To April-2021.**

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INTERNSHIP CERTIFICATE

This is to certify that **Miss. KOKA NAGA SRI**, Regd. No.: Y15PHD0115, D/o. KOKA NAGESWARA RAO has successfully completed her **INTERNSHIP** as per the Academic curriculum of **DOCTOR OF PHARMACY (PHARM.D)** prescribed by Pharmacy Council of India (Under Regulation 16 and Appendix C of Doctor of Pharmacy Council Regulation 2008), New Delhi and the Acharya Nagarjuna University, Nagarjuna Nagar, Guntur in Govt. General Hospital, Guntur, Andhra Pradesh, India from **May-2020 To April-2021.**

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PEDIATRICS	Dr. C. N. MOHAN CHANDRAN	01-03-2021 To 30-04-2021	02 Months
OBSTETRICS & GYNECOLOGY	Dr. P. CHANDRA SEKHAR RAO	01-07-2020 To 31-08-2020	02 Months
PSYCHIATRY	Dr. P. LOKESWARA REDDY	01-05-2020 To 30-06-2020	02 Months

She is eligible for award of the Doctor of Pharmacy (Pharm.D) Degree of the Acharya Nagarjuna University, Guntur, A.P. During this period her work has been Satisfactory.

Dr. N. Prabhavathi
Medical Superintendent,
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Guntur, A.P., India
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Govt. General Hospital
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CHALAPATHI INSTITUTE OF PHARMACEUTICAL SCIENCES
Dt. 15/06/2021
LAM, GUNTUR-34.

15/6/2021
Prof. Rama Rao Nadendla
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<>NIRF-All India 54th Rank-2020<>

INTERNSHIP CERTIFICATE

This is to certify that **Mr. KONDAREDDY SAI PRAVEEN KUMAR**, Regd. No.: Y15PHD0116, S/o. SRINIVASA RAO has successfully completed his **INTERNSHIP** as per the Academic curriculum of **DOCTOR OF PHARMACY (PHARM.D)** prescribed by Pharmacy Council of India (Under Regulation 16 and Appendix C of Doctor of Pharmacy Council Regulation 2008), New Delhi and the Acharya Nagarjuna University, Nagarjuna Nagar, Guntur in Govt. General Hospital, Guntur, Andhra Pradesh, India from **May-2020 To April-2021.**

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OBSTETRICS & GYNECOLOGY	Dr. P. CHANDRA SEKHAR RAO	01-09-2020 To 31-10-2020	02 Months
PSYCHIATRY	Dr. P. LOKESWARA REDDY	01-07-2020 To 31-08-2020	02 Months

He is eligible for award of the Doctor of Pharmacy (Pharm.D) Degree of the Acharya Nagarjuna University, Guntur, A.P. During this period his work has been Satisfactory.

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INTERNSHIP CERTIFICATE

This is to certify that **Miss. MALLIPEDDI BHARGAVI,** Regd. No.: Y15PHD0117, D/o. MALLIPEDDI RAMESH has successfully completed her **INTERNSHIP** as per the Academic curriculum of **DOCTOR OF PHARMACY (PHARM.D)** prescribed by Pharmacy Council of India (Under Regulation 16 and Appendix C of Doctor of Pharmacy Council Regulation 2008), New Delhi and the Acharya Nagarjuna University, Nagarjuna Nagar, Guntur in Govt. General Hospital, Guntur, Andhra Pradesh, India from **May-2020 To April-2021.**

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OBSTETRICS & GYNECOLOGY	Dr. P. CHANDRA SEKHAR RAO	01-03-2021 To 30-04-2021	02 Months
PSYCHIATRY	Dr. P. LOKESWARA REDDY	01-01-2021 To 28-02-2021	02 Months

She is eligible for award of the Doctor of Pharmacy (Pharm.D) Degree of the Acharya Nagarjuna University, Guntur, A.P. During this period her work has been Satisfactory.

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INTERNSHIP CERTIFICATE

This is to certify that **Mr. MOHAMMAD ASLAM,** Regd. No.: Y15PHD0118, S/o. MOHAMMAD KHALEEL has successfully completed his **INTERNSHIP** as per the Academic curriculum of **DOCTOR OF PHARMACY (PHARM.D)** prescribed by Pharmacy Council of India (Under Regulation 16 and Appendix C of Doctor of Pharmacy Council Regulation 2008), New Delhi and the Acharya Nagarjuna University, Nagarjuna Nagar, Guntur in Govt. General Hospital, Guntur, Andhra Pradesh, India from **May-2020 To April-2021.**

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PSYCHIATRY	Dr. P. LOKESWARA REDDY	01-03-2021 To 30-04-2021	02 Months

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INTERNSHIP CERTIFICATE

This is to certify that **Miss.** MOPARTHI SWAPNA, Regd. No.: Y15PHD0119, D/o. MOPARTHI SURI BABU has successfully completed her **INTERNSHIP** as per the Academic curriculum of **DOCTOR OF PHARMACY (PHARM.D)** prescribed by Pharmacy Council of India (Under Regulation 16 and Appendix C of Doctor of Pharmacy Council Regulation 2008), New Delhi and the Acharya Nagarjuna University, Nagarjuna Nagar, Guntur in Govt. General Hospital, Guntur, Andhra Pradesh, India from **May-2020 To April-2021.**

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She is eligible for award of the Doctor of Pharmacy (Pharm.D) Degree of the Acharya Nagarjuna University, Guntur, A.P. During this period her work has been Satisfactory.

Dr. N. Prabhavathi
Medical Superintendent,
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15/06/2021

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INTERNSHIP CERTIFICATE

This is to certify that **Miss. NADENDLA BALA SARASWATHI,** Regd. No.: Y15PHD0120, D/o. NADENDLA SUBBA RAO has successfully completed her **INTERNSHIP** as per the Academic curriculum of **DOCTOR OF PHARMACY (PHARM.D)** prescribed by Pharmacy Council of India (Under Regulation 16 and Appendix C of Doctor of Pharmacy Council Regulation 2008), New Delhi and the Acharya Nagarjuna University, Nagarjuna Nagar, Guntur in Govt. General Hospital, Guntur, Andhra Pradesh, India from **May-2020 To April-2021.**

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INTERNSHIP CERTIFICATE

This is to certify that **Miss. NAGULA PRATHYUSHA**, Regd. No.: Y15PHD0121, D/o. N VISHNUVARDHAN has successfully completed her **INTERNSHIP** as per the Academic curriculum of **DOCTOR OF PHARMACY (PHARM.D)** prescribed by Pharmacy Council of India (Under Regulation 16 and Appendix C of Doctor of Pharmacy Council Regulation 2008), New Delhi and the Acharya Nagarjuna University, Nagarjuna Nagar, Guntur in Govt. General Hospital, Guntur, Andhra Pradesh, India from **May-2020 To April-2021.**

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Dr. N. Prabhavathi
Medical Superintendent,
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DEPARTMENT OF PHARMACY PRACTICE
GOVERNMENT GENERAL HOSPITAL, GUNTUR

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INTERNSHIP CERTIFICATE

This is to certify that **Miss.** **NAVUDURI SRI NAGA SWATHI GOWRI**, Regd. No.: Y15PHD0122, D/o. NAVUDURI SRINIVASA RAO has successfully completed her **INTERNSHIP** as per the Academic curriculum of **DOCTOR OF PHARMACY (PHARM.D)** prescribed by Pharmacy Council of India (Under Regulation 16 and Appendix C of Doctor of Pharmacy Council Regulation 2008), New Delhi and the Acharya Nagarjuna University, Nagarjuna Nagar, Guntur in Govt. General Hospital, Guntur, Andhra Pradesh, India from **May-2020 To April-2021.**

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INTERNSHIP CERTIFICATE

This is to certify that **Miss. PILLI OLIVE NAVANEETHAM**, Regd. No.: Y15PHD0123, D/o. PILLI VINAYA KUMAR has successfully completed her **INTERNSHIP** as per the Academic curriculum of **DOCTOR OF PHARMACY (PHARM.D)** prescribed by Pharmacy Council of India (Under Regulation 16 and Appendix C of Doctor of Pharmacy Council Regulation 2008), New Delhi and the Acharya Nagarjuna University, Nagarjuna Nagar, Guntur in Govt. General Hospital, Guntur, Andhra Pradesh, India from **May-2020 To April-2021.**

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PSYCHIATRY	Dr. P. LOKESWARA REDDY	01-05-2020 To 30-06-2020	02 Months

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INTERNSHIP CERTIFICATE

This is to certify that **Mr. PULIVARTHI VENKATA SAI SRINIVAS**, Regd. No.: Y15PHD0124, S/o. PULIVARTHI RAMANAIAH has successfully completed his **INTERNSHIP** as per the Academic curriculum of **DOCTOR OF PHARMACY (PHARM.D)** prescribed by Pharmacy Council of India (Under Regulation 16 and Appendix C of Doctor of Pharmacy Council Regulation 2008), New Delhi and the Acharya Nagarjuna University, Nagarjuna Nagar, Guntur in Govt. General Hospital, Guntur, Andhra Pradesh, India from **May-2020 To April-2021.**

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PSYCHIATRY	Dr. P. LOKESWARA REDDY	01-07-2020 To 31-08-2020	02 Months

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INTERNSHIP CERTIFICATE

This is to certify that **Miss. SATHINENI JYOTHI NAGA MOHANA**, Regd. No.: Y15PHD0125, D/o. SATHINENI SUBBA RAO has successfully completed her **INTERNSHIP** as per the Academic curriculum of **DOCTOR OF PHARMACY (PHARM.D)** prescribed by Pharmacy Council of India (Under Regulation 16 and Appendix C of Doctor of Pharmacy Council Regulation 2008), New Delhi and the Acharya Nagarjuna University, Nagarjuna Nagar, Guntur in Govt. General Hospital, Guntur, Andhra Pradesh, India from **May-2020 To April-2021.**

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INTERNSHIP CERTIFICATE

This is to certify that **Mr. SURESH DAVALA,** Regd. No.: Y15PHD0127, S/o. NAGESWARA RAO has successfully completed his **INTERNSHIP** as per the Academic curriculum of **DOCTOR OF PHARMACY (PHARM.D)** prescribed by Pharmacy Council of India (Under Regulation 16 and Appendix C of Doctor of Pharmacy Council Regulation 2008), New Delhi and the Acharya Nagarjuna University, Nagarjuna Nagar, Guntur in Govt. General Hospital, Guntur, Andhra Pradesh, India from **May-2020 To April-2021.**

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PEDIATRICS	Dr. C. N. MOHAN CHANDRAN	01-01-2021 To 28-02-2021	02 Months
OBSTETRICS & GYNECOLOGY	Dr. P. CHANDRA SEKHAR RAO	01-05-2020 To 30-06-2020	02 Months
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Department	Under Doctor	Period	Duration
GENERAL MEDICINE	Dr. Y. V. L. NARASIMHAM	01-09-2020 To 28-02-2021	06 Months
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GENERAL MEDICINE	Dr. Y. V. L. NARASIMHAM	01-11-2020 To 30-04-2021	06 Months
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GENERAL MEDICINE	Dr. Y. V. L. NARASIMHAM	01-07-2020 To 31-12-2020	06 Months
PEDIATRICS	Dr. C. N. MOHAN CHANDRAN	01-01-2021 To 28-02-2021	02 Months
OBSTETRICS & GYNECOLOGY	Dr. P. CHANDRA SEKHAR RAO	01-05-2020 To 30-06-2020	02 Months
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DESIGN, CHARACTERIZATION AND *IN-VITRO* EVALUATION OF FAVIPIRAVIR LOADED MOUTH DISSOLVING TABLETS USING SUPERDISINTEGRANTS

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)

Submitted by

D.Avinash
(Y19MPHPC401)

Under the guidance of

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1. ABSTRACT

Favipiravir is a novel drug used in treatment of many viral diseases such as Ebola, covid-19.Mouth dissolving tablets is the most suitable drug delivery at a faster rate and improve patient compliance. They release drug by disintegrating within minute. The preparation of the mouth dissolving tabets was done by using wet granulation technique, and study was based on the formulating the tablets using different superdisintegrants. The main objective of this research is to study the effect of superdisintegrant on drug release of the mouth dissolving tablets. The optimization of the tablets was totally based on evaluating the various parameters such as hardness, thickness, friability, percent weight variation, drug content disintegration time, wetting time, water absorption ratio, *in-vitro* drug release data was evaluated and the optimized formulation was found and subjected to the accelerated stability studies.

