# PROJECT REPORT

FORMULATION AND OPTIMIZATION OF CHITOSAN-COATED LIPID-BASED NANO-CARRIER FOR ORAL BIOAVAILABILITY ENHANCEMENT OF INDOMETHACIN

Submitted for Partial fulfillment of the requirement for the award of the degree of

MASTER OF PHARMACY (PHARMACEUTICS)



**SESSION: 2021-2022** 

SUPERVISED BY
Dr. SHIVANI R. PALIWAL

(M. Pharm., Ph.D.)

Assistant Professor,
Pharmaceutics

SUBMITTED BY

Miss SHIKHA PANDEY

Enrollment No.: GGV/20/06338 Roll No.: 20704007

DEPARTMENT OF PHARMACY,
GURU GHASIDAS VISHWAVIDYALAYA, BILASPUR (C.G.)
(A Central University Established by the Central Universities Act 2009 No. 25 of 2009)

#### A

#### PROJECT REPORT ON

# FORMULATION AND OPTIMIZATION OF CHITOSAN-COATED LIPID-BASED NANO-CARRIER FOR ORAL BIOAVAILABILITY ENHANCEMENT OF INDOMETHACIN

Submitted for Partial fulfillment of the requirement for the award of the degree of

MASTER OF PHARMACY (PHARMACEUTICS)



**SESSION: 2021-2022** 

#### SUPERVISED BY

#### Dr. SHIVANI R. PALIWAL

(M. Pharm., Ph.D.)

Assistant Professor,
Pharmaceutics

#### SUBMITTED BY

#### Miss SHIKHA PANDEY

Enrollment No.: GGV/20/06338 Roll No.: 20704007

# DEPARTMENT OF PHARMACY, GURU GHASIDAS VISHWAVIDYALAYA, BILASPUR (C.G.)

(A Central University Established by the Central Universities Act 2009 No. 25 of 2009)



## **DEPARTMENT OF PHARMACY**

GURU GHASIDAS VISHWAVIDYALAYA, BILASPUR (C.G.) 495009

(A Central University Established by the Central Universities Act 2009 No. 25 of 2009)
Tel. No. 07752-260027, Fax No.: 07752-260148

# Forwarding Certificate

This is to certify that Miss SHIKHA PANDEY, D/o Mr. SHIV DAYAL PANDEY, is a student of M. Pharm. IV Semester (Pharmaceutics) at Department of Pharmacy, Guru Ghasidas Vishwavidyalaya, Bilaspur (C.G.) has submitted her project work entitled "FORMULATION AND OPTIMIZATION OF CHITOSAN-COATED LIPID-BASED NANO-CARRIER FOR ORAL BIOAVAILABILITY ENHANCEMENT OF INDOMETHACIN" for the partial fulfillment of the requirement for the degree of Master of Pharmacy (Pharmaceutics). She has completed her project work under the supervision of Dr. Shivani R. Paliwal (Assistant Professor). Her work is original, satisfactory and is not submitted anywhere else for the award of any degree.

I hereby forward her project work in M. Pharm. (Pharmaceutics) during the academic session 2021-2022.

Forwarded by

(Associate Professor and HOD)

ah\_bharti@yahoo.com

+91 94252-22614
HEAD

S.L.T. Institute of Pharm. Sciences
Guru Ghasidas Vishwavidyalaya.
Bilaspur (C.G.)



#### **DEPARTMENT OF PHARMACY**

GURU GHASIDAS VISHWAVIDYALAYA, BILASPUR (C.G.) 495009 (A Central University Established by the Central Universities Act 2009 No. 25 of 2009)
Tel. No. 07752-260027, Fax No.: 07752-260148

# Certificate

This is to certify that Miss SHIKHA PANDEY, D/o Mr. SHIV DAYAL PANDEY, is a student of M. Pharm. IV Semester (Pharmaceutics) at Department of Pharmacy, Guru Ghasidas Vishwavidyalaya, Bilaspur (C.G.) has submitted her project work entitled "FORMULATION AND OPTIMIZATION OF CHITOSAN-COATED LIPID-BASED NANO-CARRIER FOR ORAL BIOAVAILABILITY ENHANCEMENT OF INDOMETHACIN" for the partial fulfillment of the requirement for the degree of Master of Pharmacy (Pharmaceutics). She has completed her project work under my supervision.

