FORMULATION AND *IN-VITRO* EVALUATION OF CARVEDILOL BUCCAL FILMS USING HPMC E15 AND SAGO STARCH AS POLYMER

Dissertation

Submitted

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

MASTER OF PHARMACY

By

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(214Q1S0310)

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Under the Guidance of

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I hereby declare that the topic entitled **"FORMULATION AND IN-VITRO EVALUATION OF CARVEDILOL BUCCAL FILMS USING HPMC E15 AND SAGO STARCH AS POLYMER"** which is submitted to Jawaharlal Nehru technological university for partial fulfilment of the requirements for the award of the degree of **Master of Pharmacy** is the work done by me under the guidance of **DR. M. KRISHNAVENI M.Pharm, PhD.**, Department of Pharmeceutics, Narayana Pharmacy College, Nellore during the academic year 2021-2023.

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FORMULATION AND EVALUATION OF CAPECITABINE MICROSPHERES FOR COLORECTAL CANCER

A Project work Submitted to

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

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

MASTER OF PHARMACY

In

PHARMACEUTICS

By

Mr.SHAIK.RABBANI

(Reg. No. 204Q1S0308)

Under the Guidance of

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Sk. Rabbani

Signature Of Student

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FORMULATION AND EVALUATION OF *INVITRO* ANTIOXIDANT AND ANTI-INFLAMMATORY ACTIVITY OF POLYHERBAL GEL

Dissertation

Submitted to

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR, ANANTHAPURAMU

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

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By

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P. SRI HARSHITHA	(194Q1R0055)
R. YAMINI	(194Q1R0072)
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SYNTHESIS,CHARACTERISATION AND IN-SILICO,IN-VITRO ANTI-CHOLINESTERASE ACTIVITY OF SOME NOVEL 2-AMINO 5-SUBSTITUTED OXADIAZOLES

Dissertation

Submitted to

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR, ANANTHAPURAMU

Inpartial fulfillment of the requirementsfor the award of the degree of

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Project Viva-voce held on 27-4-2024

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27.4.24
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FORMULATION AND *IN VITRO* EVALUATION OF FLUTRIMAZOLE MICROSPHERES LOADED TRANSDERMAL GEL

Dissertation

Submitted

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

MASTER OF PHARMACY

By

KAMJULA MATHA PRIYA, B. Pharm

(214Q1S0307)

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR, ANANTHAPURAMU

Under the Guidance of

Dr. S.SUJATHA M. Pharm., Ph.D.
Professor,
Department of Pharmaceutics

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S. Sujatha 1/11/2023

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DECLARATION

I hereby declare that the topic entitled **"FORMULATION AND IN-VITRO EVALUATION OF FLUTRIMAZOLE MICROSPHERE LOADED TRANSDERMAL GEL"** which is submitted to Jawaharlal Nehru technological university for partial fulfillment of the requirements for the award of degree of **Master of Pharmacy** is the work done by me under the guidance of **Dr. S.SUJATHA,** M. Pharm, Ph.D, Professor, Department of Pharmaceutics, Narayana Pharmacy college, Nellore during the academic year 2022-2023.

I further declare that the result of this work has not been submitted for any degree or fellowship.

K. Mathapriya

KAMJULA MATHA PRIYA

(214Q1S0307)