FORMULATION AND PRECLINICAL EVALUATION OF ANTI - INFLAMMATORY ACTIVITY OF TRITICUM AESTIVUM

Thesis submitted to

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ABSTRACT

A wide scope of medical advantages has been credited to wheatgrass, the young grass of the wheat plant Tritium aestivum. Wheat grass is a wellspring of mineral supplements. It contains critical measures of iron, phosphorous, magnesium, manganese, copper and zinc. Wheatgrass is a rich supplement of tocopherols with high vitamin E content. Wheatgrass is beneficial in restoring more infections due to its significant function that, it can arrest the development of antagonistic microbes which are responsible for spreading certain diseases. Constituents of wheatgrass may be obtained from fresh juice, frozen juice, powder, tablets with compositions differing as per their production methods which otherwise depends on growing conditions of wheatgrass. In this flaxseed gel, starch, magnesium stearate and talc are added to drug to prepare the tablets. The prepared dry granules were made into wheatgrass tablets by wet granulation. Experimental trials were performed for all 6 formulations. For all formulations, the precompression and post-compression parameters were studied. Based upon the trails optimized formulation F6 was selected as having the disintegration time 6 min 4 sec and %drug release 98.9±0.51 respectively. Anti-inflammatory activity of wheatgrass tablets was assessed by using formalin induced rat paw edema model. The results obtained were compared with aceclofenac, standard drug.

Keywords: Triticum aestivum, Flaxseed gel, Anti-inflammatory, Aceclofenac, Formalin.

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FORMULATION AND CHARACTERIZATION OF IBUPROFEN AND ALOE VERA -TRANSEMULGEL

Dissertation submitted to

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In partial fulfillment of the requirements
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ABSTRACT

The current research work is done on ibuprofen emulgel with a formulation that is carried out by using aloe vera gel and clove oil which serves as a permeation enhancer for easy penetration of drug into the skin. Propylene glycol is used as a solvent for dissolution of ethyl and propyl parabens. Tween 80 and span 80 are used as emulsifiers and ethyl and methyl parabens are used as preservatives and carbopol (934, 940 or sodium carboxy methyl cellulose (CMC) as gelling agent. All the pre formulation studies, FTIR studies, physical examination of drug content was done along with emulgel formulation. The emulgel formulation was found to be stable when compared with other drug formulations. Since emulgel had appeared as a novel technique for topical drug delivery, it can be very efficient for hydrophobic drugs.

KEY WORDS: Emulgel, topical drug delivery

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DESIGN, DEVELOPMENT AND EVALUATION OF INTRANASAL, HERBAL AEROSOL FORMULATION FOR MITIGATION OF ASTHMA

Dissertation submitted to

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ABSTRACT

The present study was aimed to develop aerosol assisted formulation for superior delivery of poly herbal formulation, this strategy could provide flexible and convenience than the alternative options for herbal based drug delivery. Spray drying technique was employed. Preliminary screening was performed by using FT-IR, SEM, Zeta potential, particle size distribution and HPTLC and optimized formulation was evaluated for Anti-Asthmatic activity by behavioral studies in guinea pigs administering it through nasal route. Spray pattern, leakage test and average weight per actuation tests were performed to evaluate the aerosol formulation. This study demonstrated that the aerosol formulation retains its physicochemical and pharmacological properties for a longer duration with proven Anti-Asthmatic activity in preclinical testing.

Key words: Aerosol, poly herbal formulation, spray drying, Anti-Asthmatic, nasal route.

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FORMULATION, CHARACTERIZATION AND *IN- VITRO* EVALUATION OF LIQUISOLID TABLETS OF EZETIMIBE

Dissertation submitted to

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ABSTRACT

Among all oral ingestion is the most suitable and convenient route of drug delivery due to its ease of administration, high patient compliance, cost effectiveness, least sterility constraints, and flexibility in the design of dosage form. Thus, many of the generic drug companies are inclined more to produce bioequivalent oral drug products.

In liquisolid tablets, non-volatile liquid vehicle was used to dissolve the solid drug, and the preparation does not involve drying and evaporation process; therefore, the drug is held in the solution even though it is in a tabletted or encapsulated dosage form. the main aim of this study to develop ezetimibe tablets using liquisolid technique to increase the solubility of ezetimibe tablets. Ezetinibe is anti epilipedemic dug used to treat hyper lipidaemia, obesity etc.

Liquisolid tablets of ezetimibe is prepared by using direct compression method. By using HPMC, Aerosil as carrier and coating materials respectively. Tablets were subjected to physicochemical characterization such as hardness, friability, weight uniformity, drug content, disintegration time, and invitro drug release studies. Out of 6 formulations F5 was optimized formulation. The invitro drug release in optimized formulation was found to be 99.6%

The tablets were showed hardness (3.76 kg/cm2), friability (0.23%), these satisfactory results which were matches to the innovator product.

Key words: Liquisolid technique, bioavailability, anti-lipidemic activity, ezetimibe, direct compression, solubility, hyper lipidaemia, Aerosil, PVP K30.

PREPARATION AND EVALUATION OF LOSARTAN POTASSIUM BUCCAL PATCHES

Dissertation 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)

Submitted By

K. Aryani, B. Pharm.,

Regd. No. **Y19MPHPC406**

Under the guidance of

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All INDIA 54th Rank 2020

EVALUATION CERTIFICATE

This is to certify that the research work presented in the dissertation entitled Preparation and Evaluation of Losartan Potassium buccal patches" being submitted by, K. Aryani (Y19MPHPC406) to Chalapathi Institute of Pharmaceutical Sciences, Lam, Guntur in partial fulfillment of the requirements for the award of degree of Master of Pharmacy in Pharmaceutics is the bonafide work carried out by her during the academic year 2019-2021 in Chalapathi Institute of Pharmaceutical Sciences, Guntur under the supervision of Dr. Sk. Arifa Begum, Associate Professor, Department of Pharmaceutics.

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ABSTRACT

The main objective of the current research was to develop buccal patches of losartan potassium, an anti-hypertensive drug by solvent casting method using different polymer in variable concentrations for sustained drug delivery. A total of nine formulations were formulated with variable concentrations of polymers such as HPMC K4M, HPMC K15M, PMC K50M and Eudragit L100. The fabricated buccal patch formulations were evaluated for physical appearance, thickness, surface pH, weight variation, folding endurance, content uniformity, swelling study, moisture content, moisture uptake, drug release and stability study. Based upon the results obtained F6 was considered as the best formulation, having folding endurance greater than 300 and swelling index (68.29%). Fourier-transform infrared spectroscopy studies have proved that there was interaction between losartan potassium and polymer used in the formulation. The best formulation F6 followed zero-order release kinetics. Hence, buccal mucoadhesive patches of losartan potassium can be developed in order to prolong the drug release and enhance its poor oral bioavailability.

Keywords: Buccal patches, losartan potassium, HPMC, eudragit, solvent casting technique.

PREPARATION AND EVALUATION OF VALSATRAN SOLIDLIPID NANOPARTICLES

Dissertation submitted to

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EVALUATION CERTIFICATE

This is to certify that the dissertation entitled **"Formulation and evaluation of valsartan solid lipid nano-particles"** was a *bonafide* research work of **M. Chandana (Reg.no.Y19MPHPC407)** carried out at Department of Pharmaceutics and submitted to Chalapathi Institute of Pharmaceutical Sciences (CLPT), Lam, Guntur was evaluated by the undersigned in partial fulfillment of the requirements for the award of **Master of Pharmacy** degree in **Pharmaceutics** during the academic year 2019-2021.

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ABSTRACT

The main objective of the present research work was to formulate and characterize the valsartan loaded solid lipid nanoparticles (SLNs). SLNs possess distinctive characteristics like small and spherical shape with an average diameter in between 10 to 1000 nm. Valsartan which is 4-hydroxyvaleryl metabolite is used for the treatment of anti-hypertension and it is a specific competitive antagonist of the angiotensin II AT_1 receptor. and its oral bioavailability is 23%. The application of biopharmaceutical principles to the physicochemical properties of drug substance are characterized with the goal of designing best drug delivery system. The current research work was to enhance the oral bioavailability of valsartan using the phospholipids like hydrogenated soya phosphatidyl choline, along with the surfactants like tween 80, and tween 20 by hot homogenization method in order to obtain the best novelty formulation. The prepared formulations have been evaluated for particle size analysis, zeta potential, percentage drug entrapment efficiency, scanning electron microscopy studies, *in-vitro* drug release kinetics and stability studies. FT-IR spectra showed the there was no incompatibility between valsartan and excipients. Formulations containing hydrogenated soya phosphatidyl choline and surfactants like, tween 80 and tween 20 showed smaller particle size, greater drug release and higher percentage entrapment efficiency. The best formulation F5 exhibited 136.5 nm particle size and 71.29% drug release.

PREPARATION AND CHARACTERIZATION OF ATENOLOL FLOATING MICROSPHERES

Dissertation submitted to

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In partial fulfillment of the requirements for

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EVALUATION CERTIFICATE

This is to certify that the research work presented in the dissertation entitled ***Preparation and Characterization of Floating Microspheres of Atenolol*** *" being submitted by,* ***M. Aravind (Y19MPHPC408)*** *to* ***Chalapathi Institute of Pharmaceutical Sciences, Lam, Guntur*** *in partial fulfillment of the requirements for the award of degree of* ***Master of Pharmacy in Pharmaceutics*** *is the bonafide work carried out by her during the academic year 2019-2021 in* ***Chalapathi Institute of Pharmaceutical Sciences, Guntur*** *under the supervision of* ***Dr. Sk. Arifa Begum****, Associate Professor, Department of Pharmaceutics.*

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ABSTRACT

Floating microspheres were prepared using ethyl cellulose polymer in different concentrations and loaded with the drug, atenolol, an anti-hypertensive agent by solvent evaporation method in order to increase gastric retention time, absorption as well as bioavailability of the drug. The prepared floating microspheres were characterized for parameters such as particle morphology, percentage yield, encapsulation efficiency and in vitro drug release studies. The microspheres were observed to be with spherical geometry, free-flowing nature and discrete morphology. The developed microspheres were found to be uniform in size and the % encapsulation efficiency was in the range of 93.17%.

Keywords: Floating microspheres, atenolol, ethyl cellulose, solvent evaporation method, encapsulation efficiency.

FORMULATION AND EVALUATION OF HERBAL AQEOUS GEL FOR MITIGATION OF MOUTH ULCER

Dissertation submitted to

CHALAPATHI INSTITUTE OF PHARMACEUTICAL SCIENCES, LAM, GUNTUR

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EVALUATION CERTIFICATE

This is to certify that the dissertation entitled **"Formulation and Evaluation of Herbal Aqueous gel for Mitigation of Mouth Ulcer"** was a *bonafide* research work of **S.SRAVANI (Y19MPHPC409)** carried out at Department of Pharmaceutics and submitted to Chalapathi Institute of Pharmaceutical Sciences (CLPT), Lam, Guntur was evaluated by the undersigned in partial ful filment of the requirements for the award of **Master of Pharmacy** degree in **Pharmaceutics** during the academic year 2020-2021.

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ABSTRACT:

Introduction: Now a days, there has been boom in the field of herbal medicine and excipients. This research aims to formulate and evaluate the Aqueous gel containing gelling agents as Carbopol 934, for the treatment of Mouth Ulcer.

Materials and methods: Formulation of Aqueous gel was prepared by using Carbopol934 as gelling agents, methyl paraben and propyl paraben as preservatives. The formulations were evaluated for physicochemical parameters, rheological studies, stability studies and antimicrobial activity.

Results and discussions: All the prepared Aqueous gels produced acceptable physical properties such as color, homogeneity, consistency, pH, Spreadability, content uniformity, anti-microbial activity and stability. Stability studies of the formulated aqueous gel were carried out as per ICH guidelines for 1 months at different temperature and humidity conditions. The results showed that all the formulations were stable throughout the period. So, it can be concluded that aqueous gel of different concentrations possesses an effective antimicrobial activity.

Key words: Aqueous gel, Guava leaf, Mouth ulcer, Carbopol 934.

