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Website : www.jkkmmrfpharmacy.edu.in / E-Mail : principal@jkkmmrfpharmacy.edu.in

Contact No : +919789456750, +919943066944, +919943069944.

Dr.N. SENTHILKUMAR, M.Pharm., Ph.D.,
Principal

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S.NO	DESCRIPTION
1	Certificate of Head of Institution
2	List of **M.Pharm [Pharmaceutical chemistry \ Analysis]** Students under taking Project work/Field work / Internship-HOI
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Contact No : +919789456750, +919943066944, +919943069944.

Dr.N. SENTHILKUMAR, M.Pharm., Ph.D.,

Principal

CERTIFICATE OF HEAD OF INSTITUTION

J.K.K. MUNIRAJAH MEDICAL RESEARCH FOUNDATION

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Website : www.jkkmmrfpharmacy.edu.in / E-Mail : principal@jkkmmrfpharmacy.edu.in

Contact No : +919789456750, +919943066944, +919943069944.

Dr.N. SENTHILKUMAR, M.Pharm., Ph.D.,

Principal

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Number of Students undertaking **Project work**/Field work / Internship for the Academic Year **2022-2023** is **15.**

The Students Participated in More than one activity has been counted as **ONE** only.

JKK MUNIRAJAH MEDICAL RESEARCH FOUNDATION ANNAI JKK SAMPOORANI AMMAL COLLEGE OF PHARMACY Komarapalayam 638 183

Dr. N.SENTHILKUMAR,
PRINCIPAL,
JKK MUNIRAJAH MEDICAL RESEARCH FOUNDATION
ANNAI JKK SAMPOORANI AMMAL COLLEGE OF PHARMACY,
ETHIRMEDU, KOMARAPALAYAM - 638 183,
NAMAKKAL DISTRICT, TAMILNADU.

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Contact No : +919789456750, +919943066944, +919943069944.

Dr.N. SENTHILKUMAR, M.Pharm., Ph.D.,

Principal

TO WHOMSOEVER IT MAY CONCERN

This to certify that the List of **M.Pharm[Pharmaceutical chemistry \ Analysis]** Students under taking **Project work**/Field work / Internship for the Academic Year 2022-2023 are given below.

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1.	261915601	R ELAKKIYA	II	ANTICONVULSANT AND ANXIOLYTIC ACTIVITY OF THE LEAVES AND ROOT ETHANOLIC EXTRACTS OF MIRABLIS JALAPA IN A RAT MODEL.	-	-
2.	261220507502	S EZHILARASAN	II	MOLECULAR DOCKING STUDIES AND SYNTHESIS OF A NOVEL 3-SUBSTITUTED CHROMANONE DERIVATIES AND EVALUATION	-	-

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Dr. N.SENTHILKUMAR,
PRINCIPAL,
JKK MUNIRAJAH MEDICAL RESEARCH FOUNDATION
ANNAI JKK SAMPOORANI AMMAL COLLEGE OF PHARMACY,
ETHIRMEDU, KOMARAPALAYAM - 638 183,
NAMAKKAL DISTRICT, TAMILNADU.

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ANNAI J.K.K. SAMPOORANI AMMAL COLLEGE OF PHARMACY

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Website : www.jkkmmrfpharmacy.edu.in / E-Mail : principal@jkkmmrfpharmacy.edu.in

Contact No : +919789456750, +919943066944, +919943069944.

Dr.N. SENTHILKUMAR, M.Pharm., Ph.D.,

Principal

				FOR THEIR ANTI-CANCER ACTIVITY		
3.	261220507503	T GOKUL	II	DESING SYNTHESIS OF NOVEL 3-SUBSTITUTED PYRAZOLE DERIVATIES AND EVALUATION OF THEIR ANTI-CANCER PROPERTIES	-	-
4.	261220507505	P RAGAVI	II	MOLECULAR DOCKING STUDIES AND INVITRO ANTI-TUBERCULAR ACTIVITY OF THE PLANT NYCTANTHES ARBOR – TRISTIS	-	-
5.	261220507506	J REVATHI	II	DESING SYNTHESIS OF NOVEL SUBSTITUTED	-	-

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Dr. N.SENTHILKUMAR,
PRINCIPAL,
JKK MUNIRAJAH MEDICAL RESEARCH FOUNDATION
ANNAI JKK SAMPOORANI AMMAL COLLEGE OF PHARMACY,
ETHIRMEDU, KOMARAPALAYAM - 638 183,
NAMAKKAL DISTRICT, TAMILNADU.

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ANNAI J.K.K. SAMPOORANI AMMAL COLLEGE OF PHARMACY
Ethirmedu, B. Komarapalayam-638 183, Namakkal Dist. Tamilnadu,India.
Approved by : Pharmacy Council of India. New Delhi & Affiliated to The Tamilnadu Dr. M.G.R Medical University, Chennai.
Website : www.jkkmmrfpharmacy.edu.in / E-Mail : principal@jkkmmrfpharmacy.edu.in
Contact No : +919789456750, +919943066944, +919943069944.

Dr.N. SENTHILKUMAR, M.Pharm., Ph.D.,
Principal

				MORPHOLINE DERIVATIVES AND EVALUATION FOR THERE ANTI CANCER ACTIVITY		
6.	261220507507	P SOMASUNDARAM	II	DESING SYNTHESIS OF NOVEL 2 AMINO SUBSTITUTED BENZOTHIAZOLE DERIVATIVES AND EVALUATION FOR THEIR ANTI CANCER ACTIVITY	-	-
7.	261220507509	P SUGANTHI	II	SYNTHESIS MOLECULAR DOCKING STUDY AND INVITRO MICROBIAL EVALUATION OF SOME NOVEL SUBSTITUED	-	-

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Dr. N.SENTHILKUMAR,
PRINCIPAL,
JKK MUNIRAJAH MEDICAL RESEARCH FOUNDATION
ANNAI JKK SAMPOORANI AMMAL COLLEGE OF PHARMACY,
ETHIRMEDU KOMARAPALAYAM - 638 183,
Namakkal Dist., TAMILNADU.

J.K.K. MUNIRAJAH MEDICAL RESEARCH FOUNDATION
ANNAI J.K.K. SAMPOORANI AMMAL COLLEGE OF PHARMACY
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Approved by : Pharmacy Council of India. New Delhi & Affiliated to The Tamilnadu Dr. M.G.R Medical University, Chennai.
Website : www.jkkmmrfpharmacy.edu.in / E-Mail : principal@jkkmmrfpharmacy.edu.in
Contact No : +919789456750, +919943066944, +919943069944.

Dr.N. SENTHILKUMAR, M.Pharm., Ph.D.,
Principal

				PYRAZOLE DERIVATIVES		
8.	261320507501	ASARUDEEN A	II	ANALYTICAL METHOD DEVELOPMENT AND VALIDATION FOR THE ESTIMATION OF TELMISARTAN AND METOPROLOL SUCCINATE IN SOLID DOSAGE FORM BY UHPLC METHOD	-	-
9.	261320507502	ASWIN KUMAR N	II	ANALYTICAL METHOD DEVELOPMENT AND VALIDATION FOR SIMULTANEOUS ESTIOMATION OF NIVOLUMAB AND RELATIMAB IN PHARAMCEUTI	-	-

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Dr. N.SENTHILKUMAR,
PRINCIPAL,
JKK MUNIRAJAH MEDICAL RESEARCH FOUNDATION
ANNAI JKK SAMPOORANI AMMAL COLLEGE OF PHARMACY,
ETHIRMEDU, KOMARAPALAYAM - 638 183,
NAMAKKAL DISTRICT, TAMILNADU.

J.K.K. MUNIRAJAH MEDICAL RESEARCH FOUNDATION
ANNAI J.K.K. SAMPOORANI AMMAL COLLEGE OF PHARMACY
Ethirmedu, B. Komarapalayam-638 183, Namakkal Dist. Tamilnadu,India.
Approved by : Pharmacy Council of India. New Delhi & Affiliated to The Tamilnadu Dr. M.G.R Medical University, Chennai.
Website : www.jkkmmrfpharmacy.edu.in / E-Mail : principal@jkkmmrfpharmacy.edu.in
Contact No : +919789456750, +919943066944, +919943069944.

Dr.N. SENTHILKUMAR, M.Pharm., Ph.D.,
Principal

				CAL DOSAGE FORM BY RT HPLC METHOD		
10.	261320507503	HARIPRAKASH K	II	BIOANALYTICAL METHOD DEVELOPMENT AND VALIDATION FOR THE QUANTIFICATION OF TRAZODONE IN HUMAN PLASMA BY HPLC-MS\MS	-	-
11.	261320507505	KATHIRAVAN K N	II	DETERMINATION OF POMALIDOMIDE IN HUAMN PLASMA BY ULTRA PERFORMANCE LIQUID CHROMATOGRAPHY – MASS SPECTROMETRY\MASS SPECTROMETRY	-	-

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Dr. N.SENTHILKUMAR,
PRINCIPAL,
JKK MUNIRAJAH MEDICAL RESEARCH FOUNDATION
ANNAI JKK SAMPOORANI AMMAL COLLEGE OF PHARMACY,
ETHIRMEDU, KOMARAPALAYAM - 638 183,
NAMAKKAL DISTRICT, TAMILNADU.

J.K.K. MUNIRAJAH MEDICAL RESEARCH FOUNDATION
ANNAI J.K.K. SAMPOORANI AMMAL COLLEGE OF PHARMACY
Ethirmedu, B. Komarapalayam-638 183, Namakkal Dist. Tamilnadu,India.
Approved by : Pharmacy Council of India. New Delhi & Affiliated to The Tamilnadu Dr. M.G.R Medical University, Chennai.
Website : www.jkkmmrfpharmacy.edu.in / E-Mail : principal@jkkmmrfpharmacy.edu.in
Contact No : +919789456750, +919943066944, +919943069944.

Dr.N. SENTHILKUMAR, M.Pharm., Ph.D.,
Principal

12.	261320507507	RAMKUMAR K	II	ANALYTICAL METHOD DEVELOPMENT ,VALIDATION AND FORCED DEGRADATION BEHAVIOUR AND SOFOSBUVIR AND SIMEPREVIR IN COMBINED DOSAGE FORM BY RP-HPLC	-	-
13.	261320507508	SATHISH KUMAR G	II	ANALYTICAL METHOD DEVELOPMENT AND VALIDATION FOR THE DETERMINATIO N OF TAMSULOSIN AND DEFLAZACORT BY UHPLC IN SOLID DOSAGE FORM	-	-
14.	261320507509	SRIVIJAY R	II	ANALYTICAL	-	-

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Dr. N.SENTHILKUMAR,
PRINCIPAL,
JKK MUNIRAJAH MEDICAL RESEARCH FOUNDATION
ANNAI JKK SAMPOORANI AMMAL COLLEGE OF PHARMACY,
ETHIRMEDU, KOMARAPALAYAM - 638 183,
NAMAKKAL DISTRICT, TAMILNADU.

J.K.K. MUNIRAJAH MEDICAL RESEARCH FOUNDATION
ANNAI J.K.K. SAMPOORANI AMMAL COLLEGE OF PHARMACY
Ethirmedu, B. Komarapalayam-638 183, Namakkal Dist. Tamilnadu,India.
Approved by : Pharmacy Council of India. New Delhi & Affiliated to The Tamilnadu Dr. M.G.R Medical University, Chennai.
Website : www.jkkmmrfpharmacy.edu.in / E-Mail : principal@jkkmmrfpharmacy.edu.in
Contact No : +919789456750, +919943066944, +919943069944.