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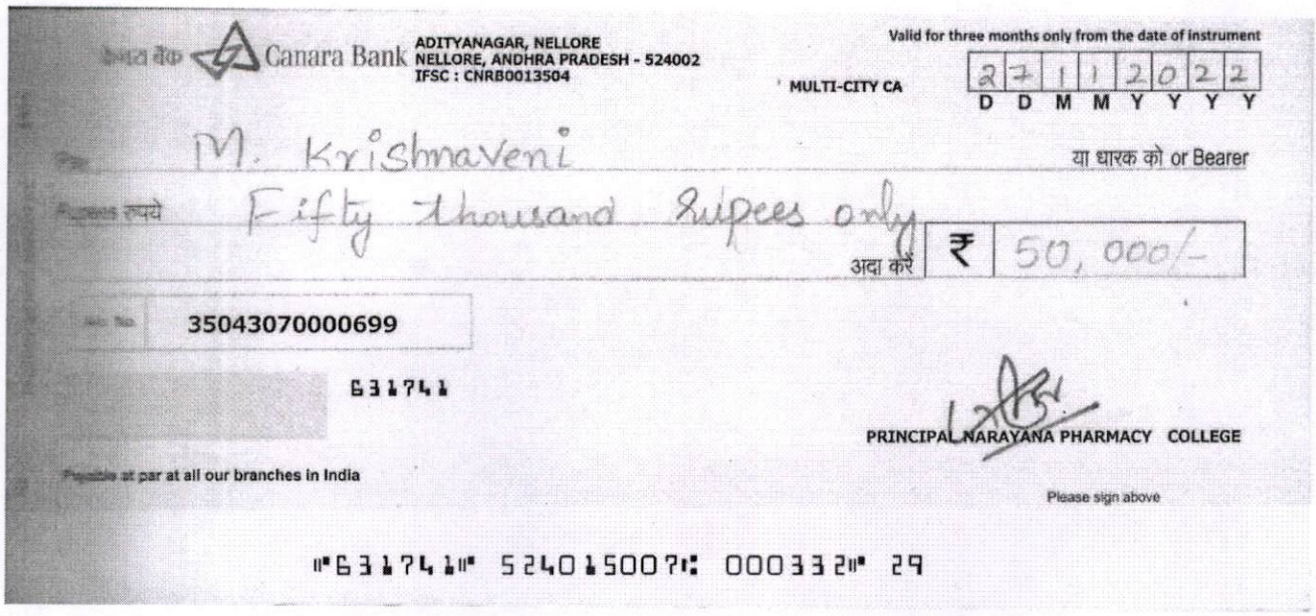

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Formulation and In -Vitro Evaluation of Flutrimazole Microspheres Loaded Transdermal Gel

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A b s t r a c t

Flutrimazole is a wide-spectrum antifungal drug. It is used for the topical treatment of superficial mycoses of the skin. Flutrimazole is an imidazole derivative. Present study was aimed to formulate and evaluate microspheres loaded transdermal gel containing Flutimazole as a model drug by employing Xanthan gum, Methocel K4M and Methocel K15M as polymers microspheres were prepared by using aqueous ionotropic gelation method. Different polymers, different drug to polymer(s) ratio(s) and other parameters were screened to study their effects on properties of microspheres and to optimize each parameter. The microspheres obtained were subjected to preformulation studies like bulk density, tapped density, angle of repose, carr's index, hausner's ratio the results obtained were with in the limit.The microspheres were characterized by Percentage yield, Drug entrapment efficiency, Particle size analysis, then the optimized microspheres formulation F8 were incorporated into the gel prepared with Methocel K100M, Sodium CMC and Guar gum as polymers and was evaluated by parameters like Visual inspection , pH measurement , Spreadability studies , Viscosity and in-vitro drug release by using franz diffusion cell for results from the diffusion results FG4 showed maximum percentage drug release of 96.85 hence it was considered as the optimized formulation.

Keywords: Flutrimazole, ionotropic gelation method,transdermal gel, Xanthan gum, Methocel K4M, Methocel K15M, Methocel K100M, Sodium CMC and Guar gum.

A r t i c l e I n f o

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CONTENTS

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ORIGINAL ARTICLE

Pharma Springs PUBLICATION

FUTURE JOURNAL OF PHARMACEUTICALS AND HEALTH SCIENCES

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Formulation and Evaluation of Capecitabine Microspheres for Colorectal Cancer

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Colorectal Cancer, Microspheres, Controlled Release