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FORMULATION AND EVALUATION OF SELF NANO EMULSIFYING DRUG DELIVERY SYSTEM OF RALOXIFENE HYDROCHLORIDE

Thesis submitted to

CHALAPATHI INSTITUTE OF PHARMACEUTICAL SCIENCES, AUTONOMUS, LAM, GUNTUR

In partial fulfillment of the requirements
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All India 54th Rank (2020)

EVALUATION CERTIFICATE

This is to certify that the dissertation entitled **"Formulation and Evaluation of Self Nano emulsifying Drug delivery system of Raloxifene Hydrochloride"** was a *bonafide* research work of **T. Gayathri (Reg.no.Y19MPHPC410)** carried out at Department of Pharmaceutics and submitted to Chalapathi Institute of Pharmaceutical Sciences (CLPT), Lam, Guntur was evaluated by the undersigned in partial fulfillment of the requirements for the award of **Master of Pharmacy** degree in **Pharmaceutics** during the academic year 2019-2021.

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ABSTRACT

Background: Self-nanoemulsifying drug delivery systems (SNEDDS) can be defined as isotropic solutions of oil and surfactant, which form o/w emulsions upon mild agitation in the presence of water. Self-emulsifying formulations spread readily in the GI tract, and the digestive motility of stomach and intestine provide the agitation necessary for self-emulsification. SEDDS typically produce emulsions with a droplet size between 100 and 300 nm while SNEDDS form transparent nanoemulsions with a droplet size of less than 50 nm. Raloxifene Hydrochloride is used in the treatment of Postmenopausal arthritis. The drug has low oral bioavailability and the drug is highly protein bound in order to overcome the problems associated with the absorption pattern of the drug it is formulated as self nanoemulsifying drug delivery system.

Materials and methods: In the present study castor oil, Tween 80 and Propylene glycol were selected as oil, surfactant and co-surfactant respectively. The eight formulations were selected from pseudoternary phase diagram and formulated successfully. Prepared liquid SNEDDS were evaluated for different parameters. From this study it was found that all formulations of liquid SNEDDS showed globule size in nanometric range, good stability with no phase separation, creaming or cracking and rapidly formed nanoemulsion which was clear and slightly bluish in appearance. Formulations were optimized on the basis of drug content, *in-vitro* drug release, globule size, PDI, zeta potential.

Results and discussion: Among all the prepared formulations formulation F5, F7 were found to be the best formulations with a globule size of 88nm, 97nm and a %drug release of 88.16 and 87.32 % respectively. The optimization of the best formulation was carried out using design expert software to find out the best formulation.

FORMULATION AND OPTIMIZATION OF ZOLMITRIPTAN ORO DISPERSIBLE TABLETS

Thesis submitted to

CHALAPATHI INSTITUTE OF PHARMACEUTICAL SCIENCES, AUTONOMUS, LAM, GUNTUR

In partial fulfillment of the requirements
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EVALUATION CERTIFICATE

This is to certify that the dissertation entitled **"Formulation and optimization of Zolmitriptan orodispersible tablets"** was a *bonafide* research work of **T. V. Hari Hara Nadh (Reg. No: Y19MPHPC411)** carried out at Department of Pharmaceutics and submitted to Chalapathi Institute of Pharmaceutical Sciences (CLPT), Lam, Guntur was evaluated by the undersigned in partial fulfillment of the requirements for the award of **Master of Pharmacy** degree in **Pharmaceutics** during the academic year 2019-2021.

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ABSTRACT

Zolmitriptan is a selective 5-hydroxytryptamine receptor subtype agonist indicated for the acute treatment of migraine attacks, having poor water solubility results in poor bioavailability. In the present study, attempt to improve the bioavailability of zolmitriptan with the help of PVP K-30 using the microwave irradiation method. The zolmitriptan and PVP K- 30 in 1:1 ratio was subjected to microwave irradiation for different times such as 60,80,100,120 seconds at 650 watts. Solid dispersion was characterized by drug content, FTIR, XRD, DSC. FTIR analysis demonstrated there are no compatibility issues. XRD studies prove that the solid dispersion was in amorphous form. DSC studies prove that solid dispersion was amorphous based on the intensity of peaks. The prepared dispersion was made into orodispersible tablets by direct compression. The optimization of these formulations was carried out by using 3^2 factorial designs on Design Expert 10.0 software. 3^2 factorial design was selected to study the influence of the individual and combined effect of independent variables Crospovidone (X_1) and croscarmellose sodium (X_2). In this design, two responses such as disintegration time and % drug release were evaluated, and experimental trials are performed for all 9 formulations. For all formulations, the precompression and post-compression parameters were studied. Based upon the model optimized formulation C1 and C2 was obtained having the disintegration time 34.4±0.84 and 39.8±0.91(seconds) and %drug release 98.7±0.42 and 93.2±0.46 respectively.

DESIGN, CHARACTERIZATION AND *IN-VITRO* EVALUATION OF FAVIPIRAVIR ORO DISPERSIBLE FILMS

Thesis submitted to

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

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EVALUATION CERTIFICATE

This is to certify that the dissertation entitled **"Design, characterization and *in-vitro* evaluation of Favipiravir orodispersible films"** was a *bonafide* research work of **Y. KALYAN CHAKRAVARTHY (Y19MPHPC412)** carried out at Department of Pharmaceutics and submitted to Chalapathi Institute of Pharmaceutical Sciences (CLPT), Lam, Guntur was evaluated by the undersigned in partial fulfillment of the requirements for the award of **Master of Pharmacy** degree in **Pharmaceutics** during the academic year 2020-2021.

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ABSTRACT

Favipiravir is a novel drug used in treatment of many viral diseases such as Ebola, covid-19. Oral films are mostly suitable for delivery of drugs at a faster rate and improve patient compliance. They release drug by disintegrating within minutes. The preparation of the films was done using solvent casting method, and study was based on different superdisintegrants. The main objective of this research is to study the effect of superdisintegrant on drug release and thickness of the film. The optimization of the oral films was based on various evaluation parameters such as thickness, physical appearance, content uniformity, moisture uptake, disintegration time and pH of the film. The *in vitro* data obtained from the films with respect to the time is evaluated.

METHOD DEVELOPMENT AND VALIDATION FOR SIMULTANEOUS ESTIMATION OF HYDROCHLOROTHIAZIDE AND IRBESARTAN BY RP-HPLC

Dissertation submitted to

CHALAPATHI INSTITUTE OF PHARMACEUTICALSCIENCES, LAM, GUNTUR

In the partial fulfillment of the requirements
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MASTER OF PHARMACY

(Pharmaceutical Analysis)

Submitted by

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EVALUATION CERTIFICATE

This is to certify that the dissertation work entitled "METHOD DEVELOPMENT AND VALIDATION FOR SIMULTANEOUS ESTIMATION OF HYDROCHLOROTHIAZIDE AND IRBESARTAN BY RP-HPLC" is a bonafide research work done by ***A. PUSHPANJALI (Y19MPHPA421)*** *and submitted in partial fulfilment of the requirements for the award of the degree of* ***MASTER OF PHARMACY*** *in* ***Pharmaceutical Analysis*** *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 2020-2021.*

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ABSTRACT

A simple precise, rapid and accurate reverse phase high performance liquid chromatography method has been developed and validated for the simultaneous estimation of hydrochlorothiazide and irbesartan. Shimadzu prominence i-series autosampler using Shimadzu column and separation was achieved with mobile phase acetonitrile: ammonium acetate (24:76 v/v) at flow rate 0.8 ml/min and wavelength is 290nm. Injection volume was 20 ul with 10min run time. The retention time for hydrochlorothiazide and Irbesartan is 7.488 and 2.746 min respectively. The linearity range for hydrochlorothiazide and irbesartan is 5-25 µg/ml and 6-30 µg/ml with correlation coefficient of 0.999. The %RSD for precision was found to be 0.93 and 0.92 for Hydrochlorothiazide and Irbesartan and % recovery for Hydrochlorothiazide and Irbesartan was 100.15 and 100.04 and method was robust. The developed method was validated according to ICH guidelines. Linearity, Accuracy, %RSD of precision, LOQ, LOD and robust values were found within the limits and the method was found to be satisfactory.

Keywords: Hydrochlorothiazide, Irbesartan, RP-HPLC.

RP-HPLC METHOD DEVELOPMENT AND VALIDATION FOR THE SIMULTANEOUS ESTIMATION OF METOPROLOL SUCCINATE AND RAMIPRIL IN BULK AND MARKETED FORMULATION

Dissertation submitted to

CHALAPATHI INSTITUTE OF PHARMACEUTICAL SCIENCES, LAM, GUNTUR

In the partial fulfillment of the requirements

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EVALUATION CERTIFICATE

*This is to certify that the dissertation work entitled "**RP-HPLC METHOD DEVELOPMENT AND VALIDATION FOR THE SIMULTANEOUS ESTIMATION OF METOPROLOL SUCCINATE AND RAMIPRIL IN BULK AND MARKETED FORMULATION**" is a bonafide research work done by **Ms. A. Sai Tejaswi (Y19MPHPA422)** and submitted in partial fulfilment of the requirements for the award of the degree of **MASTER OF PHARMACY** in **Pharmaceutical Analysis** 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 2020-2021.*

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ABSTRACT

The main aim of this research work is to estimate and validate the Metoprolol Succinate and Ramipril in bulk and marketed formulation. Method development was carried out by autosampler HPLC Shimadzu 2030C 3D plus was used with stationary phase YMC column (150 × 4.6 mm, 3 µm) with ambient temperature. The mobile phase-A consisting of 0.1 mL orthophosphoric acid in 100 mL water and mobile phase-B consisting of Acetonitrile in gradient mode was pumped into the column at a flow rate of 1.0 mL/min. The injection volume was 20 µL with photo diode array detector at 225 nm. Validation was done according to ICH Q2(R1) guidelines. Linearity for Metoprolol Succinate was 50-250µg/mL. and Ramipril was 10-50µg/mL with the correlation coefficient 0.9998 and 0.9994. The %recoveries ranged for Metoprolol Succinate and Ramipril were found to be 100.56% and 100.78%. Precision results were found to be within limits and method was found to be robust with %RSD limit of NMT 2.0. The method was validated statistically and was applied successfully for estimation of Metoprolol Succinate and Ramipril. All the parameters like theoretical plates, resolution, tailing factor and %RSD was within the acceptance limits. Hence the proposed method can be successfully applied to routine analysis.

Key Words: Metoprolol Succinate, Ramipril, RP-HPLC, Validation.

APPLICATION OF RP-HPLC FOR THE ESTIMATION OF ALLOPURINOL AND ITS RELATED SUBSTANCES IN BULK AND TABLET DOSAGE FORM

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

(Pharmaceutical Analysis)

Submitted by

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ABSTRACT:

A reverse phase HPLC method was developed for the estimation of allopurinol and its impurity-A in bulk and tablet dosage form. The analysis was carried out by using Schimadzu, Prominence-i series LC 3D-Plus autosampler embedded with lab solutions software, equipped with PDA detector. Method development was carried out by using YMC column (150mm X 4.6mm, 3µm) and 0.1M Ammonium acetate buffer [prepared by dissolving 1.7gms of ammonium acetate in 100mL of water] as a mobile phase in the ratio of 100% at a flow rate of 1.0 mL/min at a wavelength of 255nm. The method was validated according to ICH guidelines. The linearity was observed in the range of 20-100 µg/mL for allopurinol and 0.1-0.5 µg/mL for imputiry-A with a regression (R^2) value of 0.9997 and 0.9994 respectively. Developed method was specific with no interactions and accurate with 100.11% for allopurinol and 99.54% for its impurity-A. The limit of detection for allopurinol was 2 µg/mL and for impurity-A was 0.01 µg/mL. The limit of quantification for allopurinol was 6 µg/mL and for impurity-A was 0.03 µg/mL respectively. The percentage relative standard deviation was found to be NMT 2 which indicates that the proposed method was precise and robust. Therefore, the developed method was simple, precise, and accurate and can be successfully employed for the estimation of allopurinol in bulk and tablet dosage form.

Keywords: Allopurinol, related substances, validation, ICH guidelines.

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QUANTITATIVE ESTIMATION OF QUERCETIN IN *NELUMBO NUCIFERA* LEAVES BY HPTLC

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

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ABSTRACT

A sensitive and reliable HPTLC method was developed for the quantitative estimation of Quercetin in *Nelumbo nucifera* leaves. Chromatographic analysis was performed by n-Butanol:Glacial Acetic Acid:Water:0.1% Formic Acid (7:1:1:0.25v/v/v/v) as mobile phase, TLC Silica gel 60 F_{254} as stationary phase with a dosage speed of 20µL/sec and detection was carried out at 254nm. R_f value of quercetin was found to be 0.907. The developed method was validated for system suitability, linearity, accuracy, precision, Limit of Detection (LOD), Limit of Quantification (LOQ) and robustness according to ICH guidelines. Linearity of Quercetin was 2000-10000ng/spot with a correlation coefficient of 0.999. The % recovery achieved was 99.70% and % RSD was <2 and the method was found to be robust. Hence, the proposed method can be applied for routine analysis in institutes and pharmaceutical laboratories.