Dr.N. SENTHILKUMAR, M.Pharm., Ph.D.,
Principal

				METHOD DEVELOPMENT AND VALIDATION FOR THE DETERMINATIO N OF DICYCLOMINE HYDROCHOLOR IDE AND DICLOFENAC POTASSIUM BY UHPLC IN SOLID DOSAGE FORM		
15.	261320507510	VIGNESH S	II	ANALYTICAL METHOD DEVELOPMENT AND VALIDATION OF CETRIZINE HYDROCHLORI DE AND FEXOFENADINE HYDROCHLORI DE IN TABLET DOSAGE FORM BY RP-HPLCSS	-	-

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Komarapalayam 638 183

Dr. N.SENTHILKUMAR,
PRINCIPAL,
JKK MUNIRAJAH MEDICAL RESEARCH FOUNDATION
ANNAI JKK SAMPOORANI AMMAL COLLEGE OF PHARMACY,
ETHIRMEDU, KOMARAPALAYAM - 638 183,
NAMAKKAL DIST., TAMILNADU.

MOLECULAR DOCKING STUDIES AND SYNTHESIS OF A NOVEL 3-SUBSTITUTED CHROMASONE DERIVATIVES AND EVALUATIONS FOR THEIR ANTICANCER ACTIVITY

Dissertation submitted to

THE TAMILNADU DR.M.G.R MEDICAL UNIVERSITY, CHENNAI-32

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

MASTER OF PHARMACY

IN

PHARMACEUTICAL CHEMISTRY

Submitted by

Mr. S. EZHILARASAN

REG.NO: 261220507502

Under the guidance of

Dr. K. SUMATHI., M. Pharm., Ph.D.,

Associate Professor

DEPARTMENT OF PHARMACEUTICAL CHEMISTRY

JKKMMRFs ANNAI JKK SAMPOORANI AMMAL COLLEGE OF PHARMACY,

KOMARAPALAYAM,

NAMAKKAL DT-638183

APRIL-2023

Dr. N. SENTHILKUMAR,
PRINCIPAL,
IKK MUNIRAJAH MEDICAL RESEARCH FOUNDATION
NNAI JKK SAMPOORANI AMMAL COLLEGE OF PHARMACY,
ETHIRMEDU, KOMARAPALAYAM - 638 183.
NAMAKKAL DISTRICT, TAMILNADU.

JKK Munirajah Medical Research Foundation, TN, India
Annai JKK Sampoorani Ammal College of Pharmacy
Komarapalayam
638 183.

JKKMMRFs ANNAI JKK SAMPOORANI
AMMALCOLLEGE
OFPHARMACY,KOMARAPALAYAM,
NAMAKKAL DT-638183
TAMILNADU

CERTIFICATE

This is to certify that the dissertation work entitled "**MOLECULAR DOCKING STUDIES AND SYNTHESIS OF A NOVEL 3 -SUBSTITUTED CHROMANONE DERIVATIVES AND EVALUATION FOR THEIR ANTI-CANCER ACTIVITY**" is the Bonafide work carried out by, **S. EZHILARASAN., (Reg.No:261220507502),** under the guidance and supervision of **Dr.K. SUMATHI., M.Pharm., Ph.D., Associate Professor,** in the Department of Pharmaceutical chemistry.

This is forwarded to the **Tamil Nadu Dr. M.G.R Medical University, Chennai**, for the partial fulfillment of requirements for the **Degree of Master of Pharmacy (2022-2023).**

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KOMARAPALAYAMDATE:

EVALUATEDON: 30/8/23

EVALUATOR(1): 30/8/23.

EVALUATOR(2):

Dr. N. SENTHILKUMAR,
PRINCIPAL,
JKK MUNIRAJAH MEDICAL RESEARCH FOUNDATION
ANNAI JKK SAMPOORANI AMMAL COLLEGE OF PHARMACY,
ETHIRMEDU, KOMARAPALAYAM - 638 183.
NAMAKKAL DISTRICT, TAMILNADU.

JKK Munirajah Medical Research Foundation, Annai JKK Sampoorani Ammal College of Pharmacy, Komarapalayam 638 183.

DECLARATION

I hereby declare that this thesis entitled "**MOLECULAR DOCKING STUDIES AND SYNTHESIS OF A NOVEL 4 - SUBSTITUTED CHROMANONE DERIVATIVES AND EVALUATION FOR THEIR ANTI-CANCER ACTIVITY**" is a bona fide and genuine research work carried out by **S.EZHILARASAN (Reg.No:261220507502)**, under the guidance of **Dr. K. SUMATHI., M. Pharm., Ph.D., Associate Professor**, in the Department of Pharmaceutical chemistry JKKMMRF's Annai JKK Sampoorani Ammal College of Pharmacy, Komarapalayam, for the partial fulfillment of requirement for the Degree of Master of Pharmacy in Pharmaceutical Chemistry.

I further declare that this work has not been submitted earlier in part or full for the award of any degree or diploma to this or any other University. The information furnished in this thesis is genuine to the best of my knowledge and belief.

Place : Komarapalayam

Date: 15.04.2024

S. EZHILARASAN

Reg.No:261220507502

Dr. N. SENTHILKUMAR,
PRINCIPAL,
JKK MUNIRAJAH MEDICAL RESEARCH FOUNDATION
ANNAI JKK SAMPOORANI AMMAL COLLEGE OF PHARMACY,
ETHIRMEDU, KOMARAPALAYAM - 638 183.
NAMAKKAL DISTRICT, TAMILNADU.

JKK Munirajah Medical Research Foundation, TN, India
Annai J.K.K. Sampoorani Ammal College of Pharmacy
Komarapalayam 638 183.

MOLECULAR DOCKING STUDIES AND SYNTHESIS OF A NOVEL 3-SUBSTITUTED CHROMANONE DERIVATIVES AND EVALUATION FOR THEIR ANTI-CANCER ACTIVITY

Abstract

The novel set of substituted 3-((E)-((4-((E)-benzylidene)amino)phenyl)imino)methyl)-4H-chromen-4-one derivatives was designed and synthesized. The docking study of the designed compound was studied against MAP kinase and the result of docking studies revealed that all the compounds possess significant to moderate interaction with the targeted enzyme. From the in-silico docking results, it is evident that the interactions are mainly lipophilic factors due to the presence of aromatic heterocyclic rings. Among the docked compounds, compound 19 possesses significant docking score **-8.4** K/cal when compared to standard drug DOX. There are 10 compounds are subjected to *in-vitro* cytotoxicity study by SRB assay method with cell lines MDA-MB-231 cell lines. All the tested compounds displayed an IC_{50} < 115 µg/mL at a concentration range of 30–250 µg/mL. Among the tested compounds, derivative 9 substituted with methyl benzene shows a significant IC_{50} value (41.94µg/ml) and fallowed by compound 10 substituted with hydroxy benzene derivative (44.51µg/ml) shows good inhibition in breast cancer cell line.

KEYWORDS

1. Molecular docking
2. MAP kinase
3. DOX
4. SRB
5. MDA-MB-231

Dr. N. SENTHILKUMAR,
PRINCIPAL,
JKK MUNIRAJAH MEDICAL RESEARCH FOUNDATION
ANNAI JKK SAMPOORANI AMMAL COLLEGE OF PHARMACY,
ETHIRMEDU KOMARAPALAYAM - 638 183.
NAMAKKAL DISTRICT, TAMILNADU.

JKK Munirajan Medical Research Foundation, TN, India
Komarapalayam 638 183.

DESIGN, SYNTHESIS OF NOVEL 3-SUBSTITUTED PYRAZOLE DERIVATIVES AND EVALUATION OF THEIR ANTI-CANCER PROPERTY

Dissertation submitted to

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MASTER OF PHARMACY

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Submitted by

GOKUL T

Reg. No: 261220507503

Under the guidance of

DR. N. SENTHILKUMAR M.Pharm., Ph.D.,

PRINCIPAL

DEPARTMENT OF PHARMACEUTICAL CHEMISTRY

JKKMMRF'S ANNAI JKK SAMPOORANI AMMAL COLLEGE OF PHARMCY

KOMARAPALAYAM – 638 183, NAMAKKAL, TAMILNADU

APRIL 2023

JKKMMRF'S ANNAI JKK SAMPOORANI AMMAL COLLEGE OF PHARMCY

KOMARAPALAYAM – 638 183.

NAMAKKAL, TAMILNADU

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This is forwarded to the Tamil Nadu Dr.M.G.R Medical University, Chennai, for the partial fulfillment of requirements for the Degree of Master of Pharmacy (2022-2023).

PRINCIPAL **HEAD OF THE DEPARTMENT** **GUIDE**

PLACE: KOMARAPALAYAM

DATE: 30/8/23

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EVALUATOR (2):

Dr. N. SENTHILKUMAR,
PRINCIPAL,
JKK MUNIRAJAH MEDICAL RESEARCH FOUNDATION
ANNAI JKK SAMPOORANI AMMAL COLLEGE OF PHARMACY,
ETHIRMEDU KOMARAPALAYAM - 638 183.
NAMAKKAL DISTRICT, TAMILNADU.

JKK Munirajah Medical Research Foundation, TN, India
Annai J.K.K. Sampoorani Ammal College of Pharmacy
Komarapalayam 638 183.

JKKMMRF'S ANNAI JKK SAMPOORANI AMMAL COLLEGE OF PHARMCY

KOMARAPALAYAM – 638 183,

NAMAKKAL, TAMILNADU

DECLARATION

I hereby declare that this thesis entitled by **"DESIGN, SYNTHESIS OF A NOVEL 3-SUBSTITUTED PYRAZOLE DERIVATIVES AND EVALUTION OF THEIR ANTI-CANCER PROPERTY"** is bonafide and a genuine research work carried out by **GOKUL T**, under the guidance of **Dr. N. SENTHILKUMAR M.Pharm., Ph.D.,** Principal JKKMMRF's Annai JKK Sampoorani Ammal College of Pharmacy, Komarapalayam, for the partial fulfillment of requirement for the Degree of Master of Pharmacy in Pharmaceutical chemistry.

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GOKUL T

REG.NO: 261220507503

Place: Komarapalayam

Date: 16.06.2023

Dr. N. SENTHILKUMAR,
PRINCIPAL,
JKK MUNIRAJAH MEDICAL RESEARCH FOUNDATION
ANNAI JKK SAMPOORANI AMMAL COLLEGE OF PHARMACY,
ETHIRMEDU, KOMARAPALAYAM - 638 183.
NAMAKKAL DISTRICT, TAMILNADU.

JKK Munirajah Medical Research Foundation, TN, India
Annai J.K.K. Sampoorani Ammal College of Pharmacy
Komarapalayam 638 183.

ABSTRACT

The prime motivation of the present work is to design a drug in such a way that it can used clinically to treat cancer. Among heterocyclic compounds containing five membered rings, the important constituents that are usually found in biologically active natural products are 3 substituted pyrazoles. The substituted pyrazole captivated importance as these compounds have been found to exhibit several biological activities such as anti-inflammatory, analgesic, antitumor, antibacterial, antihistaminic, antiviral, cytotoxic. Keeping in view of the above facts, a series of 3 substituted pyrazole derivatives were prepared from four compounds substituted benzoic acid, ethanol, hydrazine hydrate and acetyl acetone by refluxed method. The synthesized 3 substituted pyrazole derivatives were docked and investigated for its anti-cancer activity against MCF cancer cell line using SRB value. These compounds also exhibited appropriate peaks corresponding δ ppm in their ^{1}H NMR spectra and corresponding molecular ion peaks in MS spectra confirmed with the assigned structure. The interpretation of IR, ^{1}H NMR, and MS spectra confirmed the structure of the title compounds. All the studied compounds show the significant docking score and which is compared with standard drug Doxorubicin. All the synthesized compounds were subjected to in vitro anti-cancer activity by SRB assay using MDA-MD-231 cell line studies.

Keywords; Heterocyclic-compound, Pyrazole, Docking, Doxorubicin, SRB assay, Anti-Cancer activity,

Dr. N. SENTHILKUMAR,
PRINCIPAL,
JKK MUNIRAJAH MEDICAL RESEARCH FOUNDATION
ANNAI JKK SAMPOORANI AMMAL COLLEGE OF PHARMACY,
ETHIRMEDU KOMARAPALAYAM - 638 183.
NAMAKKAL DISTRICT, TAMILNADU.