ABSTRACT

The present study aimed to formulate and evaluate Capecitabine microspheres for colorectal cancer, reduce dosing frequency, and improve patient compliance. Microspheres were prepared by emulsion solvent evaporation using polymers like ethyl cellulose (E.C.) and HPMC K-I00 in different ratios. The prepared microspheres were evaluated for flaw properties, percentage yield, drug entrapment efficiency, and *in vitro* dissolution studies. Results showed that as the concentration of polymer ratio increases, it affects the particle size, percentage yield, and drug release from the microspheres. The percentage yield of F6 microspheres was up to 95.13%. The release study was done with simulated intestinal fluid (SIF - pH 7.4) for 24 hours. It showed that the drug was protected from being released in the physiological environment of the intestine and efficiently released in the colon (95.85%). The optimized formulation F6 exhibited the drug release in a sustained manner arid following zero order, non-Fickian diffusion mechanism. An accelerated stability study was carried out for the optimized formulation. The results showed no significant changes in percentage drug entrapment efficiency, particle size, and *in vitro* controlled release of Capecitabine. The surface morphology analysis formulation F6 showed a spherical structure with smooth surface morphology. The prepared microspheres are promising drug delivery for sustained oral administration to target the colon and provide a better kinetic profile with improved bioavailability.

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INTRODUCTION

Colorectal cancer has been the 2nd most frequent cancer killer as a whole, as well as the most frequent cause of lung cancer-related mortality with in united states, both in females and males. Colorectal drug delivery, like a safe and effective therapeutic colorectal cancer, will provide effective concentration like an anti-cancer advisor at receptor sites but also spare the traditional cells for lowered dote and lowered duration of treatment [1]. Its effective active targeting of opioids towards the colorectal through the digestive tract (GIT) did require a shield of such an opioid from degeneration and discharge within the stomach and intestine and afterward makes sure sustained release inside the proximal intestines.

Minimize a dose intensity and mitigate adverse effects compared with conventional medicine. Capecitabine is an orally administered chemother-

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Synthesis,Characterisation, insilico&invitro anticholinesterase activity of some novel 2 amino 5-substituted oxadiazoles

We are pleased to inform you that the above manuscript has been accepted for online publication in Volume 4, Issue 3, July 2024 at Future Journal of Pharmaceuticals and Health Sciences (ISSN: 2583-116X)

M.Suchitra[1*], P.Deepika[1], K.Joshna[1], SK.Arshiya[1], G.Navya Sree[1], M.Swarupa[1]

Deapartment of Pharmaceutical Chemistry, Narayana Pharmacy College, Nellore

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To develop and evaluate the *in-vitro* anti oxidant and anti-inflammatory activity of polyherbal Gel

Suchitra M*[1], Harinadha Baba K[2], Yamini R[3], Sri Harshitha P[3], Surekha G[3], Pavani T[3], Sakshi Jain[3]

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Herbal treatments, in-vitro, World Health Organisation, Curcuma longa

ABSTRACT

Herbal medicines are used for their safety, efficacy, cultural acceptability and lesser side effects. The chemical constituents present in plants are a part of the physiological functions of living system and hence they are believed to have better compatibility with the human body. These drugs are made from renewable resources of raw materials by eco-friendly processes and will bring economic prosperity. An herb is a plant or plant part used for its scent, flavor, or therapeutic properties. They are sold as tablets, capsules, powders, teas, extracts, and fresh or dried plants. People use herbal medicines to try to maintain or improve their health. Products made from botanicals, or plants, that are used to treat diseases or to maintain health are called herbal products, botanical products, or phytomedicines. A product made from plants and used solely for internal use is called an herbal supplement.

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INTRODUCTION

Herbal treatments are employed because they are safe, effective, culturally acceptable, and have fewer negative effects. Because plant chemical ingredients are part of the physiological operations of living systems, they are thought to be more compatible with the human body [1]. These pharmaceuticals will create economic prosperity because they are made from renewable raw ingredients using eco-friendly procedures [2]. Herbs are plants or plant parts that are utilised for their smell, flavour, or therapeutic effects. Dietary supplements include herbal medicines [3]. They are available in the form of tablets, capsules, powders, teas, extracts, and fresh or dried plants. Herbal remedies are used by people in an attempt to preserve or enhance their health [4]. Herbal products, botanical products, or phytomedicines are products made from botanical or plants that are used to treat illnesses or maintain health [5]. An herbal supplement is a plant-derived substance that is only used internally. Medicinal plants, commonly referred to as medicinal herbs, have been identified and utilised in traditional therapeutic practises since prehistoric times. Plants generate hundreds of chemical substances for a number of purposes, including resistance and protection from insects, fungi, illnesses, as well as herbivorous mammals. Whether in modern or traditional medicine, medicinal plants are used to preserve health, to treat a specific illness, or both. In 2002, the Food and Agriculture Organisation estimated that over 50,000 medicinal plants were utilised globally. In 2016, the