Keywords: Quercetin, *Nelumbo nucifera*, HPTLC

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A NOVEL VALIDATED ANALYTICAL METHOD FOR SIMULTANEOUS ESTIMATION OF EMTRICITABINE, TENOFOVIR DISOPROXIL FUMARATE AND RILPIVIRINE-HYDROCHLORIDE BY RP-HPLC

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

(Pharmaceutical Analysis)

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ABSTRACT

A simple, precise, accurate, efficient and reproducible, isocratic Reverse Phase High Performance Liquid Chromatography (RP-HPLC) method was developed and validated for the simultaneous estimation of Emtricitabine, Tenofovir disoproxil fumarate and Rilpivirine-hydrochloride in bulk and tablet dosage form. Emtricitabine, Tenofovir disoproxil fumarate and Rilpivirine-hydrochloride were separated using an Phenomenex C8(2),150cm x 4.5mm; 3µ and the mobile phase used was a mixture of 10mM Ammonium acetate (pH adjusted to 5.7 with 0.1% triethylamine), Acetonitrile and Methanol (30:55:15v/v/v). The flow rate was set to 0.8ml/min with the response measured at 250nm. The retention time of Emtricitabine, Tenofovir disoproxil fumarate and Rilpivirine-hydrochloride was found to be 2.079min, 2.726min, 3.982min respectively with a resolution of 3.283, 5.675. Linearity was established in the range of 10-50µg/ml for Emtricitabine, 5-40µg/ml for Tenofovir disoproxil fumarate, 20-100µg/ml for Rilpivirine-hydrochloride with correlation coefficient of 0.9998, 0.999 and 0.9993. The percentage recoveries were found to be 99.98%, 100.03%, 100.05% respectively. Validation parameters such as specificity, linearity, precision, accuracy, robustness, limit of detection (LOD), limit of quantification (LOQ) was evaluated for the method according to the International Conference on Harmonization (ICH) Q2 R1 guidelines.

Key words: Emtricitabine, Tenofovir disoproxil fumarate and Rilpivirine-hydrochloride RP-HPLC, ICH.

QUANTIFICATION OF VITAMIN-B2, B6 IN *SPINACIA OLERACEA* BY HPTLC

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

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EVALUATION CERTIFICATE

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ABSTRACT

A new HPTLC (High Performance Thin Layer Chromatography) method was developed for the quantification of vitamin-B2, B6 in *Spinacia oleracea*. Separation of vitamins was achieved by using mobile phase as methanol: benzene: 0.1% formic acid (5: 4: 1 v/v), stationary phase as TLC silica gel 60 F_{254} (Aluminium sheets). The sample volume sprayed was 30µL with dosage speed of 20 µL/sec. The detection was carried out at UV 254nm. The developed method was validated as per ICH guidelines. The method was linear in the range of 2000 to 10000 ng/mL with correlation coefficient of 0.9992, 0.9993 and R_f values are 0.874, 0.780 for vitamin-B2, B6 respectively. The % RSD was found to be NMT 2.0 and method was said to be precise. The method was accurate with the values of 100.06% for vitamin-B2, 99.98% for vitamin-B6 and was robust with the % RSD values of all the parameters were within acceptable limits. The method was simple, accurate, precise and successfully applied for the routine quantitative analysis.

Keywords: *Spinacia oleracea* (spinach), HPTLC, Quantification, Vitamin-B2, B6.

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METHOD DEVELOPMENT AND VALIDATION OF RP-HPLC METHOD FOR SIMULTANEOUS ANALYSIS OF THREE COMPONENT TABLET DOSAGE FORM CONTAINING GLIBENCLAMIDE, METFORMIN HYDROCHLORIDE AND PIOGLITAZONE HYDROCHLORIDE

Dissertation submitted to

Department of Pharmaceutical Analysis

CHALAPATHI INSTITUTE OF PHARMACEUTICAL SCIENCES, LAM, GUNTUR

in partial fulfillment of the requirements

for the award of the degree of

MASTER OF PHARMACY

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ABSTRACT

Reverse phase High performance liquid chromatography method has developed and validated for the simultaneous analysis of glibenclamide, metformin hydrochloride and pioglitazone hydrochloride in tablet dosage form. The chromatographic separation of drugs was achieved at ambient temperature with isocratic mode by using C_{18} Hypersil BDS (150 x 4.6 mm, 5 µm) column with mobile phase containing acetonitrile: 0.1M potassium dihydrogen orthophosphate buffer (pH 4.5 adjusted with 10% sodium hydroxide solution) in the ratio 55: 45 v/v at flow rate 0.7 mL/min. The run time was 11 min and injection volume 20 µL. The eluent was monitored at 255 nm by using PDA detector. The method was validated as per ICH guidelines. The selected chromatographic conditions effectively separated metformin, pioglitazone and glibenclamide with retention time 2.1, 3.0 and 7.1 min respectively. The mean percentage recoveries were found in the range of 98-102 % which shows accuracy of the developed method. The linearity range for metformin, Pioglitazone and glibenclamide is found in the range of 50-400 µg/mL, 1-12 µg/mL and 0.5-4 µg/mL respectively. Limit of detection were 5, 0.1, 0.05 µg/mL and limit of quantification were 15, 0.3, 0.15 µg/mL for metformin, Pioglitazone and glibenclamide, respectively. The developed method was found to be specific, accurate, precise and economic.

Keywords: Metformin Hydrochloride, Pioglitazone Hydrochloride, Glibenclamide, RP-HPLC and Validation.

METHOD DEVELOPMENT AND VALIDATION FOR THE SIMULTANEOUS ESTIMATION OF RITONAVIR, LOPINAVIR AND EFAVIRENZ BY RP-HPLC

Dissertation submitted to

CHALAPATHI INSTITUTE OF PHARMACEUTICAL SCIENCES, LAM, GUNTUR

In the Partial Fulfillment of the Requirements

For the award of the Degree of

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EVALUATION CERTIFICATE

This is to certify that the dissertation work entitled "METHOD DEVELOPMENT AND VALIDATION FOR THE SIMULTANEOUS ESTIMATION OF RITONAVIR, LOPINAVIR AND EFAVIRENZ BY RP-HPLC" is a bonafide research work done by ***K.KEERTHI (Y19MPHPA428)*** *and submitted in partial fulfilment of the requirements for the award of the degree of* ***MASTER OF PHARMACY*** *in* ***Pharmaceutical Analysis*** *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 2020-2021.*

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ABSTRACT

A precise and accurate reverse phase HPLC method was developed for the estimation of Ritonavir, Lopinavir, and Efavirenz in pharmaceutical tablet formulation. The analysis was carried out by using Schimadzu, Prominence-i series LC 3D-Plus autosampler embedded with lab solutions software, equipped with shimadzu column (150mm X 3mm, 3µm) and PDA detector. Method development was carried out by using 0.02M potassium Di hydrogen Ortho phosphate buffer [prepared by dissolving 0.2721gms of potassium Di hydrogen Ortho phosphate in 100ml of water as a mobile phase in the ratio of 60:40%v/v at a flow rate of 1.4 ml/min at a wavelength of 233nm. The method was validated according to ICH guidelines. The linearity was observed in the range of Lopinavir 50-250 µg/ml, Ritonavir 10-50µg/ml, Efavirenz 10-50µg/ml with regression (R^2) value 0.999 the percentage relative standard deviation of six replicate measurements was found to be NMT 2 which indicates that the proposed method was precise. Therefore, the developed method was simple, precise and accurate and can be successfully employed for the estimation of Ritonavir, Lopinavir and Efavirenz in bulk and tablet dosage form.

Key words: Ritonavir, Lopinavir, Efavirenz, shimadzu, validation, ICH guidelines.

ANALYTICAL METHOD DEVELOPMENT AND VALIDATION OF LAMIVUDINE AND DOLUTEGRAVIR BY RP-HPLC METHOD

Dissertation submitted to

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In the Partial Fulfillment of the Requirements

For the award of the Degree of

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*This is to certify that the dissertation work entitled "**ANALYTICAL METHOD DEVELOPMENT AND VALIDATION OF LAMIVUDINE AND DOLUTEGRAVIR BY RP-HPLC METHOD**" is a bonafide research work done by **M.NAGARAJU (Y19MPHPA429)** and submitted in partial fulfilment of the requirements for the award of the degree of **MASTER OF PHARMACY** in **PHARMACEUTICAL ANALYSIS** 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 2020-2021.*

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ABSTRACT:

The main aim of this research work is to estimate and validate the Lamivudine and Dolutegravir in bulk formulation. Lamivudine is an inhibitor of HIV-1 reverse transcriptase, it is used as an antiviral in the treatment of AIDS and hepatitis B. which is used to for the treatment of HIV-1 infection, announced ViiV Healthcare. Dolutegravir is in a class of medications called HIV integrase inhibitors. It works by decreasing the amount of HIV in your blood and increasing the number of immune cells that help fight infections in your body. Dolutegravir is in a class of medications called HIV integrase inhibitors (INSTI). It works by decreasing the amount of HIV in your blood and increasing the number of immune cells that help fight infections in your body. Autosampler HPLC Shimadzu 2030C 3Dplus was used with stationary phase Shimadzu column (150 × 4.6 mm, 3 µm) with ambient temperature. The mobile phase consisting of methanol: 0.1% Trifluoroacetic Acid (TFA) in the ratio 65:35 v/v was pumped into the column at a flow rate of 1.0 ml/min. The retention time is 11.0min. The injection volume was 20.0µl. with photo diode array detector at 266.0nm. Validation was done according to ICH Q2(R_1) guidelines like system suitability, specificity, linearity, accuracy, precession, limit of detection, limit of quantification and robustness. The linearity of Lamivudine and Dolutegravir were observed in the range of 12-60µg/mL and 03-10µg/ml. with the correlation coefficient is 0.9997, and 0.9993. All the parameters like theoretical plates, resolution, tailing factor and %RSD was within the acceptance limits. This can be used for routine analysis in laboratory and industriesas it is simple, precise, accurate, economic and robust method.

Key Words: Lamivudine, Dolutegravir, RP-HPLC and ICH.

VALIDATED RP-HPLC ANALYTICAL METHOD FOR SIMULTANEOUS ESTIMATION OF IMATINIB MESYLATE AND ANASTRAZOLE IN PHARMACEUTICAL FORMULATION

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

(Pharmaceutical Analysis)

Submitted by

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Under the guidance of

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ABSTRACT

A simple, precise, accurate, efficient and reproducible, isocratic Reverse Phase- High Performance Liquid Chromatography (RP-HPLC) method was developed and validated for the simultaneous estimation of Imatinib mesylate and Anastrazole in pharmaceutical formulation. Imatinib mesylate and Anastrazole were separated using an Phenomenex Luna 3µ C8(2) 100A°, LC Column 150 x 45, Shimadzu of 2030 LC Prominence i-series with high detection capabilities of PDA detector and the mobile phase contained a mixture of 0.02M sodium dihydrogen phosphate (pH adjusted to 2 with 0.1% orthophosphoric acid), acetonitrile and water (30:55:15,v/v/v). The flow rate was set to 1ml/min with the response detected at 228nm. The retention time of Imatinib mesylate and Anastrazole was found to be 1.88min, 3.139 min. Linearity for imatinib mesylate, in the range of 100-500µg/ml, for anastrazole in the range of 1-5µg/ml with correlation coefficient of 0.9999. The percentage recovery of Imatinib mesylate and anastrazole was found to be 100.27, 99.75 respectively. Validation parameters such as specificity, linearity, precision, accuracy, robustness, limit of detection (LOD), limit of quantification (LOQ) were evaluated for the method according to the International Conference on Harmonization (ICH) Q2 R1 guidelines.

Key words: Imatinib mesylate , Anastrazole, RP-HPLC, ICH, LOD, LOQ.