JKK Munirajah Medical Research Foundation, TN, India
Annai J.K.K. Sampoorani Ammal College of Pharmacy
Komarapalayam 638 183.

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IN

PHARMACEUTICAL CHEMISTRY

Submitted by

Mrs. P. RAGAVI.

Reg. No. 261220507505.

Under the Guidance of

Dr. K. SUMATHI. M. Pharm. Ph.D.,

Associate Professor

DEPARTMENT OF PHARMACEUTICAL CHEMISTRY

JKKMMRF'S ANNAI JKK SAMPOORANI AMMAL

COLLEGE OF PHARMACY

B. KOMARAPALAYAM-638 183.

APRIL-2023.

Dr. N. SENTHILKUMAR,
PRINCIPAL,
JKK MUNIRAJAH MEDICAL RESEARCH FOUNDATION
ANNAI JKK SAMPOORANI AMMAL COLLEGE OF PHARMACY,
ETHIRMEDU, KOMARAPALAYAM - 638 183.
NAMAKKAL DISTRICT, TAMILNADU.

JKK Munirajah Medical Research Foundation, TN, India
Annai J.K.K. Sampoorani Ammal College of Pharmacy
Komarapalayam 638 183

JKKMMRF'S ANNAI JKK SAMPOORANI AMMAL
COLLEGE OF PHARMACY,
B.KOMARAPALAYAM,
NAMAKKAL DT-638183
TAMILNADU

CERTIFICATE

This is to certify that the dissertation work entitled **"MOLECULAR DOCKING STUDIES AND *IN-VITRO* ANTI-TUBERCULAR ACTIVITY OF THE PLANT *NYCTANTHES ARBOR-TRISTIS*"** is the bonafide work carried out by, **Mrs.P. RAGAVI., Reg. No: 261220507505** under the guidance and supervision of **Dr. K. Sumathi. M.Pharm., Ph.D.,** Associate Professor, in the Department of Pharmaceutical Chemistry.

This is forwarded to The Tamil Nadu Dr.M.G.R Medical University, Chennai, for the partial fulfillment of requirements for the Degree of Master of Pharmacy in Pharmaceutical Chemistry (2021-2022).

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Dr. N. SENTHILKUMAR,
PRINCIPAL,
JKK MUNIRAJAH MEDICAL RESEARCH FOUNDATION
ANNAI JKK SAMPOORANI AMMAL COLLEGE OF PHARMACY,
ETHIRMEDU, KOMARAPALAYAM - 638 183.
NAMAKKAL DISTRICT, TAMILNADU.

JKK Munirajah Medical Research Foundation, TN, India
Annai J.K.K. Sampoorani Ammal College of Pharmacy
Komarapalayam 638 183.

DECLARATION

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I further declare that this work is original and has not been submitted to this dissertation previously for the award of any degree.

P. Ragavi

Mrs. P. RAGAVI,

Reg. No: 261220507505

PLACE: KOMARAPALAYAM

DATE: .....

Dr. N. SENTHILKUMAR,
PRINCIPAL,
JKK MUNIRAJAH MEDICAL RESEARCH FOUNDATION
ANNAI JKK SAMPOORANI AMMAL COLLEGE OF PHARMACY,
ETHIRMEDU, KOMARAPALAYAM - 638 183.
NAMAKKAL DISTRICT, TAMILNADU.

JKK Munirajah Medical Research Foundation, TN, India
Annai JKK Sampoorani Ammal College of Pharmacy
Komarapalayam 638 183.

ABSTRACT

Traditional herbal remedy *Nyctanthes arbor-tristis* offers various therapeutic advantages. It belongs to Oleaceae family and is frequently referred to as " Night Jasmine ". Phytoconstituents were extracted using various solvents, afterwards, they underwent a qualitative analysis. The Agar Plate Diffusion technique was used to investigate the extract's antibacterial properties. MABA technique of the extract demonstrates sensitivity to the Mycobacterium TB strain (vaccine strain, H37 RV strain). By using GC-MS analysis, ethanolic extract components were identified and characterized. The interpreted compounds were compared to the earlier identified compounds, resulting in the emergence of seven compounds (Calceolarioside A, Betulinic acid,1-(8-Hydroxy-7-((4-nitrophenyl) (phenylamino)methyl) quinoline-3-yl) acetic acid, 1-(8-Hydroxy-7-((4-nitrophenyl) (phenylamino)methyl) quinoline-3-yl) propane-2-one, Lupeol, Arborside B,1-Cyclohexyl-3-(pyridin-3-ylmethyl)urea (cocrystal ligand), C DOCKER software was used to dock those compounds. Among that phytochemicals, the compound Calceolarioside A contained in *Nyctanthes arbor-tristis*, which exhibits excellent binding energy (-50.9972), C Docker Energy(28.1659), and C Docker Interaction Energy (48.9139).

KEYWORDS: *Nyctanthes arbor-tristis, Mycobacterium TB strain,* GC-MS, Calceolarioside A, C DOCKER software

Dr. N. SENTHILKUMAR,
PRINCIPAL,
JKK MUNIRAJAH MEDICAL RESEARCH FOUNDATION
ANNAI JKK SAMPOORANI AMMAL COLLEGE OF PHARMACY
ETHIRMEDU, KOMARAPALAYAM - 638 183.
NAMAKKAL DISTRICT, TAMILNADU.

JKK Munirajah Medical Research Foundation, TN, India
Annai JKK Sampoorani Ammal College of Pharmacy
Komarapalayam 638 183.

DESIGN, SYNTHESIS OF A NOVEL SUBSTITUTED MORPHOLINE DERIVATIVES AND EVALUATION FOR THEIR ANTI-CANCER ACTIVITY

Dissertation submitted to

THE TAMILNADU DR.M.G.R MEDICAL UNIVERSITY,

CHENNAI-32

In partial fulfillment of the requirements

for the award of the degree of

MASTER OF PHARMACY

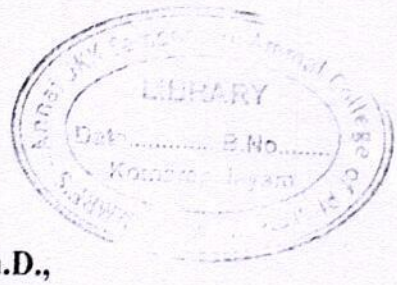
IN

PHARMACEUTICAL CHEMISTRY

Submitted by

Mrs. J.REVATHI

REG.NO: 261220507506



Under the guidance of

Dr.A.CHITRA M.Pharm., Ph.D.,

Associate Professor

DEPARTMENT OF PHARMACEUTICAL CHEMISTRY

JKKMMRFs ANNAI JKK SAMPOORANI AMMAL COLLEGE OF PHARMACY,

KOMARAPALAYAM,

NAMAKKAL DT-638183

APRIL-2023

Dr. N. SENTHILKUMAR,
PRINCIPAL,
JKK MUNIRAJAH MEDICAL RESEARCH FOUNDATION
ANNAI JKK SAMPOORANI AMMAL COLLEGE OF PHARMACY,
ETHIRMEDU, KOMARAPALAYAM - 638 183.
NAMAKKAL DISTRICT, TAMILNADU.

JKKMMRF's ANNAI JKK SAMPOORANI AMMAL COLLEGE OF PHARMACY,

B.KOMARAPALAYAM, NAMAKKAL DT-638183TAMILNADU

CERTIFICATE

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This is forwarded to the Tamil Nadu Dr. M.G.R Medical University, Chennai, for the partial fulfillment of requirements for the Degree of Master of Pharmacy (2022-2023).

PRINCIPAL **HEAD OF THE DEPARTMENT** **GUIDE**

PLACE: KOMARAPALAYAM

DATE: 15/06/2023

EVALUATED ON: 30/8/23

Dr. N. SENTHILKUMAR,
PRINCIPAL,
JKK MUNIRAJAH MEDICAL RESEARCH FOUNDATION
ANNAI JKK SAMPOORANI AMMAL COLLEGE OF PHARMACY,
ETHIRMEDU KOMARAPALAYAM - 638 183.
NAMAKKAL DISTRICT, TAMILNADU.

JKK Munirajah Medical Research Foundation, T.N. India
Annai J.K.K. Sampoorani Ammal College of Pharmacy
Komarapalayam 638 183.

EVALUATOR (1): 30/8/23

EVALUATOR (2): 30/8/23

DECLARATION

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I further declare that this work has not been submitted earlier in part or full for the award of any degree or diploma to this or any other University. The information furnished in this thesis is genuine to the best of my knowledge and belief.

J.REVATHI

Reg.No:261220507506

Place: komarapalayam

Date: 15/06/2023

Dr. N. SENTHILKUMAR,
PRINCIPAL,
JKK MUNIRAJAH MEDICAL RESEARCH FOUNDATION
ANNAI JKK SAMPOORANI AMMAL COLLEGE OF PHARMACY,
ETHIRMEDU, KOMARAPALAYAM - 638 183.
NAMAKKAL DISTRICT, TAMILNADU.

JKK Munirajah Medical Research Foundation, TN, India
Annai J.K.K. Sampoorani Ammal College of Pharmacy
Komarapalayam 638 183.

Synthesis and design of a novel substituted morpholine derivatives and evaluation for their anti-cancer activity.

A.chitra,J.Revathi,N.Senthilkumar and Department of pharmaceutical chemistry,
JKKMMRF's Annai JKK Sampoorani Ammal College of Pharmacy, Komarapalayam.

ABSTRACT :

Synthesis and design of a novel substituted morpholine derivatives and evaluation for their anti-cancer activity. The docking study of designed compound was studied against topoisomerase and the result of docking studies revealed that all compound posses significant to moderate interaction with the target enzyme.among these compounds are subjected to *in-vitro* cytotoxicity study by SRB assay method with cell lines MDA-MB-231 cell lines. All the tested compounds displayed an IC_{50}> 115 µg/mL at a concentration range of 30–250 µg/mL. Among the tested compounds, derivative M5 substituted with methoxy shows a significant IC_{50} value (81.92 µg/ml) and followed by compound M2 substituted with methyl derivative (88.27 µg/ml) shows good inhibition in breast cancer cell line.Remaining all other tested compounds shows good to moderate cytotoxic activity on tested cell line

Key words:Docking study, topoisomerase II ,Docking study, in-vitro studies,MDA-MB-231,cytotoxiic activity .

Corresponding author

Dr A Chitra

Associate professor

Department of pharmaceutical chemistry, JKKMMRF's–Annai JKK Sampoorani Ammal College of Pharmacy, Komarapalayam, Nammakkal Dt,

Cell 6382348857

Dr. N. SENTHILKUMAR,
PRINCIPAL,
JKK MUNIRAJAH MEDICAL RESEARCH FOUNDATION
ANNAI JKK SAMPOORANI AMMAL COLLEGE OF PHARMACY,
ETHIRMEDU, KOMARAPALAYAM - 638 183.
NAMAKKAL DISTRICT, TAMILNADU.

JKK Munirajah Medical Research Foundation, TN, India
Sampoorani Ammal College of Pharmacy
Komarapalayam 638 183.

DESIGN, SYNTHESIS OF A NOVEL 2 AMINO SUBSTITUTED BENZO THIAZOLE DERIVATIVES AND EVALUATION FOR THEIR ANTI-CANCER ACTIVITY

Dissertation submitted to

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for the award of the degree of

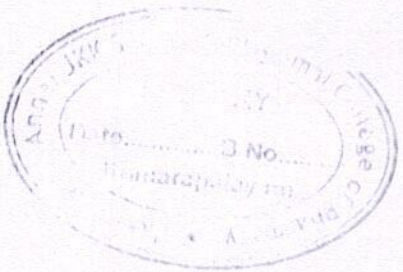
MASTER OF PHARMACY
IN
PHARMACEUTICAL CHEMISTRY

Submitted by

MR. P.SOMASUNDARAM
REG.NO: 261220507507

Under the guidance of

Dr.T.VENKATACHALAM M. Pharm., Ph.D.,
Professor and Head
DEPARTMENT OF PHARMACEUTICAL CHEMISTRY



JKKMMRFs ANNAI JKK SAMPOORANI AMMAL
COLLEGE OF PHARMACY,
B.KOMARAPALAYAM,
NAMAKKAL DT-638183

APRIL-2023

Dr. N. SENTHILKUMAR,
PRINCIPAL,
JKK MUNIRAJAH MEDICAL RESEARCH FOUNDATION
ANNAI JKK SAMPOORANI AMMAL COLLEGE OF PHARMACY,
ETHIRMEDU KOMARAPALAYAM - 638 183.
NAMAKKAL DISTRICT, TAMILNADU.