I hereby recommend her project work for M. Pharm. (Pharmaceutics) during the academic session 2021- 2022.

Supervisor)

Dr. SHIVANI R. PALIWAL (M. Pharm., Ph.D.)

Assistant Professor GGV, Bilaspur.

Dr. Shivani Rai Paliwal

M. Pharm Ph D.

Assistant Professor

Department of Pharmacy

Guru Ghasidas Vishwavidyalaya
(ACentral University)Bilaspur(C G)(495009)



#### DEPARTMENT OF PHARMACY

GURU GHASIDAS VISHWAVIDYALAYA, BILASPUR (C.G.) 495009

(A Central University Established by the Central Universities Act 2009 No. 25 of 2009) Tel. No. 07752-260027, Fax No.: 07752-260148

# **Declaration**

I hereby declare that my project work entitled "FORMULATION AND **OPTIMIZATION OF** CHITOSAN-COATED LIPID-BASED NANO-CARRIER **FOR** ORAL **BIOAVAILABILITY ENHANCEMENT** INDOMETHACIN" was done by me. The entire work was done with the guidance and suggestion received from my supervisor Dr. Shivani R. Paliwal (Assistant Professor) at Department of Pharmacy, Guru Ghasidas Vishwavidyalaya, Bilaspur (C.G.). The thesis is submitted at Department of Pharmacy, Guru Ghasidas Vishwavidyalaya, Bilaspur (C.G.) for the partial fulfillment of the requirement for the degree of Master of Pharmacy (Pharmaceutics).

I hereby declare that I have not submitted this thesis previously for the award of any degree or diploma.

Date: 28/10/22

Place: Bilaspur

Miss Shikha Pandey

M. Pharm. (4<sup>th</sup> semester)

(Pharmaceutics)

Enroll No.: GGV/20/06338

Roll No.: 20704007

### **ACKNOWLEDGEMENTS**

My heart is overwhelmed and words are few to express my deep sense of gratitude towards "GOD", the Almighty, who was so merciful to fulfil my ever-increasing wishes and made it possible for me to reach this stage of life.

It will always be a matter of pride and honour to be a student at Department of Pharmacy, Guru Ghasidas Viswavidyalaya, Bilaspur, C.G. Apart from the education, the university also gave me a golden opportunity to interact with people from all parts of the country and imbibe different cultures.

Completion of this M. Pharm. dissertation was possible with the support of several people. This dissertation has been kept on track and been seen through to completion with the support and encouragement of numerous people, including my well-wishers, my friends, colleagues, and various institutions.

At this moment of thesis submission, I would like to express my sincere gratitude to my research guide, **Dr. Shivani Rai Paliwal**, Assistant Professor (Pharmaceutics), Department of Pharmacy, Guru Ghasidas Vishwavidyalaya, Bilaspur, C.G., for her valuable guidance, scholarly input, and consistent encouragement I received throughout the research work. This feat was possible only because of the unconditional support and motivation provided by Ma'am.

Ma'am is a person with an amicable and positive disposition. She has always made herself available to clarify my doubts despite her busy schedules, and I consider it a great opportunity to do my M-pharm programme under her guidance and to learn from her research expertise. I learnt a lot of things from her Thank you, Mam, for all your unconditional help and support throughout this journey.

I am also thankful with regards to my university, Guru Ghasidas Vishwavidyalaya, Bilaspur, C.G., and our honourable Dean, **Prof. S. S.** Singh, sir, and HOD **Prof. Bharti Ahirwar**, ma'am, for providing me with facilities throughout the dissertation.

I would like to extend my sincere appreciation and gratitude to my teachers Dr. Alpana Ram madam, Dr. Sunil Jain sir, Dr. K. Kesavan sir, Dr. SK. Lanjhiyana sir, Dr Ravi Shankar Pandey sir, Dr. Manoj Kumar sir, Dr. K.P. Meena sir, and Dr. Akhilesh Jain whose support was just very important.