Research Work: "Formulation and In-Vitro Evaluation of Carvedilol Buccal Films Using HPMC E15 and Sago Starch as Polymer"

Researchers:

- **Krishnaveni Manubolu**
- **Mohammad Amisha Sulthana**
- **Dr. K. Harinadha Baba**

Funding:
The research work was generously funded with a grant of **₹50,000** provided by the Narayana Research Fund for Advanced Pharmaceutical Studies. The grant enabled the successful completion of the formulation and evaluation of carvedilol buccal films using HPMC E15 and Sago starch as polymers.

Link of the published work: DOI: http://dx.doi.org/10.22376/Ijpbs.2024.15.2.p14-30

Project Overview

The study aimed to address the challenge of low oral bioavailability of **Carvedilol**, a drug with α1-, β1-, and β2-adrenergic blocker activity. Due to the drug's significant first-pass metabolism (resulting in only 25-35% bioavailability), the research focused on developing buccal mucoadhesive films to improve bioavailability and provide controlled drug release.

Objective:
The primary goal was to formulate carvedilol buccal films using semi-synthetic polymer **HPMC E15** and natural polymer **Sago starch** to bypass hepatic metabolism, reduce dosing frequency, and enhance patient compliance.

Methods and Results:

- **Preparation**: Carvedilol buccal films were formulated using solvent casting methods with HPMC E15 and Sago starch as primary polymers.
- **Evaluation**: The films were evaluated for various parameters including:
  - **Thickness and Weight Uniformity**: Both were within satisfactory limits.
  - **Folding Endurance**: The films showed excellent endurance with over 300 folds.
  - **Surface pH**: Films exhibited neutral pH (6.4-7), ensuring minimal irritation to the buccal mucosa.
  - **Drug Content Uniformity**: Consistent drug distribution across the films.
  - **Swelling Index**: Higher swelling was observed in HPMC E15 films compared to Sago starch films.
  - **In-Vitro Residence Time**: More than 7 hours, ensuring prolonged drug release.
  - **Permeation Studies**: Conducted using goat buccal mucosa, the films demonstrated 95.04% permeation in 8 hours.

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- **In-Vitro Drug Release**: The optimized film (S3) showed a controlled release of 98.96% over 8 hours.
- **Kinetic Modeling**: Data fitted into Higuchi and Korsmeyer-Peppas models indicated a combination of zero-order and first-order release mechanisms, along with diffusion-based drug release.

The study successfully demonstrated that the formulation of carvedilol-loaded buccal films using HPMC E15 and Sago starch provides controlled drug release and effectively overcomes the first-pass metabolism of Carvedilol.

Expenditure Breakdown

The grant of ₹50,000 was utilized as follows:

1. **Materials and Reagents**: ₹20,000
   - Purchase of polymers (HPMC E15, Sago starch)
   - Carvedilol (active pharmaceutical ingredient)
   - Solvents and chemicals for formulation and evaluation
2. **Laboratory Equipment and Supplies**: ₹15,000
   - Glassware, solvent casting apparatus, and tools for film preparation
   - Franz diffusion cell for permeation studies
   - pH meters and other analytical instruments
3. **Testing and Evaluation**: ₹10,000
   - In-vitro and ex-vivo studies, including dissolution testing
   - FTIR analysis for compatibility studies
   - Kinetic modeling software for release profile analysis
4. **Documentation and Publication**: ₹5,000
   - Printing, documentation, and publication fees for research dissemination

Total Expenditure: ₹50,000

Future Requirements

For the continuation and further enhancement of this research, the following resources and support are required:

1. **Additional Funding**:
   To expand the research scope, including clinical trials and scalability studies, an estimated additional funding of ₹1,00,000 is needed.
2. **Advanced Analytical Equipment**:
   Acquiring high-performance liquid chromatography (HPLC) and other sophisticated analytical instruments for more detailed pharmacokinetic studies.