JKKMMRFs ANNAI JKK SAMPOORANI AMMAL
COLLEGE OF PHARMACY,
B.KOMARAPALAYAM,
NAMAKKAL DT-638183
TAMILNADU

CERTIFICATE

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This is forwarded to the Tamil Nadu Dr. M.G.R Medical University, Chennai, for the partial fulfillment of requirements for the Degree of Master of Pharmacy (2022-2023).

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Dr. N. SENTHILKUMAR,
PRINCIPAL,
JKK MUNIRAJAH MEDICAL RESEARCH FOUNDATION
ANNAI JKK SAMPOORANI AMMAL COLLEGE OF PHARMACY,
ETHIRMEDU, KOMARAPALAYAM - 638 183.
NAMAKKAL DISTRICT, TAMILNADU.

JKK Munirajah Medical Research Foundation, TN, India
Annai JKK Sampoorani Ammal College of Pharmacy
Komarapalayam 638 183.

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P. Som

P SOMASUNDARAM

Reg.No:261220507507

Place: komarapalayam

Date: 15/6/2023

Dr. N. SENTHILKUMAR,
PRINCIPAL,
JKK MUNIRAJAH MEDICAL RESEARCH FOUNDATION
ANNAI JKK SAMPOORANI AMMAL COLLEGE OF PHARMACY,
ETHIRMEDU KOMARAPALAYAM - 638 183.
NAMAKKAL DISTRICT, TAMILNADU.

JKK Munirajah Medical Research Foundation, TN, India
Annai JKK Sampoorani Ammal College of Pharmacy
Komarapalayam 638 183.

ABSTRACT

The novel 2 amino substituted benzo thiazole derivatives was designed and synthesized. The docking study of designed compound was studied against Topo II and the result of docking studies revealed that all the compounds possess significant to moderate interaction with the targeted enzyme. Among them compound 1d (-9.1 K/cal) and 24d (-9.1 K/cal) showed similar C-docker energy compared to adriamycin (-9.58 K/cal). All the synthesized compounds were screened for their in vitro anticancer activity by SRB method using MDA –MB -231 cell lines Among the tested compounds , derivative 24d substituted with naphthalene shows a significant IC_{50} value (76.23µg/ml) and followed by compound substituted with chlorine derivative (78.43 µg/ml) shows good inhibition in breast cancer cell line. Remaining all other tested compounds shows good to moderate cytotoxic activity on tested cell line.

Key words: Docking study, Topo II, Docking study, in-vitro studies, MDA –MB -231, Cytotoxic activity

Dr. N. SENTHILKUMAR,
PRINCIPAL,
JKK MUNIRAJAH MEDICAL RESEARCH FOUNDATION
ANNAI JKK SAMPOORANI AMMAL COLLEGE OF PHARMACY,
ETHIRMEDU, KOMARAPALAYAM - 638 183.
NAMAKKAL DISTRICT, TAMILNADU.

JKK Munirajah Medical Research Foundation, TN, India
Sampoorani Ammal College of Pharmacy
Komarapalayam 638 183.

SYNTHESIS, MOLECULAR DOCKING STUDY AND *IN-VITRO* MICROBIAL EVALUATION OF SOME NOVEL SUBSTITUTED PYRAZOLE DERIVATIVES

Dissertation submitted to

THE TAMILNADU DR.M.G.R MEDICAL UNIVERSITY,CHENNAI-32

In partial fulfillment of the requirements

for the award of the degree of

MASTER OF PHARMACY

IN

PHARMACEUTICAL CHEMISTRY

Submitted by

Mrs. P.SUGANTHI

REG.NO: 261220507509

Under the guidance of

Dr.A.CHITRA M.Pharm., Ph.D.,

Associate Professor

DEPARTMENT OF PHARMACEUTICAL CHEMISTRY

JKKMMRF'S ANNAI JKK SAMPOORANI AMMAL

COLLEGE OF PHARMACY, KOMARAPALAYAM,

NAMAKKAL DT-638183

APRIL-2023

JKKMMRF'S ANNAI JKK SAMPOORANI
AMMAL COLLEGE OF PHARMACY,
KOMARAPALAYAM,
NAMAKKAL DT-638183
TAMILNADU

CERTIFICATE

This is to certify that the dissertation work entitled **"SYNTHESIS, MOLECULAR DOCKING STUDY AND *IN-VITRO* MICROBIAL EVALUATION OF SOME NOVEL SUBSTITUTED PYRAZOLE DERIVATIVES"** is the Bonafide work carried out by, **P.SUGANTHI., (Reg.No:261220507509)**, under the guidance and supervisionof **Dr.A.CHITRA. M.Pharm., Ph.D., Associate Professor,** in the Department of Pharmaceutical chemistry.

This is forwarded to the Tamil Nadu Dr. M.G.R Medical University, Chennai. for thepartial fulfillment of requirements for the Degree of Master of Pharmacy (2022-2023).

PRINCIPAL HEAD OF THE DEPARTMENT GUIDE

PLACE: KOMARAPALAYAM
DATE: 15/6/23

EVALUATED ON: 30/8/23

EVALUATOR (1): 30/8/23

Dr. N. SENTHILKUMAR,
PRINCIPAL,
MUNIRAJAH MEDICAL RESEARCH FOUNDATION
JKK SAMPOORANI AMMAL COLLEGE OF PHARMACY,
ETHIRMEDU, KOMARAPALAYAM - 638 183.
NAMAKKAL DISTRICT, TAMILNADU.

EVALUATOR (2): 30/8/23

Munirajah Medical Research Foundation, TN, India
JKK Sampoorani Ammal College of Pharmacy
Komarapalayam 638 183.

DECLARATION

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P.SUGANTHI

Reg.No:261220507509

Place: Komarapalayam

Date: 15/6/23

Dr. N. SENTHILKUMAR,
PRINCIPAL,
JKK MUNIRAJAH MEDICAL RESEARCH FOUNDATION
ANNAI JKK SAMPOORANI AMMAL COLLEGE OF PHARMACY,
ETHIRMEDU, KOMARAPALAYAM - 638 183.
NAMAKKAL DISTRICT, TAMILNADU.

JKK Munirajah Medical Research Foundation, TN, India
Annai JKK Sampoorani Ammal College of Pharmacy
Komarapalayam 638 183

Synthesis, molecular docking study and in-vitro microbial evaluation of some novel substituted pyrazole derivatives

A. Chitra, P. Suganthi, N. Senthilkumar

Department of pharmaceutical chemistry, JKKMMRF's-Annai JKK Sampoorani Ammal college of Pharmacy,Komarapalayam, Namakkal Dt, The Tamil Nadu Dr MGR medical university, Chennai.

Abstract

The alarming rise of bacterial resistance is occurring worldwide and endangering the efficacy of antibiotics. Therefore, development of new and efficient antibacterial agents remains paramount. A series of novel pyrazole moiety was synthesized and characterized by means of 1H NMR and MS spectra. All the designed compounds subjected for docking studies, among the docked compounds, compound 18d possesses significant docking score -8 K/cal when compared to standard drug ciprofloxacin. The compound 3d and 4d shows a significant docking score of -7.7 K/cal along. The remaining docked compound shows a docking score range from 6 to 9 K/cal along with one or two hydrogen bond interactions. The MIC value of all the synthesized compounds was evaluated by broth microdilution method using Mueller Hinton medium. Tested compounds showed variable activity against the tested Gram-positive and Gram-negative bacterial strains. Compounds 6d, 7d, 11d, 15d and 16d showed high activity against S. aureus and S. epidermidis and also exhibited bactericidal activity against this strain in MBC determination. The whole study was compared with Ciprofloxacin. Based on above binding this study may be concluded as the substitution in the pyrazalone molecules blocks the activity of DNA Gyrase B enzyme in bacterial organism.

Key word: Pyrazole, docking studies, Synthesis, Ciprofloxacin, MIC

Corresponding author

Dr.A.Chitra.,M.Pharm., Ph.D.,

Associate Professor,

JKKMMRF's-Annai JKK SampooraniAmmal college of Pharmacy,

Komarapalayam,Namakkal Dt,

Dr. N. SENTHILKUMAR,
PRINCIPAL,
JKK MUNIRAJAH MEDICAL RESEARCH FOUNDATION
ANNAI JKK SAMPOORANI AMMAL COLLEGE OF PHARMACY,
ETHIRMEDU, KOMARAPALAYAM - 638 183.
NAMAKKAL DISTRICT, TAMILNADU.

JKK Munirajah Medical Research Foundation, TN, India
Sampoorani Ammal College of Pharmacy
Komarapalayam 638 183.

"SYNTHEIS AND CHARACTERIZATION OF A SUBSTITUTED BENZOTHIAZOLE DERIVATIVES AS MURD INHIBITORS EVALUATION FOR THEIR ANTI-MICROBIAL ACTIVITY "

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CHENNAI- 600 032.

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MASTER OF PHARMACY

IN

PHARMACEUTICAL CHEMISTRY

Submitted by

Mrs. ELAKKIYA.R

Reg.No: 261915601

Under the guidance of

Dr. T. Venkatachalam, M. Pharm., Ph.D.,

Professor &Head

Department of Pharmaceutical Chemistry

Evaluated

1. 10/5/23

2. 10/5/23

JKKMMRF'S ANNAI JKK SAMPOORANI AMMAL

COLLEGE OF PHARMACY

KOMARAPALAYAM - 638 183,

TAMILNADU.

OCTOBER-2022

JKK MUNIRAJAH MEDICAL RESEARCH FOUNDATION ANNAI JKK SAMPOORANI AMMAL COLLEGE OF PHARMACY Komarapalayam 638 183

Dr. N.SENTHILKUMAR,
PRINCIPAL
JKK MUNIRAJAH MEDICAL RESEARCH FOUNDATION
ANNAI JKK SAMPOORANI AMMAL COLLEGE OF PHARMACY
ETHIRMEDU, KOMARAPALAYAM - 638 183.
NAMAKKAL DISTRICT. TAMILNADU. INDIA.

Dr.T.VENKATACHALAM,M.Pharm, Ph.D.,
Professor & Head
Department of pharmaceutical chemistry
JKKMMRF'S – Annai JKK Sampoorani Ammal College of Pharmacy,
Komarapalayam,
Namakkal - 638183

CERTIFICATE

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Dr.T. VENKATACHALAM, M.Pharm,Ph.D.,
Professor &Head
Department of pharmaceutical chemistry
JKKMMRF'S – Annai JKK Sampoorani Ammal College of Pharmacy,
Komarapalayam,
Namakkal - 638183

Place : Komarapalayam
Date : 10/3/23

JKK MUNIRAJAH MEDICAL RESEARCH FOUNDATION
ANNAI JKK SAMPOORANI AMMAL COLLEGE OF PHARMACY
Komarapalayam 638 183

Dr. N.SENTHILKUMAR,
PRINCIPAL
JKK MUNIRAJAH MEDICAL RESEARCH FOUNDATION
ANNAI JKK SAMPOORANI AMMAL COLLEGE OF PHARMACY
ETHIRMEDU, KOMARAPALAYAM - 638 183.
NAMAKKAL DISTRICT. TAMILNADU. INDIA.