I would also like to acknowledge the help provided by **Dr. Rishi Paliwal** sir of INDIRA GANDHI NATIONAL TRIBAL UNIVERSITY, AMARKANTAK throughout the studies. He is an inspiration to me for doing work.

I owe a special thanks to the entire fraternity of Ph.D. scholars for their kind help, motivation, and guidance in all stages specially to **Vibhuti Dubey** ma'am.

A friend in need is a friend indeed. A friend gives hope when life is low. I would like to express my special thanks to my dear friends, especially, B. G. V. S. Jagan and Pooja Nayak, who supported and motivated me throughout this journey; Tripty Karri, Balram Kaushik, Vagesh Verma, Bharti Reddy, and Priya Tiwari; and all my M. Pharm. course mates for their well wishes and support.

I am also thankful to the non-teaching staff especially Mr. Devi Prasad Miri and Mr. Muralidhar Gupta, for their kind help and providing me facilities rendered during study.

I owe a lot to my parents, who encouraged and helped me at every stage of my personal and academic life and longed to see this achievement come true. My words fail to express my feelings of gratitude to my mother, Mrs. Upma Pandey, and my father, Mr. Shiv Dayal Pandey. And my two elder brothers, Saurabh Pandey and Shashank Pandey, who trust and support me to make a career and guide me to choose the right things in life. They are both my legal advisors and have been a great support during all phases of my life. Also, I would like to thank my sisters-in-law, Shilpi Pandey and Shivani Pandey, for their love and support. Their positivism has made me stronger day by day. Last but not least, my nephew Shivay Pandey, who always makes me smile. I am very much indebted to my family, who supported me in every possible way to see the completion of this work.

Above all, I owe it all to Almighty God for granting me the wisdom, health and strength to undertake this research task and enabling me to its completion.

I express my gratitude and apologize to everyone whose contribution could not be mentioned in these pages.

(SHIKHA PANDEY)

# CONTENTS

S. No.	CHAPTER		Page No.		
•	List o	List of Tables			
•	List of Figures				
•	List of Abbreviations				
1.	INTRODUCTION				
	1.1	Nanocarrier based drug delivery system	1-3		
	1.2	Nano structured lipid carrier (NLC)	4-6		
	1.3	Polymer	7-8		
	1.4	Oral route of drug delivery	8-11		
	1.5	Oral Bioavailability	11-14		
2.	REVIEW OF LITERATURE				
3.	OBJECTIVE AND PLAN OF WORK		20-22		
	3.1	Research envisaged	20		
	3.2	Aim and Objective	21		
	3.3	Plan of work	22		
4.	DRUG AND POLYMER PROFILE 2				
	4.1	Drug Profile	23-27		
	4.2	Polymer Profile	27-29		
5.	PREF	DRMULATION STUDIES	30-40		
	5.1	Identification of drug	30-35		
	5.2	Characterization of drug	35-38		
	5.3	Results and Discussion	39-40		
6.	FORM	FORMULATION AND OPTIMIZATION 41-57			
	6.1	Formulation Development	41-43		
	6.2	Optimization of NLCs Formulation by Quality by Design	43-48		
	6.3	Results and Discussion	48-57		
7.	CHARA	ACTERIZATION STUDIES OF CF-NLCs NPs	58-69		
	7.1	Particle size, Zeta potential, Polydispersity Index	58-59		
	7.2	Entrapment Efficiency	60		
	7.3	Microscopic Analysis	60-61		
	7.4	Drug Release	62-63		
	7.5	Pharmacokinetic Modelling of Drug Release	64-68		
	7.6	Results and Discussion	68-69		
8.	STABII	STABILITY STUDIES 70-			
	8.1	Effect Of Storage on PS, PDI, ZP	70		
	8.2	Effect of storage on residual drug content	71		
	8.3	Results and Discussion	71-73		

9.	IN-VIVO STUDIES		74-80
	9.1	Histology studies	74
	9.2	Materials and Methods	75-77
	9.3	Results and Discussion	77-80
10.	CONCLUSION		81
11.	REFERENCES		82-86