VALIDATED CHROMATOGRAPHIC METHOD FOR SIMULTANEOUS ESTIMATION OF SALBUTAMOL SULPHATE, GUAIFENESIN AND AMBROXOL HYDROCHLORIDE IN BULK DRUG AND MARKETED FORMULATION

Dissertation submitted to

CHALAPATHI INSTITUTE OF PHARMACEUTICAL SCIENCES, LAM, GUNTUR

In the partial fulfillment of the requirements

for the award of the degree of

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ABSTRACT

The main aim of this research work is to estimate and validate the salbutamol sulphate, guaifenesin and ambroxol hydrochloride in bulk drug and marketed formulation. Salbutamol sulphate is short-acting β-2 agonist which is used to treat diseases such as asthma. Guaifenesin is an expectorant and widely used in the treatment of coughing. Ambroxol hydrochloride is used as broncho secrolytic and an expectorant drug. Autosampler HPLC Shimadzu 2030C 3D plus was used with stationary phase YMC column (150 × 4.6 mm, 3 µm) with ambient temperature. The mobile phase consisting of 1 ml orthophosphoric acid in 1000 ml water [pH – 3 adjusted with 1 M Sodium hydroxide]: methanol in the ratio 70:30 v/v was pumped into the column at a flow rate of 0.9 ml/min. The injection volume was 20 µl with photo diode array detector at 233 nm. Validation was done according to ICH Q2(R1) guidelines like system suitability, specificity, linearity, accuracy, precession, limit of detection, limit of quantification and robustness. Linearity for salbutamol sulphate was 1-5µg/mL, guaifenesin was 50-250µg/mL and for ambroxol hydrochloride was 30-120µg/mL with the correlation coefficient 0.9998, 0.9999 and 0.9997. All the parameters like theoretical plates, resolution, tailing factor and %RSD was within the acceptance limits. This can be used for routine analysis in laboratory and industries as it is simple, precise, accurate, economic and robust method.

Keywords: Salbutamol sulphate, Guaifenesin, Ambroxol hydrochloride, Ascoril.

VALIDATED HPTLC METHOD FOR QUANTIFICATION OF ASPIRIN AND CLOPIDOGREL BISULPHATE IN COMBINED DOSAGE FORM

Dissertation submitted to

CHALAPATHI INSTITUTE OF PHARMACEUTICAL SCIENCES, LAM, GUNTUR

In the partial fulfillment of the requirements

for the award of the degree of

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ABSTRACT

A simple high performance thin layer chromatography (HPTLC) method has been developed and validated for quantification of Aspirin and Clopidogrel bisulphate simultaneously in tablet dosage. The samples were applied on an aluminum TLC plate pre-coated with silica gel 60F-254 for separation, the solvent system consisted of Methanol: Toluene (7:3v/v) and images was captured at 254nm.This system was found to give compact spots for both Aspirin and Clopidogrel bisulphate (Rf value 0.79 and 0.85 respectively). The linear regression data for the calibration plots showed good linear relationship with r^2 0.9999 and 0.9999 for Aspirin and Clopidogrel in the concentration range of 100-500 ng/spot for both Aspirin and Clopidogrel bisulphate respectively. the percentage recoveries were found to be within the acceptance criteria between the ranges of 98-102%. The limit of detection and quantification were 1.65 and 5.00 ng/spot for Clopidogrel and 12.55 and 38.04 ng/spot for Aspirin respectively. system precision and method precision were found to be within limits and method was found to be robust (The %RSD should be NMT 2.0%). The % Assay of Aspirin and clopidogrel bisulphate was found to be within the acceptable limit. This method was validated according to ICH guidelines.

KEY WORDS: HPTLC, Aspirin, Clopidogrel Bisulphate, LOD, LOQ.

DEVELOPMENT AND VALIDATION OF STABILITY-INDICATING RP-HPLC METHOD FOR SIMULTANEOUS ESTIMATION OF THEOPHYLLINE AND MONTELUKAST SODIUM IN BULK AND PHARMACEUTICAL DOSAGE FORM

Dissertation submitted to

CHALAPATHI INSTITUTE OF PHARMACEUTICAL SCIENCES, LAM, GUNTUR

In the partial fulfillment of the requirements

for the award of the degree of

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ABSTRACT

The prime essence of this current study is to develop a simple, precise and accurate stability indicating RP-HPLC method for simultaneous estimation of Theophylline and Montelukast Sodium in bulk and pharmaceutical dosage form. The separation was achieved by using Hypersil BDS column, (150×4.6mm, particle size 5µ) with mobile phase containing 0.1% TFA: Acetonitrile: Methanol in the ratio 25:50:25 v/v/v at a flow rate of 0.7 mL/ min at detection of 250 nm. The developed method was validated according to ICH guidelines and was found to be linear, precise, accurate and robust. The linear response was observed in the range of 40-120 µg/mL for Theophylline and 0.5-5 µg/ mL for Montelukast Sodium. Method was precise with %RSD values of NMT 2 and was accurate with mean % recovery of 99.81% and 100.21% for Theophylline and Montelukast Sodium respectively. The method was robust enough to reproduce acceptable results under different method conditions. Upon performing the forced degradation studies for pharmaceutical dosage form with stress conditions such as acidic (0.1 M HCl), alkaline (0.1 M NaOH), oxidative (3.0% H_2O_2) and thermal (80^0 C), the amount of degradation achieved was within the acceptance limits *i.e.*, 5-20%. This method can be applied efficaciously for estimation of Theophylline and Montelukast Sodium quantitatively in the routine analysis and reliable for demonstrating and detecting any expected change or degradation in the drug product during stability studies.

Keywords: RP-HPLC, Theophylline, Motelukast Sodium, Validation, Forced degradation studies.

QUANTIFICATION OF ANTI-DIABETIC COMBINATION DRUGS BY HPTLC METHOD

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

(Pharmaceutical Analysis)

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ABSTRACT

Pioglitazone and Glimepiride are used for the treatment of type 2 diabetes mellitus. Accurate, rapid, simple, precise high performance thin layer chromatographic method (HPTLC) for simultaneous determination of Pioglitazone and Glimepiride has been established and validated according to ICH guideline. Separation was achieved on silica gel 60 F254 plates with Toluene: Ethyl acetate: Diethyl ether (6:3:1v/v/v) used as mobile phase. Densitometric quantification was performed at 254nm.The Rf values for Pioglitazone and Glimepiride was found to be 0.88 and 0.79. Pioglitazone and Glimepiride results were linear in range of 600-1200 µg/ml for Pioglitazone and 80-160 µg/ml for Glimepiride. The repeatability testing of both sample and standard solutions was found as %RSD NMT 2.0% which was within the acceptable limits showing that the method is precise. Percentage recovery for Pioglitazone is 100.06% and for Glimepiride is 99.94%. LOD for Pioglitazone and Glimepiride was found to be 2.75 µg/ml and 1.10 µg/ml and LOQ for Pioglitazone and Glimepride was 8.34 µg/ml and 3.33 µg/ml. The developed method was validated for linearity, precision, accuracy, robustness, limit of detection, limit of quantification according to ICH guideline.

KEY WORDS: HPTLC, Pioglitazone, Glimepiride, LOD, LOQ, PIO, GLI.

ANALYTICAL METHOD DEVELOPMENT AND VALIDATION FOR SIMULTANEOUS ESTIMATION OF EZETIMIBE AND FENOFIBRATE IN BULK AND MARKETED FORMULATION BY RP-HPLC METHOD

Dissertation submitted to

CHALAPATHI INSTITUTE OF PHARMACEUTICAL SCIENCES, LAM, GUNTUR

In the partial fulfillment of the requirements

for the award of the degree of

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ABSTRACT

A precise and accurate RP-HPLC method was developed for the estimation of Ezetimibe and Fenofibrate in bulk and tablet dosage form. The analysis was carried out by using Schimadzu, Prominence-i series LC 3D-Plus autosampler embedded with lab solutions software, YMC C_8 column (150mm X 4.6mm, 3µm) and PDA detector at 255nm. Method development was carried out by using Acetonitrile: Methanol: Phosphate buffer [prepared by dissolving 0.680gm of disodium hydrogen phosphate in 100ml of HPLC water adjusted to pH 3 with Ortho Phosphoric Acid] as a mobile phase in the ratio of 55:15:30 v/v/v at the flowrate of 1.0 mL/min at a wavelength of 255nm. The method was validated according to ICH guidelines. The linearity was observed in the range of 2-10µg/mL for ezetimibe and 60-180µg/mL for fenofibrate with the regression (R^2) value 0.999 for ezetimibe and 0.999 for fenofibrate. The percentage recovery of ezetimibe was found to be 100.02% and for fenofibrate was found to be 99.25%. The %RSD of six replicate measurements was found to be NMT 2 which indicates that the proposed method was precise. Therefore, the developed method was simple, precise and accurate and can be successfully employed for the estimation of ezetimibe and fenofibrate in bulk and tablet dosage form.

Key words: Ezetimibe, Fenofibrate, validation, ICH guidelines.

"HEPATOPROTECTIVE ACTIVITY OF AQUEOUS SEED EXTRACT OF *ALLIUM CEPA* (ONION) IN PARACETAMOL INDUCED HEPATOTOXICITY IN RATS"

Dissertation submitted to

CHALAPATHI INSTITUTE OF PHARMACEUTICAL SCIENCES

In the Partial Fulfillment of the Requirements

For the award of the Degree of

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This is to certify that the dissertation work entitled "HEPATOPROTECTIVE ACTIVITY OF AQUEOUS SEED EXTRACT OF ALLIUM CEPA (ONION) IN PARACETAMOL INDUCED HEPATOTOXICITY IN RATS" submitted by **B. DEEPTHI (Y19MPHPY441),** *in partial fulfilment for the award of the degree in* **MASTER OF PHARMACY** in **PHARMACOLOGY** *is the bonafide research work carried out by the candidate in the Department of Pharmacology, Chalapathi Institute of Pharmaceutical Sciences, Lam, Guntur and was evaluated by us during the academic year* **2020-2021.**

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ABSTRACT:

The present study articulates the phytochemical and pharmacological screening of seeds of *Allium cepa*, for the hepatoprotective activity. Seeds of *A. cepa* were extracted using water as solvent and the extract obtained was subjected for phytochemical and quantitative analysis. The extract was further investigated for hepatoprotective activity in rats. Phytochemical evaluation evidenced the presence of alkaloids, carbohydrates, volatile oils, phenols, flavonoids, saponins, fixed oils etc. Aqueous seed extract of *Allium cepa* can protect against paracetamol induced hepatotoxicity. *A. cepa* seed extract was able to reduce significantly all the elevated serum enzymes and total bilirubin levels.

Key words: *A. cepa* seeds, Types of Hepatotoxicity, Hepatoprotective.

EFFECT OF *PHASEOLUS VULGARIS* SEEDS ON LEARNING, BEHAVIOUR AND MEMORY ENHANCEMENT IN RATS

Dissertation submitted to

CHALAPATHI INSTITUTE OF PHARMACEUTICAL SCIENCES

In the Partial Fulfillment of the Requirements

For the award of the Degree of

MASTER OF PHARMACY

(Pharmacology)

Submitted by

B.PADMAVATHI

(Y19MPHPY442)

Under the guidance of

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EVALUATION CERTIFICATE

This is to certify that the dissertation work entitled "EFFECT OF *PHASEOLUS VULGARIS* SEEDS ON LEARNING, BEHAVIOUR AND MEMORY ENHANCEMENT IN RATS" *submitted by* **B. PADMAVATHI (Y19MPHPY442)** *in partial fulfilment for the award of the degree in* **MASTER OF PHARMACY in PHARMACOLOGY** *is the bonafied research work carried out by the candidate in the Department of Pharmacology, Chalapathi Institute of Pharmaceutical Sciences, Lam, Guntur and was evaluated by us during the academic year* **2020-2021**.

Place: Guntur

Date: 28/7/2021

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ABSTRACT

Objective:

To carry out the Learning, behaviour and memory enhancement activity of *Phaseolus vulgaris* seeds in rats.

Methodology:

The preclinical evaluation of standardized Memory enhancement activity of EEPV was carried by using the following models:

a) Hebb's William Maze
b) Labyrinth Maze
c) Rectangular Maze
d) 8-Arm Radial Maze

Results:

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

Key words: Learning and Memory, *Phaseolus vulgaris*

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INVESTIGATION OF THE PROTECTIVE EFFECT OF METHANOLIC EXTRACT OF *ARECA CATECHU* NUT ON ALCOHOL WITHDRAWAL-INDUCED ANXIETY AND DEPRESSION BEHAVIOR IN MICE

Dissertation submitted to

CHALAPATHI INSTITUTE OF PHARMACEUTICAL SCIENCES

In the Partial Fulfillment of the Requirements

For the award of the Degree of

MASTER OF PHARMACY

(Pharmacology)

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"INVESTIGATION OF THE PROTECTIVE EFEECT OF METHANOLIC EXTRACT OF *ARECA CATECHU* NUT ON ALCOHOL WITHDRAWAL-INDUCED ANXIETY AND DEPRESSION BEHAVIOR IN MICE"

ABSTRACT

Objective:

To investigate the protective effect of methanolic extract of *Areca catechu* nut on alcohol withdrawal-induced anxiety and depression behavior in mice.