Dr.N. SENTHILKUMAR, M.Pharm, Ph.D.,
Principal
JKKMMRF'S – Annai JKK Sampoorani Ammal College of Pharmacy,
Komarapalayam,
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Dr.N. SENTHILKUMAR, M.Pharm, Ph.D.,
Principal
JKKMMRF'S – Annai JKK Sampoorani Ammal College of Pharmacy,
Komarapalayam, Namakkal - 638183

Place : Komarapalayam

Date : 16/3/20

JKK MUNIRAJAH MEDICAL RESEARCH FOUNDATION
ANNAI JKK SAMPOORANI AMMAL COLLEGE OF PHARMACY
Komarapalayam 638 183

Dr. N.SENTHILKUMAR,
PRINCIPAL
JKK MUNIRAJAH MEDICAL RESEARCH FOUNDATION
ANNAI JKK SAMPOORANI AMMAL COLLEGE OF PHARMACY
ETHIRMEDU, KOMARAPALAYAM - 638 183.
NAMAKKAL DISTRICT. TAMILNADU. INDIA.

DECLARATION

The research work embodied in this dissertation work entitled "SYNTHESIS AND CHARACTERIZATION OF A SUBSTITUTED BENZOTHIAZOLE DERIVATIVES AS MURD INHIBITORS EVALUATION FOR THEIR ANTI-MICROBIAL ACTIVITY" is based on the original work carried out by us in the department of Pharmaceutical Chemistry under the guidance and supervision of Dr. T. Venkatachalam, M. Pharm., Ph.D., Professor, Department of Pharmaceutical Chemistry for submission to The Tamilnadu Dr. M. G. R Medical University, Chennai, in the partial fulfillment for the degree of MASTER OF PHARMACY. The information furnished in this dissertation is genuine to the best of our knowledge and belief.

R. Elakkiya

Mrs.ELAKKIYA .R

(261915601)

JKK MUNIRAJAH MEDICAL RESEARCH FOUNDATION
ANNAI JKK SAMPOORANI AMMAL COLLEGE OF PHARMACY
Komarapalayam 638 183

Dr. N.SENTHILKUMAR,
PRINCIPAL
JKK MUNIRAJAH MEDICAL RESEARCH FOUNDATION
ANNAI JKK SAMPOORANI AMMAL COLLEGE OF PHARMACY
ETHIRMEDU, KOMARAPALAYAM - 638 183.
NAMAKKAL DISTRICT. TAMILNADU. INDIA.

7.SUMMARY AND CONCLUSION

- In the present work we designed the novel set of benzothiazole molecule as MurD inhibitors.
- All the designed compounds were subjected to molecular docking studies using discovery studio software.
- Based on docking score all the compounds show significant docking score among them compound 5, 6, 7, 14, 17, 18, 21, 22, 23, and 24 shows top ten compound. Further we selected these compounds for synthesis in conventional method.
- We performed hydroxybenzotriazole (HOBt) and 1-(3- dimethylaminopropyl)-3-ethylcarbodiimide hydrochloride (EDCI) mediated synthesis of a series of N'-(1,3-benzothiazol-2-yl)-substituted aryl/aralkylhydrazides.
- High yields (80-95%) were obtained under relatively milder reaction conditions using N,N- dimethylformamide and acetone as solvent.
- All our synthesized compounds were purified by column chromatography and characterized by FT-IR, ^{1}H-NMR, ^{13}C-NMR and HRMS spectral data.
- In the ^{1}H-NMR spectra splitting patterns for the aromatic protons were observed to be in agreement with the substitution pattern of respective compounds.
- In the ^{13}C-NMR spectrum of synthesized compounds the carbonyl carbon of benzamide, azomethine carbon of benzothiazole and aromatic SP^{2} hybridized carbon signals appeared in the expected region.
- The MIC value of all the synthesized compounds was evaluated by broth microdilution method using Mueller Hinton medium.
- Tested compounds showed variable activity against the tested Gram-positive and Gram-negative bacterial strains. Compounds 17, 18, 22, and 23 showed high activity against S. aureus and S. epidermidis and also exhibited bactericidal activity against this strain in MBC determination. The whole study was compared with Ciprofloxacin.
- Based on docking study may be concluded as the substitution in benzothiazole molecule blocks the activity of MurD enzyme in bacterial organism.

ANALYTICAL METHOD DEVELOPMENT AND VALIDATION FOR THE ESTIMATION OF TELMISARTAN AND METOPROLOL SUCCINATE IN SOLIDE DOSAGE FORM BY UHPLC METHOD

A Dissertation submitted to
THE TAMILNADU Dr. M.G.R. MEDICAL UNIVERSITY
CHENNAI – 600032

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

MASTER OF PHARMACY
IN
PHARMACEUTICAL ANALYSIS

Submitted by
ASARUDEEN A
REGISTRATION NO: 261320507501

Under the Guidance of

Dr.M.CHITRA, M.Pharm., Ph.D.,
ASSOCIATE PROFESSOR

DEPARTMENT OF PHARMACEUTICAL ANALYSIS
JKKMMRF's ANNAI JKK SAMPOORANI AMMAL
COLLEGE OF PHARMACY
KOMARAPALAYAM– 638 183

APRIL – 2023

JKKMMRFs ANNAI JKK SAMPOORANI
AMMAL COLLEGE OF PHARMACY,
B.KOMARAPALAYAM,
NAMAKKAL DT-638183
TAMILNADU

CERTIFICATE

This is to certify that the dissertation work entitled **"ANALYTICAL METHOD DEVELOPMENT AND VALIDATION FOR THE ESTIMATION OF TELMISARTAN AND METOPROLOL SUCCINATE IN SOLID DOSAGE FORM BY UHPLC METHOD"** is the bonafide work carried out by, **ASARUDEEN A (Reg.No:261320507501),** under the guidance and supervision of **Dr. M.CHITRA, M.Pharm., Ph.D.,** Associate Professor in the Department of Pharmaceutical Analysis.

This is forwarded to the Tamil Nadu Dr.M.G.R Medical University, Chennai, for the partial fulfillment of requirements for the Degree of Master of Pharmacy (2020-2023).

PRINCIPAL **HEAD OF THE DEPARTMENT** **GUIDE**

Dr. N. SENTHILKUMAR,
PRINCIPAL,
JKK MUNIRAJAH MEDICAL RESEARCH FOUNDATION
ANNAI JKK SAMPOORANI AMMAL COLLEGE OF PHARMACY
ETHIRMEDU, KOMARAPALAYAM - 638 183.
NAMAKKAL DISTRICT, TAMILNADU.

Annai Munirajan Medical Research Foundation, TN, India
Annai J.K.K. Sampoorani Ammal College of Pharmacy
Komarapalayam 638 183.

PLACE: KOMARAPALAYAM

DATE: 16.06.2023

EVALUATED ON: 01.09.2023

EVALUATOR (1):

Dr. (Josp Gnana Babu)
Prof
T John College of Pharmacy
Karnataka

EVALUATOR (2):

1/9/23
Professor
ANNAI JKK SAMPOORANI
AMMAL COLLEGE OF
PHARMACY
Komarapalayam

DECLARATION

The work presented in this dissertation entitled **"ANALYTICAL METHOD DEVELOPMENT AND VALIDATION FOR THE ESTIMATION OF TELMISARTAN AND METOPROLOL SUCCINATE IN SOLID DOSAGE FORM BY UHPLC METHOD"** was carried out by me, under the guidance of **Dr.M.CHITRA M.Pharm., Ph.D.,** Associate professor, Department of Pharmaceutical Analysis, JKKMMRF'S Annai JKK Sampoorani Ammal college of Pharmacy, Komarapalayam.

This work is Original and has not been submitted in part or full for the award of any other degree or diploma of any other university.

ASARUDEEN A
(Reg.No: 261320507501)

Place: Komarapalayam

Date: 16/06/2023

Dr. N. SENTHILKUMAR,
PRINCIPAL,
JKK MUNIRAJAH MEDICAL RESEARCH FOUNDATION
ANNAI JKK SAMPOORANI AMMAL COLLEGE OF PHARMACY,
ETHIRMEDU. KOMARAPALAYAM - 638 183.
NAMAKKAL DISTRICT, TAMILNADU.

JKK Munirajah Medical Research Foundation, TN, India
Annai J.K.K. Sampoorani Ammal College of Pharmacy
Komarapalayam 638 183.

ABSTRACT

This study's objective was to design and validate a new Ultra-High-Performance Liquid Chromatography (UHPLC) method for the simultaneous determination of Telmisartan and Metoprolol Succinate in tablet formulations. This method was developed with an emphasis on accuracy, reproducibility, and a lower relative standard deviation (RSD), compliant with International Council for Harmonization (ICH) guidelines for method validation. The method's precision was confirmed by the low percent relative standard deviation (%RSD) values, with Telmisartan and Metoprolol Succinate recording 0.49 and 0.59 respectively. This implies the high reliability of the assay and retention times across repeated measurements. System suitability parameters were evaluated to ensure the efficiency of the chromatographic system, indicated by a plate count greater than 2000. A tailing factor below 2 further reinforced the method's efficiency, suggesting symmetrical and well-shaped peaks. The robustness of the method was further underscored by its excellent linearity. The linearity equations for Telmisartan ($y = 0.0298x - 0.0285$) and Metoprolol Succinate ($y = 14.5718x + 0.1282$) both produced correlation coefficients (R^2) close to 1, demonstrating excellent linearity in the relationship between concentration and peak area. The method's accuracy was established by calculating the mean percent recovery after performing triplicate injections at each level. The method achieved high mean percent recovery values for both Telmisartan (98.95% and 100.19%) and Metoprolol Succinate (99.68% and 100.21%). Finally, the method precision and intermediate precision were confirmed by the low %RSD values for both drugs (0.27% for Telmisartan and 0.23% for Metoprolol Succinate), which fell below the acceptable limit of 2. The robustness of the method was further corroborated when system suitability parameters remained unaffected despite variations in conditions. In conclusion, the newly developed UHPLC method provides an efficient, robust, and precise tool for the simultaneous estimation of Telmisartan and Metoprolol Succinate in tablet formulations. This facilitates accurate drug content assessments in routine quality control tests for pharmaceutical companies. This study makes a significant contribution to the evolution of pharmaceutical analytical techniques, offering valuable insights into the use of validated UHPLC methods.

KEYWORDS: Telmisartan, Metoprolol succinate, UHPLC, Method Validation

Dr. N. SENTHILKUMAR,
PRINCIPAL,
JKK MUNIRAJAH MEDICAL RESEARCH FOUNDATION
ANNAI JKK SAMPOORANI AMMAL COLLEGE OF PHARMACY,
ETHIRMEDU, KOMARAPALAYAM - 638 183.
NAMAKKAL DISTRICT, TAMILNADU.

JKK Munirajah Medical Research Foundation, Annai J.K.K. Sampoorani Ammal College of Pharmacy, Komarapalayam 638 183. Tamil Nadu, India

ANALYTICAL METHOD DEVELOPMENT AND VALIDATION FOR SIMULTANEOUS ESTIMATION OF NIVOLUMAB AND RELATLIMAB IN PHARMACEUTICAL DOSAGE FORM BY RP HPLC METHOD

A Dissertation submitted to
THE TAMILNADU Dr. M.G.R. MEDICAL UNIVERSITY
CHENNAI – 600032

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

MASTER OF PHARMACY
IN
PHARMACEUTICAL ANALYSIS

Submitted by
ASWIN KUMAR N
REGISTRATION NO: 261320507502

Under the Guidance of

Dr.M.CHITRA, M.PHARM., Ph.D
ASSOCIATE PROFESSOR

DEPARTMENT OF PHARMACEUTICAL ANALYSIS
JKKMMRF's ANNAI JKK SAMPOORANI AMMAL
COLLEGE OF PHARMACY
KOMARAPALAYAM– 638 183

APRIL – 2023

Dr. N. SENTHILKUMAR,
PRINCIPAL,
JKK MUNIRAJAH MEDICAL RESEARCH FOUNDATION
ANNAI JKK SAMPOORANI AMMAL COLLEGE OF PHARMACY,
ETHIRMEDU. KOMARAPALAYAM - 638 183.
NAMAKKAL DISTRICT. TAMILNADU.

