DESIGN AND CHARACTERIZATION OF DRUG DELIVERY SYSTEM USING HOT-MELT COATING TECHNIQUE

हॉट–मेल्ट कोटिंग तकनीक का उपयोग करके दवा वितरण प्रणाली का डिजाइन और लक्षण वर्णन

A

Thesis

Submitted for the Award of the Ph.D. degree of

PACIFIC ACADEMY OF HIGHER EDUCATION AND RESEARCH UNIVERSITY

By

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PACIFIC ACADEMY OF HIGHER EDUCATION AND RESEARCH UNIVERSITY, UDAIPUR

2024

DECLARATION

I**, LAKDE SATISHKUMAR KACHARAPPA S/O Mr. KACHARAPPA,** resident of B-13 , 108 Green Society, Infront of Kamalnayan Bajaj Hospital, Beed Bypass, Chh. Sambhaji Nagar, Maharashtra 431005, hereby declare that the research work incorporated in the present thesis entitled **"DESIGN AND CHARACTERIZATION OF DRUG DELIVERY SYSTEM USING HOT-MELT COATING TECHNIQUE"** is my original work. This work (in part or in full) has not been submitted to any University for the award of a Degree or a Diploma. I have properly acknowledged the material collected from secondary sources wherever required.

I solely own the responsibility for the originality of the entire content.

Signature of the Candidate

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Dr. RAKTE AMOL SHARANAPPA
Professor

CERTIFICATE

It gives me immense pleasure in certifying that the thesis **"DESIGN AND CHARACTERIZATION OF DRUG DELIVERY SYSTEM USING HOT-MELT COATING TECHNIQUE"** and submitted by **LAKDE SATISHKUMAR KACHARAPPA** is based on the research work carried out under my guidance. He / She has completed the following requirements as per Ph.D. regulations of the University;

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I, **LAKDE SATISHKUMAR KACHARAPPA**, hereby declare that the Pacific Academy of Higher Education and Research University, Udaipur, Rajasthan, shall have the rights to preserve, use and disseminate this dissertation entitled **"DESIGN AND CHARACTERIZATION OF DRUG DELIVERY SYSTEM USING HOT-MELT COATING TECHNIQUE"** in print or in electronic format for the academic / research purpose.

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DATE: - **LAKDE SATISHKUMAR KACHARAPPA**

DEDICATED TO MY
BELOVED BROTHER
LATE. SANTOSH LAKDE

PREFACE

Better patient compliance, reduced adverse effects and more efficient delivery of active ingredients are primary goals of product researchers and formulators, who have at their disposal an array of new drug delivery technologies to assist them with their work. The ways in which medicinal agents are administered have gained increasing attention in the past three decades. Major attention has been focused on methods for giving these biologically active agents, continuously for prolonged time periods and in a controlled fashion. The oral route of drug administration can be considered the simplest and safest because of its excellent patient compliance.

Waxes obtained from the natural origin are the mostly the ingredients of food can be served as release retardant to achieve modified release of drugs. Some of these waxes were useful alone whereas some of them were useful in combination. Very little research has been carried out by using waxes as a hot melt coating agent.

Looking at incredible merits of hot melt coating technology and recommendations of the regularity authorities, in future the water based and solvent based coating technologies will be replaced by hot melt coating technology. The future hot melt coating agents can expect many more waxes for the preparation of dosage form. Such approaches seem, likely to provide considerable scope for creative approaches, and formulation scientists are interestingly enjoy fulfilling the requirements of newer drug delivery.

The present work was under taken to confirm taste masking potential natural film formers using hot melt coating technique and enhancing stability of water sensitive drug from environment. The suitability of drug delivery systems to increase the patient compliance and providing the quality and stable medication will be focused. These systems provide more safety and quality dosage form to obtain higher therapeutic efficacy.

ABBREVIATIONS

ABBREVIATIONS	ABBREVIATIONS TERMINOLOGY
TDF	Tenofovir Disoproxil Fumarate
SPM	Sitagliptin Phosphate Monohydrate
g or gm	Gram
FDA	Food and Drug Administration
API	Active Pharmaceutical Ingredients
BA	Bioavailability
BE	Bioequivalence
BCS	Biopharmaceutics Classification System
EPA	Environmental Protection Agency
°C	Degree Celsius
M	Molar
DT	Disintegration Time
N	Normal
DSC	Differential Scanning Calorimetry
(f2)	Similarity Factor
FTIR	Fourier Transform Infrared Spectroscopy
GIT	Gastrointestinal Tract
HCl	Hydrochloric Acid
HLB	Hydrophilic-lipophilic Balance
HMC	Hot Melt Coating
ICH	International Conference on Harmonization
IR	Infrared Spectroscopy
Log P = Ko/w	Distribution/Partition Coefficient
LOD	Loss on Drying
MP	Melting Point
NLT	Not Less Than
NMT	Not More Than
OSHA	Occupational Safety and Health Administration
EPA	Environment Protection Agency

% w/w	Percent Weight by Weight
% w/v	Percent Weight by Volume
% v/v	Percent Volume by Volume
PEG	Polyethylene Glycol
pH	Negative Logarithm of Hydrogen Ion Concentration.
pKa	Negative log of Dissociation Constant
PVP	Polyvinyl pyrrolidone
Q.S.	Quantity Sufficient
RH	Relative Humidity
rpm	Revolutions Per Minute
S.D.	Standard Deviation
SSG	Sodium Starch Glycolate
λmax	Absorption Maxima
USA	United States of America
USP	United State Pharmacopoeia
UV	Ultraviolet
Vs	Verses
WHO	World Health Organization
XRD	X-ray diffraction

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