Methodology:

- To prepare methanolic extract of *Areca catechu* nut (MAN) by maceration method and analyze its various secondary metabolites.
- To evaluate MAN for anxiolytic and antidepressant activities in alcohol withdrawn mice using the following mouse models:
- Anxiolytic activity screening models
    a. Handling induced convulsions (HIC)
    b. Open field test (OFT)
    c. Elevated plus maze (EPM)
    d. Marble burying test (MBT)
- Anti-depressant activity screening model
    a. Sucrose preference test (SPT)

Results:

The methanolic extract of *Areca catechu* nut showed significant anxiolytic and antidepressant activities at the doses of 50 and 100 mg/kg, p.o. in alcohol-withdrawn mice based on various evaluation parameters like convulsion score (HIC), no. of center and peripheral line crossings (OFT), % no. of entries and % time spent in central and peripheral compartment (OFT), % no. of entries and % time spent in open arms (EPM), no. of marbles buried (MBT), and amount of sucrose intake (SPT).

Key words: *Areca catechu* nut, alcohol withdrawal, anxiolytic activity, antidepressant activity, mice.

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"Therapeutic potential of *Morinda citrifolia* Linn. fruit against alcohol withdrawal in mice"

Dissertation submitted to

CHALAPATHI INSTITUTE OF PHARMACEUTICAL SCIENCES

In the Partial Fulfillment of the Requirements

For the award of the Degree of

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"Therapeutic potential of Morinda citrifolia Linn. fruit against alcohol withdrawal in mice"

ABSTRACT

Objective:

To investigate the therapeutic potential of *Morinda citrifolia* Linn. fruit against alcohol withdrawal in mice.

Methodology:

- The standardised methanolic extract of *Morinda citrifolia* fruit (MMC) obtained from Sun Pure Extracts Private Limited, India was analysed for the presence of various secondary metabolites.
- The preclinical evaluation of standardized methanolic extract of the *Morinda citrifolia* fruit (MMC) for anxiolytic and antidepressant activities in alcohol-withdrawn mice was carried out by using the following mouse models:
  - Anxiolytic activity screening models
    a. Handling induced convulsions (HIC)
    b. Open field test (OFT)
    c. Elevated plus maze (EPM)
    d. Marble burying test (MBT)
  - Antidepressant activity screening model
    a. Sucrose preference test (SPT)

Results:

The methanolic extract of *Morinda citrifolia* fruit showed a significant anxiolytic and antidepressant activities at the dose of 500 and 1000 mg/kg, p.o. in alcohol-withdrawn mice based on the various evaluation parameters like convulsion score (HIC), no. of center and peripheral line crossings (OFT), % time spent in central and peripheral compartment (OFT), % no. of entries and % time spent (EPM), no. of marbles buried (MBT), and amount of sucrose intake (SPT).

Key words: Neurological process, *Morinda citrifolia* fruit, anxiety and depression.

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PHARMACOLOGICAL AMPLIFICATION BY COMBINATION OF EXTRACTS OF *ARTEMISIA VULGARIS* AND *CHANNA STRIATUS* FILLET IN MICE MODELS OF DEPRESSION

Dissertation submitted to

CHALAPATHI INSTITUTE OF PHARMACEUTICAL SCIENCES

In the Partial Fulfillment of the Requirements

For the award of the Degree of

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"PHARMACOLOGICAL AMPLIFICATION BY COMBINATION OF EXTRACTS OF ARTEMISIA VULGARIS AND CHANNA STRIATUS FILLET IN MICE MODELS OF DEPRESSION"

ABSTRACT

Background: The leaves, roots and oils extracted of *Artemisia vulgaris* plant have been used traditionally to treat various diseases. Though, it has not yet been pharmacologically assessed for depression. *Channa striatus* fish has been used as a dish to eat and it naturally contains anti-depressant activity.

Objective: The objective of the present study is to evaluate the anti-depressant potential of aqueous extracts of *Artemisia vulgaris* and *Channa striatus* fish fillet.

Methods: Preliminary phytochemical analysis was carried out by using standard procedures. Anti-depressant potential was evaluated in-vivo via forced swimming induced depression model at 200mg/kg and 40%w/v concentration doses.

Results: The results revealed the presence of alkaloids, flavonoids, phenols, volatile terpenes, coumarines, insulin, etc. The results of Forced swimming test and Tail suspension test significantly had shown anti-depressant activity by decreasing the immobility time of the mice.

Conclusion: The results support the traditional use of *Artemisia vulgaris and Channa striatus* as potential anti-depressant agent and can be used for the treatment of depression.

Keywords: Artemisia vulgaris, Channa striatus, Depression, Forced swimming test, Tail suspension test.

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"EVALUATION OF NOOTROPIC ACTIVITY OF *PHYLLANTHUS EMBLICA* AND *TAMARINDUS INDICA* LEAF EXTRACTS IN RODENTS"

Dissertation submitted to

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In the Partial Fulfillment of the Requirements

For the award of the Degree of

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ABSTRACT

Objective:

To carry out the Evaluation of Nootropic activity of *Phyllanthus emblica* and *Tamarindus indica* leaf extracts in rodents.

Methodology:

The preclinical evaluation of standardized nootropic activity of HAPE and EATI was carried by using the following models:

a) Hebb's William Maze
b) Labrynth Maze
c) Rectangular Maze
d) Evaluation of Brain AchE enzyme using Ellman's method

Results:

Behavioural models that affect the cognitive processes was standardized and evaluated by using HAPE and EATI. Both extracts shown significant nootropic activity due to the presence of flavonoids. Latency time was considered for the evaluation parameters. From the observed results the latency scores of extract having higher concentration showed significant values by using statistical analysis. Ellman's Reagent was used for estimating the brain AchE levels and UV absorbance was used to calculate the % inhibition.

Key words: Nootropic activity, *Phyllanthus emblica*, *Tamarindus indica*, Ellman's method, Learning and Memory.

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"NEUROPROTECTIVE AND BRAIN STIMULATIVE EFFECT OF *LINUM USITATISSIMUM* IN ALBINO MICE"

Dissertation submitted to

CHALAPATHI INSTITUTE OF PHARMACEUTICAL SCIENCES

In the Partial Fulfillment of the Requirements

For the award of the Degree of

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(Pharmacology)

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ABSTRACT

Objective:

To carry out the assessment of Neuroprotective and brain stimulative effect of *Linum usitatissimum* mucilage extract in mice.

Methodology:

The preclinical assessment of standardized mucilage extracts of the seeds of *Linum usitatissimum* for Neuroprotective and brain stimulative effect was carried by using the following exteroceptive aversive stimuli models:

a) 8-arm radial Maze
b) Morris water Maze
c) Hebbs -Willium Maze
d) Percentage inhibition of Acetylcholinesterase activity

Results:

Behavioral models for studying drugs or conditions that affect cognitive processes was standardized and evaluated by using seed extract of *Linum usitatissimum*. The mucilage seed extract of *Linum usitatissimum* has shown significant Neuroprotective and brain stimulative effect by all the employed exteroceptive aversive stimuli models due to the presence of flavonoids. Time to reach the reward chamber (TRC), Escape latency time are considered as evaluation parameters. Ellman's Reagent was used in identifying the brain Ach esterase levels and UV absorbance was used to calculate the % AchE inhibition.

Key words: Neuroprotective, brain stimulative effect, *Linum usitatissimum*, flavonoids, latency time, Ach esterase levels.

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PHARMACOLOGICAL AND PHYTOCHEMICAL EVALUATION OF *CAPPARIS ZEYLANICA* LEAVES FOR ANTIHYPERLIPIDEMIC ACTIVITY USING INVIVO MODELS ON RATS

Dissertation submitted to

CHALAPATHI INSTITUTE OF PHARMACEUTICAL SCIENCES

In the Partial Fulfillment of the Requirements

For the award of the Degree of

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"PHARMACOLOGICAL AND PHYTOCHEMICAL EVALUATION OF CAPPARIS ZEYLANICA FOR ANTIHYPERLIPIDEMIC ACTIVITY USING INVIVO MODELS ON RATS"

ABSTRACT

Objective:

To carry out the Pharmacological and phytochemical evaluation of *Capparis zeylanica* leaf extract for Anti hyperlipidemic activity in Rats.

Methodology:

The preclinical evaluation of standardized ethanolic and methanolic extracts of the leaves of *Capparis zeylanica* for Anti hyperlipidemic activity was carried by using the following methods:

INVIVO METHODS

EXERCISE MODELS

Results:

The results show that there were significant increase in Total serum cholesterol and low density lipoprotein, very low density lipoprotein and reduction in High density lipoprotein in High fat diet induced hyperlipidemic rats after 14 days. Oral administration of Ethanolic and Methanolic extracts of Capparis zeylanica leaves for a period of 14 days shows the decrease in Total serum cholesterol, low density lipoprotein, very low density lipoprotein and increase in high density lipoprotein in high fat induced hyperlipidemic rats.

Key words: Antihyperlipidemic, *Capparis zeylanica*, Serum cholesterol.

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"PHARMACOLOGICAL EVALUATION OF ANTIASTHAMATIC ACTIVITY OF AZIMA TETRACANTH LEAVES EXTRACTS IN MICE"

Dissertation submitted to

CHALAPATHI INSTITUTE OF PHARMACEUTICAL SCIENCES

In the Partial Fulfillment of the Requirements

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EVALUATION CERTIFICATE

This is to certify that the dissertation work entitled "PHARMACOLOGICAL EVALUATION OF ANTIASTHAMATIC ACTIVITY OF AZIMA TETRACANTHA LEAVES EXTRACTS IN MICE" *submitted by* **R. NAVEEN(Y19MPHPY449)** *in partial fulfilment for the award of the degree in* **MASTER OF PHARMACY in PHARMACOLOGY** *is the bonafied research work carried out by the candidate in the Department of Pharmacology, Chalapathi Institute of Pharmaceutical Sciences, Lam, Guntur and was evaluated by us during the academic year* **2020-2021**.

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Abstract

Azima tetracantha lam (family:Salvadoraceae),commonly known as thella uppichettu is used for it's medicinal values in india since ancient times.the present study was undertaken to evaluate the antiasthmatic activity properties of ethanolic extract of Azima tetracntha leaves at dose at dose 100,200 mg/kg by milk induced eosinophilia and leucocytosis and clonidine induced catalepsy in mice methods.phytochemical screening were carried out for EEAT and found the presence of alkaloids,flavonoids,glucosinolates,steroids,saponins,tannins from the experimental study,it was controlled ethanolic extract of *Azima tetracantha lam* has shown significant in the anti-asthmatic activity.the signifiacant in the anti asthmatic activity may be due to the presence of alkaloids and glucosinolates.

Keywords: Azima tetracantha lam,anti-asthmatic activity,milk induced eosinophilia and leucocytosis,clonidine induced catalepsy in mice.

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"EVALUATION OF ANTIDEPRESSANT AND ANXIOLYTIC ACTIVITIES OF METHANOLIC EXTRACT OF *PIPER BETLE* LINN. LEAF IN ALCOHOL WITHDRAWN MICE"

Dissertation submitted to

CHALAPATHI INSTITUTE OF PHARMACEUTICAL SCIENCES

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 antidepressant and anxiolytic activities of methanolic extract of *Piper betle* Linn. leaf in alcohol withdrawn mice"

ABSTRACT

Objective:

To evaluate antidepressant and anxiolytic activities of methanolic extract of *Piper betle* Linn. leaf in alcohol withdrawn mice.

Methodology:

The preclinical evaluation of standardized methanolic extract of the leaves of *Piper betel* leaf for antidepressant and anxiolytic activity was carried by using the following animal models:

a) Open Field Test (OFT)
b) Elevated Plus Maze (EPM)
c) Marble Burying Test (MBT)
d) Sucrose Preference Test (SPT)

Results:

The methanolic extract of *Piper betel* leaf has shown significant antidepressant and anxiolytic activity in alcohol withdrawn mice using OFT, EPM, MBT and SPT. The various parameters significantly altered are the time spent and no of entries in central compartment (OFT), time spent and no of entries in open arm (EPM), no. of marbles buried (MBT) and increase in sucrose intake ratio (SPT).