JKKMMRFs ANNAI JKK SAMPOORANI
AMMAL COLLEGE OF PHARMACY,
B.KOMARAPALAYAM,
NAMAKKAL DT-638183
TAMILNADU

CERTIFICATE

This is to certify that the dissertation work entitled "**ANALYTICAL METHOD DEVELOPMENT AND VALIDATION FOR SIMULTANEOUS ESTIMATION OF NIVOLUMAB AND RELATLIMAB IN PHARMACEUTICAL DOSAGE FORM BY RP HPLC METHOD** " is the bonafide work carried out by, **ASWIN KUMAR N (Reg.No:261320507502),** under the guidance and supervision of **Dr. M. Chitra M.Pharm., Ph.D.,** Associate Professor of Department of Pharmaceutical Analysis.

This is forwarded to the Tamil Nadu Dr.M.G.R Medical University, Chennai, for the partial fulfillment of requirements for the Master of Pharmacy (2022-2023).

PRINCIPAL **HEAD OF THE DEPARTMENT** **GUIDE**

PLACE: KOMARAPALAYAM

DATE: 16/06/2023

EVALUATED ON: 01/09/2023

Dr. N. SENTHILKUMAR,
PRINCIPAL,
JKK MUNIRAJAH MEDICAL RESEARCH FOUNDATION
ANNAI JKK SAMPOORANI AMMAL COLLEGE OF PHARMACY,
ETHIRMEDU, KOMARAPALAYAM - 638 183.
NAMAKKAL DISTRICT, TAMILNADU.

EVALUATOR (1):

Prof
JOSE BINOY BABU
T JOHN COLLEGE OF PHARMACY
Karnataka.

EVALUATOR (2):

01/9/23
Professor
RVIDYAMANDIRAM
ANNAI JKK SAMPOORANI AMMAL
COLLEGE OF PHARMACY
Komarapalayam

DECLARATION

The work presented in this dissertation entitled **"ANALYTICAL METHOD DEVELOPMENT AND VALIDATION FOR SIMULTANEOUS ESTIMATION OF NIVOLUMAB AND RELATLIMAB IN PHARMACEUTICAL DOSAGE FORM BY RP HPLC METHOD"** was carried out by me, under the guidance of **Dr.M.CHITRA MPharm., PhD** Associate professor, Department of Pharmaceutical Analysis, JKKMMRF'S Annai JKK Sampoorani Ammal college of Pharmacy, Komarapalayam.

This work is Original and has not been submitted in part or full for the award of any other degree or diploma of any other university.

ASWIN KUMAR N
(Reg.No: 261320507502)

Place: Komarapalayam

Date: 16/06/2023

Dr. N. SENTHILKUMAR,
PRINCIPAL,
JKK MUNIRAJAH MEDICAL RESEARCH FOUNDATION
ANNAI JKK SAMPOORANI AMMAL COLLEGE OF PHARMACY,
ETHIRMEDU, KOMARAPALAYAM - 638 183.
NAMAKKAL DISTRICT, TAMILNADU.

JKK Munirajah Medical Research Foundation, TN, India
Annai J.K.K. Sampoorani Ammal College of Pharmacy
Komarapalayam 638 183.

ABSTRACT

To gain some additional advantages over other methods already created for this combination, a rapid and stability-indicating reversed phase high-performance liquid chromatography (RP-HPLC) method was developed for simultaneous quantification of Nivolumab and Relatlimab in their combined dosage form. According to USP guidelines for accuracy, precision, specificity, linearity, solution stability, robustness, sensitivity, and system appropriateness, the method was validated. According to the International Conference on Harmonisation (ICH), the forced degradation study was verified. According to the International Conference on Harmonisation (ICH), the forced degradation study was verified. For this, an isocratic condition of mobile phase was maintained on RP C18 (octadecylsilane (ODS), 150 4.6 mm, 5 m, Phenomenex Inc.) column at room temperature. The mobile phase consisted of phosphate buffer (pH 6.8) and acetonitrile at a ratio of 70:30, v/v, With correlation coefficient (R2) values of 0.999 and 1.0 for Nivolumab and Relatlimab, respectively, the method demonstrated excellent linear response and was within the correlation coefficient's range (R2≥ 0.995). Two medication's percent recoveries fell within the acceptable range of (99.60-99.82.%).The novel method's intra- and inter-day precision assessments showed that the relative standard deviation (%RSD) was less than the 2.0 maximum permitted limit. According to ICH guidelines, the drug product was forced to degrade in order to determine its stability-indicating ability and learn more about the degradation pathways, degradation products, and how the quality of a drug substance and drug product varies over time under different stressful conditions. Relatlimab degradation was within the acceptable range (5-20%, per ICH guidelines), however Nivolumab demonstrated a 20% degradation in oxidation and basic condition.

Keywords: RP-HPLC, stability indicating, Nivolumab , Relatlimab.

Dr. N. SENTHILKUMAR,
PRINCIPAL,
JKK MUNIRAJAH MEDICAL RESEARCH FOUNDATION
ANNAI JKK SAMPOORANI AMMAL COLLEGE OF PHARMACY,
ETHIRMEDU KOMARAPALAYAM - 638 183.
NAMAKKAL DISTRICT, TAMILNADU.

JKK Munirajah Medical Research Foundation, Annai J.K.K. Sampoorani Ammal College of Pharmacy, Komarapalayam 638 183, TN, India

BIOANALYTICAL METHOD DEVELOPMENT AND VALIDATION FOR THE QUANTIFICATION OF TRAZODONE IN HUMAN PLASMA BY HPLC-MS/MS

A Dissertation submission of

THE TAMILNADU Dr.M.G.R.MEDICAL UNIVERSITY
CHENNAI –600032.

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

MASTER OF PHARMACY
IN
PHARMACEUTICAL ANALYSIS

Submitted by
HARIPRAKASH. K
Reg.No: 261320507503

Under the Guidance of
Mrs. B. ANBARASI, M.Pharm., (Ph.D)
ASSOCIATE PROFESSOR

DEPARTMENT OF PHARMACEUTICAL ANALYSIS

JKKMMRF'S ANNAI JKK SAMPOORANI AMMAL COLLEGE OF PHARMACY,KOMARAPALAYAM-638183.

APRIL-2023

Dr. N. SENTHILKUMAR,
PRINCIPAL,
JKK MUNIRAJAH MEDICAL RESEARCH FOUNDATION
ANNAI JKK SAMPOORANI AMMAL COLLEGE OF PHARMACY,
ETHIRMEDU. KOMARAPALAYAM - 638 183.
NAMAKKAL DISTRICT. TAMILNADU.

JKKMMRF's ANNAI JKK SAMPOORANI
AMMAL COLLEGE OF PHARMACY,
B.KOMARAPALAYAM,
NAMAKKAL DT-638183

CERTIFICATE

This is to certify that the dissertation work entitled **"BIOANALYTICAL METHOD DEVELOPMENT AND VALIDATION FOR THE QUANTIFICATION OF TRAZODONE IN HUMAN PLASMA BY HPLC-MS/MS"** is the bonafide work carried out by, **Mr.K.HARIPRAKASH (Reg.No:261320507503)** under the guidance and supervision of **Mrs.B.ANBARASI M.Pharm., (Ph.D)** Associate Professor, in the Department of Pharmaceutical Analysis.

This is forwarded to the Tamil Nadu Dr.M.G.R Medical University, Chennai, for the partial fulfillment of requirements for the Degree of Master of Pharmacy in Pharmaceutical analysis(2022-2023).

PRINCIPAL **HEAD OF THE DEPARTMENT** **GUIDE**

PLACE: KOMARAPALAYAM

DATE: 16/06/2023

EVALUATED ON: 01/09/2023

EVALUATOR (1):

Prof Jose Giriana Babu
Principal College of Pharmacy
Karnataka

EVALUATOR (2): 1/9/23
Professor
R. Vijaya Amirthapriya
Annai Jkk Sampoorani
Ammal college of pharm
Komarapalayam

Dr. N. SENTHILKUMAR
PRINCIPAL,
IKK MUNIRAJAH MEDICAL RESEARCH FOUNDATION
ANNAI JKK SAMPOORANI AMMAL COLLEGE OF PHARMACY,
ETHIRMEDU, KOMARAPALAYAM - 638 183.
NAMAKKAL DISTRICT.

Jkk Munirajah Medical Research Foundation, TN, India
Annai J.K.K. Sampoorani Ammal College of Pharmacy
Komarapalayam 638 183.

DECLARATION

This is to certify that the works embodied in this dissertation entitled **"BIOANALYTICAL METHOD DEVELOPMENT AND VALIDATION FOR THE QUANTIFICATION OF TRAZODONE IN HUMAN PLASMA BY HPLC-MS/MS"** was carried out by me, guidance of **Mrs. B. ANBARASI M.Pharm.,(Ph.D)** Associate professor, Department of Pharmaceutical Analysis, J.K.K.Munirajah Medical Research Foundation College of Pharmacy, Komarapalyam.

This work is Original and has not been submitted in part or full for the award of any other degree or diploma of any other university.

K. HARIPRAKASH

(Reg. No. 261320507503)

Place: Komarapalayam.

Date: 16-06-2023

Dr. N. SENTHILKUMAR,
PRINCIPAL,
JKK MUNIRAJAH MEDICAL RESEARCH FOUNDATION
ANNAI JKK SAMPOORANI AMMAL COLLEGE OF PHARMACY,
ETHIRMEDU, KOMARAPALAYAM - 638 183.
NAMAKKAL DISTRICT, TAMILNADU.

JKK Munirajah Medical Research Foundation, TN, India
Annai J.K.K. Sampoorani Ammal College of Pharmacy
Komarapalayam 638 183.

BIOANALYTICAL METHOD DEVELOPMENT AND VALIDATION FOR THE QUANTIFICATION OF TRAZODONE IN HUMAN PLASMA BY HPLC-MS/MS

ABSTRACT

The development and validation of a bioanalytical process approach for assessing the antidepressant medication Traz in human plasma is the ultimate goal of the current investigation.The method involves tandem mass spectroscopy combined with HPLC SPE technique bioanalytic method development and validation conducted for the first time. Using Aceton-M: 5 mM ammonium formate buffer (90:10% V/V) at a 1.00 mL/min flow rate with 10 microliter of injection volume allowed for excellent separation and elimination. This chromatographic analysis analyte and IS were started under isocratic conditions to develop an easier separation technique in a shorter run time. According to the method, the range of the calibration curve is from 25.2640 to 352.3060 ng/ml. By using numerous supporting data points, including batch recovery percentages of 85.0433% and 82.3800% over TRAZ and TRAZD6, technique validation has been established.A simple, highly accurate, precise, sturdy, reproducible, and reliable HPLC-MS/MS technique was formed that proves all the stability parameters and is suitable for the bioequivalence study in the future. This method may also be applicable for the combined formulations.

KEYWORDS: Trazodone, LC-MS/MS, Trazodone D6, LLOQ, USFDA

Dr. N. SENTHILKUMAR,
PRINCIPAL,
JKK MUNIRAJAH MEDICAL RESEARCH FOUNDATION
ANNAI JKK SAMPOORANI AMMAL COLLEGE OF PHARMACY,
ETHIRMEDU, KOMARAPALAYAM - 638 183.
NAMAKKAL DISTRICT, TAMILNADU.

JKK Munirajah Medical Research Foundation, TN, India
Annai JKK Sampoorani Ammal College of Pharmacy
Komarapalayam 638 183.

DETERMINATION OF POMALIDOMIDE IN HUMAN PLASMA BY ULTRA PERFORMANCE LIQUID CHROMATOGRAPHY MASS SPECTROMETRY / MASS SPECTROMETRY

A Dissertation submission of

THE TAMILNADU Dr.M.G.R.MEDICAL UNIVERSITY

CHENNAI –600032.