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3. **Collaborations**:
   Collaboration with clinical research organizations (CROs) for advanced ex-vivo and in-vivo testing, particularly for human trials.
4. **Green Chemistry Initiatives**:
   Implementing sustainable and eco-friendly practices in the preparation of buccal films, which would require investment in green chemistry technologies.

Conclusion

The research on **"Formulation and In-Vitro Evaluation of Carvedilol Buccal Films"** has successfully laid the groundwork for innovative drug delivery systems aimed at improving patient outcomes. The promising results of this study highlight the potential for further exploration in buccal film technology, with the hope of advancing pharmaceutical care for patients requiring carvedilol therapy.

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PREPARATION AND EVALUATION OF PRELIMINARY BUCCAL FILMS USING SAGO STARCH AND HPMC E_{15} POLYMERS

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ABSTRACT

The main aim of this work is to design mucoadhesive buccal films using natural and semi-synthetic polymers such as Sago Starch and Hydroxy Propyl Methyl Cellulose (HPMC E_{15}). The mucoadhesive buccal films were prepared using the solvent casting method. The natural polymer and semi-synthetic polymer are used in the preparation of blank buccal films as they are biocompatible, biodegradable, non-toxic and safe to use. The blank films were prepared to understand the physicochemical characteristics of the different polymeric films before formulating drug-loaded films. The prepared buccal films were studied for physicochemical properties and various evaluation parameters such as thickness, folding endurance, weight variation, swelling index, and statistical analysis. The blank buccal films show good physicochemical properties and evaluation parameters were in acceptable range. These preliminary results indicate that polymeric films can represent a valid vehicle for the buccal delivery of drugs.

KEYWORDS: HPMC E_{15}, Sago Starch, Blank Buccal films, Buccal Drug Delivery, fast-pass metabolism.

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Formulation and In-Vitro Evaluation of Carvedilol Buccal Films Using HPMC E15 and Sago Starch as Polymer

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Abstract:

The study aimed to formulate and evaluate carvedilol-loaded buccal films using Sago starch and HPMC E15 as polymers. Carvedilol (Dose-3.125-25 mg) has α1-, β1- and β2-adrenergic blocker activity with other activities like antioxidant, calcium antagonist blocking, and smooth muscle proliferation action. Its oral bioavailability is 25-35% because of first-pass metabolism. Hence the main research objective is to formulate a buccal mucoadhesive dosage form for Carvedilol in the form of buccal Films by using two different semi-synthetic and natural polymers, Hydroxy Propyl Methyl Cellulose HPMC E15 and Sago Starch, to overcome the hepatic metabolism, reduce dosing frequency, low bioavailability, and to give controlled release of a drug and to improve patients' compliance. The FTIR method revealed no interaction between carvedilol or any other polymers. Carvedilol buccal films were prepared using HPMC E15 and Sago starch solvent casting. The films were evaluated for thickness uniformity, folding endurance, weight uniformity, and content uniformity, swelling index, mucoadhesive strength, surface pH, kinetic, in-vitro, and Ex-vivo permeation studies. The thickness and weight uniformity of the prepared buccal films were found to be in a satisfactory range, the films have good folding-endurance over 300 folds, and the surface pH of the films ranged from 6.4-7 neutral pH. The drug content of the films was found to be uniform. The swelling index of buccal films was higher in the HPMC E15 films than in sago starch films. All buccal films have more than 7 hours of in-vitro residence time. The permeation studies were performed using goat buccal mucosa in a modified Franz diffusion cell for carvedilol-loaded buccal films in phosphate buffer for 8 hours, showing 95.04% permeation. In-vitro release studies were performed for carvedilolloaded buccal films in a phosphate buffer (6.8 pH) solution. The optimized film (S3) exhibited drug release 98.96% in 8 hours. Data from in-vitro release and ex-vivo permeation studies of films were fitted into kinetic models (Higuchi, Korsmeyer-Peppas models) to explain release profiles. The optimized formulations showed zero-order release followed by first-order and diffusion

Pharmaceutical Fields

- Pharmaceutics
- Novel drug delivery system
- Nanotechnology
- Pharmacology
- Pharmacognosy

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