Key words: Anxiolytic, antidepressant activity, *Piper betel* leaf, open field test (OFT), elevated plus maze (EPM), marble burying test (MBT), sucrose preference test (SPT).

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PHARMACOLOGICAL EVALUATION OF ANTICONVULSANT ACTIVITY OF ETHANOLIC EXTRACT OF *EUPHORBIA CYATHOPHORA* LEAVES BY *IN-VIVO* METHODS ON ALBINO MICE.

Dissertation submitted to

CHALAPATHI INSTITUTE OF PHARMACEUTICAL SCIENCES

In the Partial Fulfillment of the Requirements

For the award of the Degree of

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ABSTRACT

Objective:

To carry out the Evaluation of Antiepileptic activity of *Euphorbia cyathophora* leaf extracts in mice.

Methodology:

The preclinical evaluation of standardized Anti epileptic activity of EEEC was carried by using the following models:

a) Pentylene tetrazole induced seizure model
b) Picrotoxin induced seizure model
c) Bicuculline induced seizure model

Animals models for studying drugs or conditions which affect latency of seizures was standardized and evaluated by using leaf extracts of *Euphorbia cyathophora*. The ethanolic extract of *Euphorbia cyathophora* has shown Antiepileptic activity by various models like Pentyene tetrazole induced model, Picrotoxin induced model and Bicuculline induced model. Statistical significance has shown has obtained when compared with standard by using statistical analysis. The activity has been shown due to presence of flavonoids. Further investigation of EEEC may reveal the mechanism of Anti epileptic activity.

Key words: Anti epileptic activity, *Euphorbia cyathophora*, picrotoxin, pentylene tetrazole, Bicuculline

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"HEPATOPROTECTIVE EFFECT OF METHANOLIC EXTRACTS OF *TIBOUCHINA URVILLEANE AND TORENIA FOURNIERI LINDEN EX E. FOURN* AGAINST CARBONTETRACHLORIDE INDUCED HEPATIC DAMGE IN RATS"

A Dissertation Submitted to

CHALAPATHI INSTITUTE OF PHARMACEUTICAL SCIENCES

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

MASTER OF PHARMACY
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ABSTRACT

Objective: To evaluate the hepatoprotective effect of *Tibouchina urvilleana (DC.) Cogn.* and *Torenia fournieri Linden ex E. Fourn* against CCl_4 induced hepatic damage in rats.

Methods: Phytochemical analysis was carried out by using standard procedures. Animals were divided into seven groups and each group contains 5 animals out of that two groups were treated with *Tibouchina urvilleana (DC.) Cogn.* (100mg/kg and 200 mg/kg) and two groups treated with *Torenia fournieri Linden ex E. Fourn* (100mg/kg and 200 mg/kg) and Silymarin (50mg/kg) for 15 days before damage the liver by CCl_4. At the end of the study Blood biochemical parameters, serum enzymes, histology of liver was evaluated

Result: The phytochemical analysis has revealed the presence of flavonoids, tannins carbohydrates, phenolic, alkaloids, and glycosides. Decreasing plasma levels of SGOT, SGPT, ALP, total bilirubin, uric acid, creatinine, blood urea nitrogen animals treated with *Tibouchina urvilleana (DC.) Cogn. and Torenia fournieri Linden ex E. Fourn* both were shown significant hepatoprotective effect.

Conclusion: The results support that traditional use of *Tibouchina urvilleana (DC.) Cogn. and Torenia fournieri Linden ex E. Fourn* as hepatoprotective property can be used for the protection of liver from various toxicity

Keywords: *Tibouchina urvilleana (DC.) Cogn. Torenia fournieri Linden ex E. Fourn* CCl_4 hepatotoxicity and liver enzymes.

EVALUATION OF ANTI-ARTHRITIC POTENTIAL OF HYPTIS SUAVEOLENS SEEDS IN RATS

Dissertation submitted to

CHALAPATHI INSTITUTE OF PHARMACEUTICAL SCIENCES

In the Partial Fulfillment of the Requirements

For the award of the Degree of

MASTER OF PHARMACY

(Pharmacology)

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ABSTRACT

Background: The seeds of *Hyptis suaveolens* (L) poit.. (Lamiaceae) have been used traditionally to treat inflammatory disorders like rheumatoid arthritis etc. Though, it has not yet been pharmacologically assessed for rheumatoid arthritis.

Objective: The objective of the present study is to evaluate the anti-arthritic potential of aqueous extract of *Hyptis suaveolens* (L) poit... seeds (AEHS).

Methods: Preliminary phytochemical analysis was carried out by using standard procedures. Anti-arthritic potential was evaluated *in-vitro* using protein denaturation method (egg albumin) at concentrations 25 - 800µg/ml and in vivo via Egg albumin induced arthritic model at 200 and 400 mg/kg doses.

Results: The results revealed the presence of alkaloids, carbohydrates, flavonoids, phenols, terpenoids etc. The *in-vitro* results exhibited maximum % inhibition of protein denaturaion at 800µg/ml i.e. 75%. The results of Egg albumin model have shown that AEHS significantly ($P < 0.0001$) prevents alterations in paw volume, joint diameter and body weight. It also ameliorates the changes in hematological, biochemical and histopathological parameters.

Conclusion: The results support the traditional use of *Hyptis suaveolens(L)poit.*. seeds as potential anti-arthritic agent and can be used for the treatment of rheumatoid arthritis.

Keywords: *Hyptis suaveolens*., Rheumatoid arthritis, Protein denaturation, Egg albumin

"ISSUES RELATED TO PATENT FOR FILING OF ANDA FROM FY 2018-2020"

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
(PHARMACEUTICAL MANAGEMENT AND REGULATORY AFFAIRS)

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ABSTRACT

USFDA is one the most regulated agencies wherein the submission process is most critical. The study depends on how to submit ANDA application as per FDA, CDER guidelines in paragraph IV submission in Federal Food, Drug, and Cosmetic Act (FD&C Act). No drug would be available in the market until and unless it get approved by Regulatory Authorities. "Paragraph IV Certification" is useful for exclusive right to market the generic drug for 180 days. Submission is for the company which is seeking to copy branded drug before expiration of patents to get benefit over it, a generic applicant must provide in its application a "certification" that a patent submitted to FDA by the brand-name drug's sponsor and listed in FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (the Orange Book). A Generic Product must meet the standards established by FDA in RLD (Reference listed drug). There are hurdles which delay the timely introduction of generic drugs into the market: use of authorized generics, continued misuse of the Citizen Petition process, the use of Free Trade Agreements and the patent reform.

Key words: ANDA, CDER, FDA, Federal Food, Drug, and Cosmetic Act (FD&C Act), Orange Book, paragraph IV, Reference listed drug (RLD), USFDA.

"RECENT TRENDS IN COMMON TECHNICAL DOCUMENT (CTD) & ELECTRONIC COMMON TECHNICAL DOCUMENT (eCTD) DOSSIER FILING"

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
(PHARMACEUTICA REGULATORY AFFAIRS)

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ABSTRACT

Electronic Common Technical Document (eCTD) is a topic of increasing interest in the pharmaceutical environment. Electronic Common Technical Document (eCTD) is an interface for the pharmaceutical industry to agency transfer of regulatory information. Since June 2003, applicants have had the option of submitting an eCTD in parallel with the paper submission (Common Technical Document), following sign-off by the International Conference on Harmonisation Steering Committee of the eCTD Specification document at Step 4. When it comes to eCTD submission, there continues to be differences among different countries and even ICH regions. The standardization that electronic submissions will bring will allow for much greater consistency not only for the regulators but also for organizations. It is important that eCTD ready documents are prepared by authoring them in eCTD compliant templates. If this is not undertaken, a large amount of the "publishing time" is spent in document reformatting. As the move from paper-based to eCTD submissions continues around the world, a multitude of challenges are to be faced regulatory departments. This describes eCTD modules, history, Benefits of Implementing, Challenges, Modules and Risks involved in eCTD publishing and Quality Control. Although a three-fourths majority of those with eCTD experience reported disadvantages in implementing eCTD, an overwhelming majority of the same group reported advantages that outweighed the disadvantages, some of them significantly. More than three-quarters of individuals with eCTD experience were able to shorten their total time to approval, and more than 90% of this group was able to demonstrate cost savings relative to paper submissions, regardless of their company kind, size, or number of submissions[1].

Key words: Electronic Common Technical Document,(eCTD)/(CTD) Benefits, Challenges, Modules, eCTD advantages and disadvantages.

"COMPREHENSIVE FDA WARNING LETTER ANALYSIS RELATED TO MANUFACTURING QUALITY OF DRUGS FROM FY 2018 - FY 2020"

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
(PHARMACEUTICAL MANAGEMENT AND REGULATORY AFFAIRS)

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Place: Guntur

Date: 29/07/21

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ABSTRACT

USFDA is one the most regulated agency. The USFDA's office of manufacturing quality (OMQ) at the Centre for Drug Evaluation and Research (CDER) evaluates compliance with cGMP for drugs based on inspection reports & evidence gathered by USFDA investigators. Matters described in FDA warning letters which may have been subject to subsequent interaction between FDA and the recipient of the letter that may have changed the regulatory status of the issues discussed in letter. An FDA Form 483 is issued to firm management at theconclusion of an inspection when an investigator(s) has observed any conditions that in their judgment may constitute violations of the Food Drug and Cosmetic (FD&C) Act and related Acts. This study is about analysis on FDA warning letters in the year 2018,2019,2020 related to Manufacturing Quality and to comparison between India and other nations. This is to analyse that the issuance of warning letters related to manufacturing quality in India or among other nations is increasing or decreasing.

Key words: USFDA, CDER, Form 483, FD&C act, cGMP.

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" TRENDS IN US FDA BIOLOGICAL LICENSE APPROVALS OVER LAST 5 FISCAL YEARS : AN OBSERVATIONAL STUDY"

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

(PHARMACEUTICAL REGULATORY AFFAIRS)

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ABSTRACT

The discovery of novel biological drugs is significant for pharmaceutical research and development as well as for patient treatment. Repurposing existing drugs that may have anticipated effects as a potential candidate is one way to congregate this important goal. Systematic investigation and comprehensive analysis of approved drugs could provide valuable insights into trends in the discovery and may contribute to further discovery of newer biological drugs systematically. Food and drug administration (FDA's) Center for Biological Evaluation and Research (CBER) every year summarizes novel drugs, some of which are truly innovative and help in advancing clinical care. This study was conducted to find a trend in Biological drug approvals by FDA in the last 5 Fiscal Years (FY) Awareness of these new Biological drugs amongst the primary care physicians is also crucial as they have been prescribing these agents in the past. In this cross-sectional study, we collected, surveyed, and analyzed Biological drugs approved by the U.S. Food and Drug Administration (USFDA) from the year 2016 till 2020 identified from the online database of FDA. Drugs approved every year were assessed for the total number and indication of approval. There has been a steady rate of introduction of new drugs by CBER over the last five financial years. Expedited approval of anticancer and biologics is seen as the recent trend in drug development. These findings reflect more emphasis being laid down in research for biologics.

Key Words: Biological drug approval, drug discovery, and development, USFDA

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"REGULATORY ASPECTS OF BIOSIMILARS AND INTERCHANGEABLE PRODUCTS IN UNITED STATES"

A Dissertation Submitted to

CHALAPATHI INSTITUTE OF PHARMACEUTICAL SCIENCES
LAM, GUNTUR

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

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ABSTRACT

The regulation of biosimilars products consists of a significant challenge, since they are the part of sector of the pharmaceutical industry and normally used by human beings. The united states enacted the Biologics Price Competition and Innovation Act (BPCI Act) under the public health service Act (PHS Act) in the end of march 2010 to provide the application pathway for follow-on biological product under licensure section 7001 to 7003 of the patent protection and affordable care Act (PPAC) and also codified in USC 262(k). the anti-cancer biosimilars have enter clinical use with many others under clinical development like all biologics. The goals of the BPCIA are to stimulate price competition and thereby facilitate greater access to biologic therapies for patients with indicated conditions. Since 2020, the FDA has approved 30 biosimilar products for cancer supportive care and the treatment of cancers and immune-mediated inflammatory diseases. The approval of biosimilars is based on the analytical study, non-clinical studies and clinical studies and for the interchangeable product the additional information for increase the therapeutical efficacy of the biosimilars. The licensure pathway of biosimilar and interchangeable product where Biologics licensing application (BLA) under sec. 351(k), the biosimilar user fee amendment is committed reviewing and acting on original 351(k) BLAs within 10 months of the 60-day filing date. And the research is about the regulation, approval process for the biosimilar products as per United States Food and Drug Administration.