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

MASTER OF PHARMACY

IN

PHARMACEUTICAL ANALYSIS

Submitted by

KATHIRAVAN.K.N

Reg. No. 261320507505

Under the Guidance of

Dr. P. Kalaiselvi M.Pharm., Ph.D

ASSOCIATE PROFESSOR

DEPARTMENT OF PHARMACEUTICAL ANALYSIS

JKKMMRF'S ANNAI JKK SAMPOORANI AMMAL COLLEGE OF PHARMACY, KOMARAPALAYAM-638183.

APRIL-2023

Dr. N. SENTHILKUMAR,
PRINCIPAL,
JKK MUNIRAJAH MEDICAL RESEARCH FOUNDATION
ANNAI JKK SAMPOORANI AMMAL COLLEGE OF PHARMACY,
ETHIRMEDU, KOMARAPALAYAM - 638 183.
NAMAKKAL DISTRICT, TAMILNADU.

JKKMMRFs ANNAI JKK SAMPOORANI
AMMAL COLLEGE OF PHARMACY,
R.KOMARAPALAYAM,
NAMAKKAL DT-638183
TAMILNADU

CERTIFICATE

This is to certify that the dissertation work entitled **" DETERMINATION OF POMALIDOMIDE IN HUMAN PLASMA BY ULTRA PERFORMANCE LIQUID CHROMATOGRAHY - MASS SPECTROMETRY / MASS SPECTROMETRY"** is the bonafide work carried out by, **KATHIRAVAN.K.N (Reg.No:261320507505)** under the guidance and supervision of **Dr. P.KALAISELVI M.Pharm., Ph.D.**, Associate Professor, in the Department of Pharmaceutical Analysis.

This is forwarded to the Tamil Nadu Dr.M.G.R Medical University, Chennai, for the partial fulfillment of requirements for the Degree of Master of Pharmacy in Pharmaceutical Analysis (2021-2022).

PRINCIPAL **HEAD OF THE DEPARTMENT** **GUIDE**

PLACE: KOMARAPALAYAM
DATE: 16/06/2023

EVALUATED ON: 01/09/2023

EVALUATOR (1):

Dr. N. SENTHILKUMAR,
PRINCIPAL,
JKK MUNIRAJAH MEDICAL RESEARCH FOUNDATION
ANNAI JKK SAMPOORANI AMMAL COLLEGE OF PHARMACY,
ETHIRMEDU, KOMARAPALAYAM - 638 183.
NAMAKKAL DISTRICT, TAMILNADU.

EVALUATOR (2):

DECLARATION

This is to certify that the works embodied in this dissertation entitled **"DETERMINATION OF POMALIDOMIDE IN HUMAN PLASMA BY ULTRA PERFORMANCE LIQUID CHROMATOGRAPHY-MASS SPECTROMETRY/ MASS SPECTROMETRY"** was carried out by me, guidance of **Dr.P. KALAISELVI M.Pharm., Ph.D.,** Associate professor, Department of Pharmaceutical Analysis, J.K.K.Munirajah Medical Research Foundation College of Pharmacy, Komarapalyam.

This work is Original and has not been submitted in part or full for the award of any other degree of any other university .

KATHIRAVAN. K. N

(Reg No:261320507505)

Place: Komarapalayam.

Date: 16/06/2023

Dr. N. SENTHILKUMAR,
PRINCIPAL,
JKK MUNIRAJAH MEDICAL RESEARCH FOUNDATION
ANNAI JKK SAMPOORANI AMMAL COLLEGE OF PHARMACY,
ETHIRMEDU, KOMARAPALAYAM - 638 183.
NAMAKKAL DISTRICT, TAMILNADU.

JKK Munirajah Medical Research Foundation, TN, India
Annai J.K.K. Sampoorani Ammal College of Pharmacy
Komarapalayam 638 183.

DETERMINATION OF POMALIDOMIDE IN HUMAN PLASMA BY ULTRA PERFORMANCE LIQUID CHROMATOGRAPHY-MASS SPECTROMETRY/ MASS SPECTROMETRY

ABSTRACT

The current investigation created and verified a delicate UPLC-MS/MS technique for the high-throughput detection of pomalidomide in human plasma with celecoxib as an IS (Internal Control). Chromatographic division was carried out on Hypersil Gold (50 mm 4.1 mm, 5m) with an isocratic mobile phase of ACN: 5mM ammonium formate (NH4HCO2) (80:20, v/v), at 0.5 mL per min flow rate and a 3 min total run time. A triple quadruple TANDEM MS with electrospray ionization in positive mode has been utilized to identify the analyte. Using multiple reaction monitoring modes and precursor-to-product ion transitions of m/z 274.43201.15 for pomalidomide and m/z 382.12362.03 for IS, respectively, pomalidomide and IS were measured. The developed technique was verified as per the regulatory standards for bioanalytical procedures validation. Other validation results also match.

KEYWORDS: POM, LLOQ, UPLC MS/MS, USFDA, ICH

Dr. N. SENTHILKUMAR,
PRINCIPAL,
JKK MUNIRAJAH MEDICAL RESEARCH FOUNDATION
ANNAI JKK SAMPOORANI AMMAL COLLEGE OF PHARMACY,
ETHIRMEDU, KOMARAPALAYAM - 638 183,
NAMAKKAL DISTRICT, TAMILNADU.

JKK Munirajah Medical Research Foundation, TN, India
Annai J.K.K. Sampoorani Ammal College of Pharmacy
Komarapalayam 638 183.

ANALYTICAL METHOD DEVELOPMENT, VALIDATION AND FORCED DEGRADATION BEHAVIOUR OF SOFOSBUVIR AND SIMEPREVIR IN COMBINED DOSAGE FORM BY RP-HPLC

A Dissertation submitted to
THE TAMILNADU Dr. M.G.R. MEDICAL UNIVERSITY
CHENNAI– 600032

In partial fulfillment of the requirements for the award of the

Degree of

MASTER OF PHARMACY
IN
PHARMACEUTICAL ANALYSIS

Submitted by
RAMKUMAR K
REGISTRATION NO: 261320507507

Under the Guidance of

Mrs. B. ANBARASI, M.Pharm., (Ph.D.)

DEPARTMENT OF PHARMACEUTICAL ANALYSIS
JKKMMRF's ANNAI JKK SAMPOORANI AMMAL
COLLEGE OF PHARMACY
B.KOMARAPALAYAM– 638183

APRIL – 2023

JKKMMRFs ANNAI JKK SAMPOORANI AMMAL
COLLEGE OF PHARMACY,
R.KOMARAPALAYAM,
NAMAKKAL DT-638183
TAMILNADU

CERTIFICATE

This is to certify that the dissertation work entitled **"ANALYTICAL METHOD DEVELOPMENT, VALIDATION AND FORCED DEGRADATION BEHAVIOUR OF SOFOSBUVIR AND SIMEPREVIR IN COMBINED DOSAGE FORM BY RP-HPLC "** is the bonafide work carried out by, **RAMKUMAR K (Reg.No: 261320507507),** under the guidance and supervision of **Mrs. B. ANBARASI, M.Pharm., (Ph.D.)** Associate Professor, in the Department of Pharmaceutical Analysis.

This is forwarded to the Tamil Nadu Dr. M.G.R Medical University, Chennai, for the partial fulfillment of requirements for the Degree of Master of Pharmacy in Pharmaceutical Analysis, April 2023.

PRINCIPAL **HEAD OF THE DEPARTMENT** **GUIDE**

PLACE: KOMARAPALAYAM
DATE: 16/06/23

EVALUATED ON: 01/09/23

EVALUATOR (1):

EVALUATOR (2):

Dr. N. SENTHILKUMAR,
PRINCIPAL,
JKK MUNIRAJAH MEDICAL RESEARCH FOUNDATION
ANNAI JKK SAMPOORANI AMMAL COLLEGE OF PHARMACY,
ETHIRMEDU, KOMARAPALAYAM - 638 183.
NAMAKKAL DISTRICT, TAMILNADU.

DECLARATION

The work presented in this dissertation entitled "**ANALYTICAL METHOD DEVELOPMENT, VALIDATION AND FORCED DEGRADATION BEHAVIOUR OF SOFOSBUVIR AND SIMEPREVIR IN COMBINED DOSAGE FORM BY RP-HPLC**" was carried out by me, under the guidance of **Mrs. B. ANBARASI, M.Pharm., (Ph.D.,)** Associate professor, Department of Pharmaceutical Analysis, JKKMMRF'S Annai JKK Sampoorani Ammal college of Pharmacy, Komarapalayam.

This work is Original and has not been submitted in part or full for the award of any other degree or diploma of any other university.

K.RAMKUMAR
(Reg.No: 261320507507)

Place: Komarapalayam

Date: 16/06/23

Dr. N. SENTHILKUMAR,
PRINCIPAL,
JKK MUNIRAJAH MEDICAL RESEARCH FOUNDATION
ANNAI JKK SAMPOORANI AMMAL COLLEGE OF PHARMACY,
ETHIRMEDU. KOMARAPALAYAM - 638 183.
NAMAKKAL DISTRICT, TAMILNADU.

JKK Munirajah Medical Research Foundation, TN, India
Annai J.K.K. Sampoorani Ammal College of Pharmacy
Komarapalayam 638 183.

ANALYTICAL METHOD DEVELOPMENT, VALIDATION AND FORCED DEGRADATION BEHAVIOUR OF SOFOSBUVIR AND SIMEPREVIR IN COMBINED DOSAGE FORM BY RP-HPLC

ABSTRACT

A simple, Accurate, precise method was developed for the simultaneous estimation of the Sofosbuvir and Simeprevir Tablet dosage form. Chromatogram was run through Std Ascentis C18 (4.6 x 150 mm, 2.8 µm) Mobile phase containing 0.01N Na_2HPO_4 Buffer : Methanol taken in the ratio 55:45 was pumped through column at a flow rate of 0.9 mL/min. Buffer used in this method was Phosphate Buffer (4.8ph) buffer. Temperature was maintained at 30°C. Optimized wavelength selected was 215.0 nm Retention time of Sofosbuvir and Simeprevir were found to be 2.512 min and 3.116 min. %RSD of the Sofosbuvir and Simeprevir were and found to be 0.2 and 0.7 respectively. % Recovery was obtained as 99.44% and 99.96% for Sofosbuvir and Simeprevir respectively. LOD, LOQ values obtained from regression equations of Sofosbuvir and Simeprevir were 0.38, 1.17 and 0.11, 0.34 respectively. Regression equation of Sofosbuvir is y =11806x + 1985.4, and y = 9492.1x + 514.5 of Simeprevir. Retention times were decreased and that run time was decreased, so the method developed was simple and economical that can be adopted in regular Quality control test in Industries.

Key Words: Sofosbuvir, Simeprevir, RP-HPLC, Method Development, Validation.

Dr. N. SENTHILKUMAR,
PRINCIPAL,
JKK MUNIRAJAH MEDICAL RESEARCH FOUNDATION
ANNAI JKK SAMPOORANI AMMAL COLLEGE OF PHARMACY,
ETHIRMEDU, KOMARAPALAYAM - 638 183.
NAMAKKAL DISTRICT, TAMILNADU.

ANALYTICAL METHOD DEVELOPMENT AND VALIDATION FOR THE DETERMINATION OF TAMSULOSIN AND DUTASTERIDE BY UHPLC IN SOLID DOSAGE FORMS

A Dissertation submitted to
THE TAMILNADU Dr. M.G.R. MEDICAL UNIVERSITY
CHENNAI – 600032

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

MASTER OF PHARMACY

IN

PHARMACEUTICAL ANALYSIS

Submitted by

SATHISH KUMAR.G

REGISTRATION NO: 261320507508

Under the Guidance of

Mr.R.VIJAYAMIRTHARAJ, M.Pharm.,

PROFESSOR

DEPARTMENT OF PHARMACEUTICAL ANALYSIS

JKKMMRF's ANNAI JKK SAMPOORANI AMMAL COLLEGE OF PHARMACY
KOMARAPALAYAM– 638 183

APRIL – 2023

Dr. N. SENTHILKUMAR,
PRINCIPAL,
JKK MUNIRAJAH MEDICAL RESEARCH FOUNDATION
ANNAI JKK SAMPOORANI AMMAL COLLEGE OF PHARMACY,
ETHIRMEDU KOMARAPALAYAM - 638 183.
NAMAKKAL DISTRICT, TAMILNADU.