Keywords: Biosimilars, regulation, FDA approved biosimilar products, interchangeability, comparative clinical studies, BSUFA.

"NUTRACEUTICAL REGULATIONS AND REGISTRATION PROCESS IN USA"

A Dissertation Submitted to

CHALAPATHI INSTITUTE OF PHARMACEUTICAL SCIENCES
LAM, GUNTUR

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Abstract

Nutraceutical is the hybrid of 'Nutrition' and 'Pharmaceutical'. Nutraceuticals, in broad, are food or part of food playing a significant role in modifying and maintaining normal physiological function that maintains healthy human beings. The principal reasons for the growth of the nutraceutical market worldwide are the current population and the health trends.Functional foods and internationally products represent a value added growth opportunity both domestically and internationally. Development of better characterized and research proven products will help enhance consumer confidence in nutraceutical and functional food products in the world.The global nutraceutical market will reach $285.0 billion by 2021 from$198.7 billion in 2016 at CAGR of 7.5% from 2016-2021. The present research has been devoted towards better understanding of the nutraceuticals and its regulation in USA.

Keywords: Nutraceuticals, dietary supplements, Regulations, Market scenario

"A PROSPECTIVE STUDY ON ORPHAN DRUG DEVELOPMENT IN MIDDLE EAST COUNTRIES"

A Dissertation Submitted to

CHALAPATHI INSTITUTE OF PHARMACEUTICAL SCIENCES
LAM, GUNTUR

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ABSTRACT :

An orphan drug is a medication that has been specially created to treat a rare medical disorder. A big public-health concern and a threat for the medical community is rare diseases (RDs). With a combined population of less than 400 million, approximately 2.8 million patients in the Middle Eastern countries are estimated to suffer from a rare disorder. In the Middle East countries, some diseases such as hemoglobinopathy, glucose-6-phosphate dehydrogenase deficiency, autosomal recessive syndromes, and several metabolic disorders are present. In order to promote the treatment of these diseases, Middle Eastern governments need to facilitate healthcare staff education and training; develop and implement orphan drug procurement and payment methods; and, finally provide domestic and in-house tax, marketing and other incentives.

Keywords: Orphan drug, rare disease, genetic disorder, Middle East countries

"SUPPLEMENTARY PROTECTION CERTIFICATES IN EUROPEAN UNION"

A Dissertation Submitted to

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ABSTRACT

In recent years, there has been increasing pressure on public health systems in high-income countries due to high medicines prices, one of the underlying causes of which are the market monopolies granted to pharmaceutical undertakings. These monopolies have been facilitated by expanded forms of intellectual property protections, including the extension of the exclusivity period after the expiration of the patent term concerning medicinal products. In the European Union such an approach lies in the Supplementary Protection Certificate, a mechanism formally introduced under Regulation 1768/92/EEC (now: Regulation 469/2009/EC, amended). After more than 20 years of implementation since it was first introduced, the common justifications for SPCs are being challenged by recent findings as to their functioning and impact. Therefore, mechanisms of patent term restoration, extension, and in Europe, SPCs were created to compensate for the lack of commercial exploitation possibilities during the years of medicines development and regulatory approval processes of a pharmaceutical product.

Keywords: approval process, Intellectual property rights, regulations, supplementary protection certificate.

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"REGULATORY COMPARATIVE STUDIES FOR THE REGISTRATION OF BIOSIMILARS IN AUSTRALIA AND SINGAPORE"

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
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ABSTRACT

The expiration of patents on many biological medicinal products has prompted the development of these products as similar biological (biosimilar) products. Biosimilar' denotes a biological medicine which is highly similar to an already authorized reference biological medicine and also referred to as Bio therapeutic products, Follow on biologics. Subsequent entry biologics, with respect to different Ministry of health. Depends on type of country regulations, and approval process of generic version of biopharmaceuticals is specified. The standard approach of demonstration of bioequivalence for chemical generic products is scientifically not applicable for biosimilar products. The biosimilar product approach, based on comparability (demonstration of similarity), should be adopted. In view of the impending submissions and to facilitate access of such products at a more affordable price in Singapore, the Regulatory Authority is Health Sciences Authority (HSA). In Australia the regulatory authority Therapeutic Goods Administration (TGA) has adopted the European Union procedure for approving biosimilars, Centralized Procedure is mandatory for Biosimilar and fall within the scope of Regulation EC 726/2004; Food drug & administration is still in the process of developing guidelines regarding these types of products. In Singapore these are approved under NDA-2, NDA-3 process. This paper aims to facilitate the regulatory requirements for the approval process of Biosimilar in Regulated and Emerging markets by establishing the foundation for a harmonized regulatory standard to meet common demands of a regions like Australia & Singapore.

Key Words: Bioequivalence Biosimilar HSA, NDA, TGA.

"REGULATION OF FALSIFIED MEDICINES DIRECTIVE IN EUROPE"

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
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ABSTRACT

The study of counterfeiting and falsification of medicinal products, from a legal perspective, is a relatively new area in the EU. Specific regulations that focus on falsification of medicines came as recently as 2011. The European Medicines Agency (EMA) is responsible for protecting public health by the scientific evaluation of innovative and high-technology medicines developed by pharmaceutical companies for use in the EU.

Falsified medicines present a threat to public health in the form of adverse reactions, dangerous ingredients interaction with other medicines, no improvement in health condition disincentive to take prescribed medicines and loss of faith in health care system. At present there is no mechanism that allows users to verify where a medicine comes from. The EU falsified medicines directive (FMD) seeks to prevent falsified medicines from entering the legitimate supply chain and reaching patients. This impact assessment considers the Article 23 flexibility within the safety features policy of the FMD. The "safety features" policy requires a unique identifier and tamper- evident features to be added to prescription medicine packs to prevent harm to people from falsified medicines and to reduce the occurrence of falsified medicines in the legitimate supply chain.

Key words: EU FMD, Falsified medicines, Falsified medicines Directive, Safety features, Supply chain

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A Dissertation Submitted to

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LAM, GUNTUR

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

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ABSTRACT

The pharmaceutical industry is one of the most regulated industries. No drug would be available in the market until and unless it get approved by Regulatory Authorities. Regulatory Affairs is a specialized profession in the pharmaceutical sector.

A Generic drug is a pharmaceutical product, usually intended to be interchangeable with a new drug (an innovator product) that is marketed after the expiry date of the patent (a monopoly right granted to the innovator for his/her invention) or other exclusivity rights. Generic product must meet the standards established by Regulatory Authorities to be approved for marketing in specified country.

The present study covers the introduction to generic drugs, and Canada and Singapore regulatory authorities. It also includes the requirements and registration of Generic Drugs in above specified countries. It also includes the checklist for ANDS filing for Generic drugs in Canada and Format of Drug Dossier for registration of generic drugs in Canada and Singapore.

Key words: ANDS, Canada, Checklist, Exclusive rights, Generic drugs, Interchangeable, Registration, Regulatory Authorities, Singapore.

"REGULATORY REQUIREMENTS COMPARISON STUDY OF MEDICAL DEVICES IN UNITED STATES AND EUROPE"

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
(PHARMACEUTICAL REGULATORY AFFAIRS)

Submitted by

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ABSTRACT

The purpose of this study is to elucidate the importance of medical devices, regulations in United States of America (USFDA) and Europe (EMA). Their overview and impacts of regulatory requirements in the registration, manufacturing and authorization process of medical devices in both countries. One of the major issues for companies developing and producing medical devices is to be updated on the basis of the regulatory requirements and implement them in the process of manufacturing.

One of the major reasons that companies want to register them in the different countries is to expand their business. In US Medical Devices are regulated by FDA- Centre for Devices & Radiological Health (CDRH). Europe is a developed country in which using of medical devices is more due to increased ratio of aged people. But these countries had different regulations to maintain the quality of medical devices marketing in their countries. Our study concludes that "Regulations for the safety of patient is same but rules and procedures followed to implement that are different"; due to the reason countries frame the guidelines as per their Authorization like CTD.

Key words: CTD, EMA, medical devices, USFDA

"ANALYSIS OF MEDICAL DEVICES RECALLS ISSUED BY FDA DURING FINANCIAL YEARS 2018 TO 2020"

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
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ABSTRACT

A recall is a mechanism for the elimination or modification of items that violate the laws of the Food and Drug Administration (FDA). The FDA medical device recalls database was used to identify recalls of medical devices. Maximum devices are worldwide distribution and some are US national wide distribution at the time of recall. Recall is voluntary action. 49 medical devices recall in 2019 compared to previous years because medical devices reliant on software or computer technology. 31 medical devices recalls in 2018 and 32 medical devices recalls in 2020. This study said that Number of medical devices recall based on their recall reason. Market numbers of medical devices are increasing that rely on computer technology it is trigger problems. If a company fails to recall any device or product associated with serious health problems or death.

KEY WORDS:

Food and Drug Administration, Medical devices, code of federal regulations, Federal Food, Drug and Cosmetic Act

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PREPARATION AND EVALUATION OF SKIN PROTECTIVE MICROEMULGEL WITH NATURAL SUN PROTECTIVE ACTIVITY

Thesis submitted to

CHALAPATHI INSTITUTE OF PHARMACEUTICAL SCIENCES,

LAM, GUNTUR

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

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Abstract: This research aims to formulate and evaluate the photo protective activity of an Emulgel containing oil in water emulsion with different natural oils in varying proportions. The formulation is evaluated for its physical, chemical, stability and organoleptic properties for 90 days. The formulation was stable, white preparation with no recognizable irritancy when tested. SPF was determined to be 59.7 that can give both UV A and UV B protection. The newly formulated sunscreen emulgel was proved to exhibit a number of promising properties and attributes that might open new opportunities for the development of more efficient, safe, and Cost-effective skincare products.

Keywords: Ultraviolet light; sun protection; sunscreen; SPF; UV A and B protection; Emulgel.

BIOAVAILABILITY ENHANCEMENT OF TELMISARTAN BY INCLUSION COMPLEXES WITH β-CYCLODEXTRINS

Thesis submitted to

CHALAPATHI INSTITUTE OF PHARMACEUTICAL SCIENCES, LAM, GUNTUR

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

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This is to certify that the dissertation entitled **"Bioavailability enhancement of telmisartan by inclusion complexes with β-cyclodextrins"** was a *bonafide* research work of **P. Sivaram Kumar Rg. No.(Y19MPHIP482)** carried out at Department of Industrial Pharmacy and submitted to Chalapathi Institute of Pharmaceutical Science (CLPT), Lam, Guntur was evaluated by the undersigned in partial fulfilment of the requirements for the award of **Master of Pharmacy** degree in **Industrial Pharmacy** during the academic year 2020-2021.

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ABSTRACT

The objective of the study is to increase the dissolution rate of telmisartan, a poorly water-soluble drug, an angiotensin-II receptor antagonist used in the treatment of hypertension. To improve the dissolution rate of telmisartan, prepared inclusion complexes with β-cyclodextrin (β-CD), hydroxypropyl-β-cyclodextrin (HP-β-CD). The phase solubility studies indicated that the solubility of telmisartan was significantly increased in the presence of β-CD and the presence of HP-β-CD and A_L type curve was obtained. The apparent stability constant (Ks) was found to be 1230 M^{-1} for β-CD and 1300 M^{-1} for HP- β-CD. The inclusion complexes in the 1:1 molar ratio of telmisartan and carriers were prepared by the spray-drying method. The prepared complexes were characterized using differential scanning calorimetry (DSC), and Powder X-ray diffractometry. The DSC and X-RD showed conversion of telmisartan from crystalline to amorphous form in the prepared complexes. The prepared complexes are made into different dispersible tablet formulations F1 to F8 by varying the percentage of super disintegrants. All the prepared formulations showed an improved dissolution rate of telmisartan. The inclusion complex prepared with HP-β-CD formulation F8 shows the enhancement of dissolution rate by three folds. The accelerated stability studies for one month indicate there is no significant difference in quality control tests, the results indicate that the prepared formulation is stable.

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