JKKMMRFs ANNAI JKK SAMPOORANI
AMMAL COLLEGE OF PHARMACY,
B.KOMARAPALAYAM,
NAMAKKAL DT-638183
TAMILNADU

CERTIFICATE

This is to certify that the dissertation work entitled **"ANALYTICAL METHOD DEVELOPMENT AND VALIDATION FOR THE DETERMINATION OF TAMSULOSIN AND DEFLAZACORT BY UHPLC IN SOLID DOSAGE FORMS"** is the bonafide work carried out by, **SATHISH KUMAR.G (Reg.No:261320507508),** under the guidance and supervision of **Mr.R.VIJAYAMITHARAJ, M.Pharm.,** Professor and Head, in the Department of Phaemaceutical analysis.

This is forwarded to the Tamil Nadu Dr.M.G.R Medical University, Chennai, for the partial fulfillment of requirements for the Degree of Pharmaceutical analysis (2022-2023).

PRINCIPAL **HEAD OF THE DEPARTMENT** **GUIDE**

PLACE: KOMARAPALAYAM

DATE:

EVALUATED ON:...01./..09./..2023

EVALUATOR (1):

By
Prof. JOSE GINDINA BAB
College of Pharma

EVALUATOR (2):

R. Vijaya Mithraj
Professor
R. VIJAYAMITHARAJ
Annai JKK Sampoorani
Ammal College of Pha
Komarapalayam

Dr. N. SENTHILKUMAR,
PRINCIPAL,
JKK MUNIRAJAH MEDICAL RESEARCH FOUNDATION
ANNAI JKK SAMPOORANI AMMAL COLLEGE OF PHARMACY,
ETHIRMEDU, KOMARAPALAYAM - 638 183.
NAMAKKAL DISTRICT, TAMILNADU.

JKK Munirajah Medical Research Foundation, TN, India
Annai J.K.K. Sampoorani Ammal College of Pharmacy
Komarapalayam 638 183.

DECLARATION

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This work is Original and has not been submitted in part or full for the award of any other degree or diploma of any other university.

G. Sathish kumar

SATHISH KUMAR.G

(Reg.No: 261320507508)

Place: Komarapalayam

Date: 16/6/23

Dr. N. SENTHILKUMAR,
PRINCIPAL,
JKK MUNIRAJAH MEDICAL RESEARCH FOUNDATION
ANNAI JKK SAMPOORANI AMMAL COLLEGE OF PHARMACY,
ETHIRMEDU, KOMARAPALAYAM - 638 183.
NAMAKKAL DISTRICT, TAMILNADU.

JKK Munirajah Medical Research Foundation, TN, India
Annai J.K.K. Sampoorani Ammal College of Pharmacy
Komarapalayam 638 183.

ABSTRACT

This study's objective was to design and validate a new Ultra-High-Performance Liquid Chromatography (UHPLC) method for the simultaneous determination of Tamsulosin and Deflazacort in tablet formulations. This method was developed with an emphasis on accuracy, reproducibility, and a lower relative standard deviation (RSD), compliant with International Council for Harmonization (ICH) guidelines for method validation. Chromatographic division was carried out on INERTSILC18(4.633×50mm:3µ) with an mobile phase Acetonitrile: methanol(500:500) at 0.7ml /min flow rate and a 20 min total run time .The method's precision was confirmed by the low percent relative standard deviation (%RSD) values, with Tamsulosin and Deflazacort recording 0.5 and 0.21 respectively. This implies the high reliability of the assay and retention times across repeated measurements. System suitability parameters were evaluated to ensure the efficiency of the chromatographic system, indicated by a plate count greater than 2000. A tailing factor below 2 further reinforced the method's efficiency, suggesting symmetrical and well-shaped peaks. The robustness of the method was further underscored by its excellent linearity. The linearity equations for Tamsulosin ($y = 0.2195x - 0.0145$) and Deflazacort ($y = 1.1069x - 0.0634$) both produced correlation coefficients (R^2) close to 1, demonstrating excellent linearity in the relationship between concentration and peak area. The method's accuracy was established by calculating the mean percent recovery after performing triplicate injections at each level. The method achieved high mean percent recovery values for both Tamsulosin (99.63% and 100.90%) and Deflazacort (99.80% and 100.90%). Finally, the method precision and intermediate precision were confirmed by the low %RSD values for both drugs (0.50% for Tamsulosin and 0.21% for Deflazacort), which fell below the acceptable limit of 2. The robustness of the method was further corroborated when system suitability parameters remained unaffected despite variations in conditions. In conclusion, the newly developed UHPLC method provides an efficient, robust, and precise tool for the simultaneous estimation of Tamsulosin and Deflazacort in tablet formulations. This facilitates accurate drug content assessments in routine quality control tests for pharmaceutical companies. This study makes a significant contribution to the evolution of pharmaceutical analytical techniques, offering valuable insights into the use of validated UHPLC methods.

KEYWORDS: Tamsulosin, Deflazacort, UHPLC, Method Validation

Dr. N. SENTHILKUMAR,
PRINCIPAL,
JKK MUNIRAJAH MEDICAL RESEARCH FOUNDATION
ANNAI JKK SAMPOORANI AMMAL COLLEGE OF PHARMACY,
ETHIRMEDU, KOMARAPALAYAM - 638 183.
NAMAKKAL DISTRICT, TAMILNADU.

ANALYTICAL METHOD DEVELOPMENT AND VALIDATION FOR THE DICYCLOMINE HYDROCHLORIDE AND DICLOFENAC POTASSIUM BY UHPLC IN SOLIDE DOSAGE FORMS

A Dissertation submitted to

THE TAMILNADU Dr.M.G.R. MEDICAL UNIVERSITY

CHENNAI– 600032

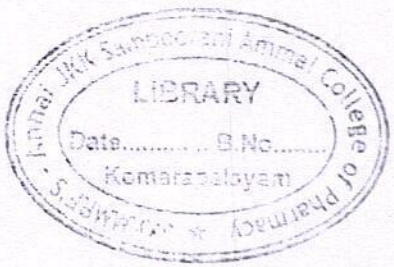
In partial fulfillment of the requirements for the award of the Degree of

MASTER OF PHARMACY
IN
PHARMACEUTICAL ANALYSIS

Submitted by
SRIVIJAY.R
REGISTRATION NO: 261320507509

Under the Guidance of

Mr.R.VIJAYAMIRTHARAJ, M.Pharm.,
PROFESSOR



DEPARTMENT OF PHARMACEUTICAL ANALYSIS

JKKMMRF's ANNAI JKK SAMPOORANI AMMAL COLLEGE OF PHARMACY
KOMARAPALAYAM– 638183

APRIL – 2023

Dr. N. SENTHILKUMAR,
PRINCIPAL,
JKK MUNIRAJAH MEDICAL RESEARCH FOUNDATION
ANNAI JKK SAMPOORANI AMMAL COLLEGE OF PHARMACY,
ETHIRMEDU, KOMARAPALAYAM - 638 183.
NAMAKKAL DISTRICT, TAMILNADU.

JKKMMRFs ANNAI JKK SAMPOORANI
AMMAL COLLEGE OF PHARMACY,
B.KOMARAPALAYAM,
NAMAKKAL DT-638183
TAMILNADU

CERTIFICATE

This is to certify that the dissertation work entitled **"ANALYTICAL METHOD DEVELOPMENT AND VALIDATION FOR THE DETERMINATION OF DICYCLOMINE HYDROCHLORIDE AND DICLOFENAC POTASSIUM BY UHPLC IN SOLID DOSAGE FORMS"** is the bonafide work carried out by, **SRIVIJAY.R (Reg.No:261320507509),** under the guidance and supervision of **Mr.R.VIJAYAMITHARAJ, M.Pharm.,** Professor and Head, in the Department of Pharmaceutical analysis.

This is forwarded to the TamilNadu Dr.M.G.R Medical University, Chennai, for the partial fulfillment of requirements for the Degree of Master of Pharmacy (2022-2023).

PRINCIPAL **HEAD OF THE DEPARTMENT** **GUIDE**

PLACE: KOMARAPALAYAM

DATE:

EVALUATED ON: 1.9.2023

Dr. N. SENTHILKUMAR,
PRINCIPAL,
JKK MUNIRAJAH MEDICAL RESEARCH FOUNDATION
ANNAI JKK SAMPOORANI AMMAL COLLEGE OF PHARMACY,
ETHIRMEDU, KOMARAPALAYAM - 638 183.
NAMAKKAL DISTRICT, TAMILNADU.

JKK Munirajah Medical Research Foundation, TN, India
Annai J.K.K. Sampoorani Ammal College of Pharmacy
Komarapalayam 638 183.

EVALUATOR (1):

Prof. Josb Benny Babu
T John College of Pharmacy.
Karnataka - 560083.

EVALUATOR (2):

1/9/23
Prof R. VIJAYAMITHRAJ
Annai JKK Sampoorani
Ammal college of
Pharmacy,
Komarapalayam

DECLARATION

The work presented in this dissertation entitled **"ANALYTICAL METHOD DEVELOPMENT AND VALIDATION FOR THE DICYCLOMINE HYDROCHLORIDE AND DICLOFENAC POTASSIUM BY UHPLC IN SOLID DOSAGE FORMS"** was carried out by me, under the guidance of **Mr.R.VIJAYAMIRTHARAJ, M.Pharm.,** professor, Department of Pharmaceutical Analysis, JKKMMRF'S Annai JKK Sampoorani Ammal college of Pharmacy, Komarapalayam.

This work is original and has not been submitted in part or full for the award of any other degree or diploma of any other university.

R.Srivijay

SRIVIJAY.R

(Reg.No: 261320507509)

Place: Komarapalayam

Date: 16-6-2023

Dr. N. SENTHILKUMAR,
PRINCIPAL,
JKK MUNIRAJAH MEDICAL RESEARCH FOUNDATION
ANNAI JKK SAMPOORANI AMMAL COLLEGE OF PHARMACY,
ETHIRMEDU, KOMARAPALAYAM - 638 183.
NAMAKKAL DISTRICT, TAMILNADU.

JKK Munirajah Medical Research Foundation, TN, India
Annai J.K.K. Sampoorani Ammal College of Pharmacy
Komarapalayam 638 183.

ABSTRACT

In pharmaceutical dosage forms, a new UHPLC method was developed and validated to simultaneously estimate Diclofenac Potassium and Dicyclomine Hydrochloride. By utilizing UHPLC, this method fills a gap in the existing literature. Optimizing various parameters of the chromatographic process was key to developing an effective method for separating and detecting drugs. International guidelines and regulatory requirements were followed for the validation of the method, including specificity, linearity, accuracy, precision, robustness, and suitability for the system.For the injection and analysis of mixed solutions containing Dicyclomine HCl and Diclofenac potassium, a Chromatographic separation was achieved on a Kromasil C18 (4.6 mm × 250 mm), 5µm. a mobile phase ratio consisting of (35:65) Water: Methanol at flow rate 1.0 ml/min, and total run time 8min,The injection volume 20µl. The detection wavelength is 263 nm. Approximately 2000 plates were found, indicating a successful chromatographic separation. With a tailing factor of less than 2 and a well-resolved peak, the peaks appear symmetrical and well-resolved.In order to ensure there were no interfering peaks, the retention times for Dicyclomine Hydrochloride and Diclofenac Potassium were found to be 2.745 min and 3.341 min.As for Dicyclomine Hydrochloride, the correlation coefficient (R^2) is 0.9999 and Diclofenac Potassium is 0.9999. This indicates a good linear relationship between drug concentrations and peak areas based on the high correlation coefficients. For Dicyclomine Hydrochloride and Diclofenac Potassium, the %RSD values were 0.87% and 1.08%, respectively, below the acceptable limit of 2%. As a result, the method is accurate and repeatable .In the study of Dicyclomine Hydrochloride, the mean percent recovery was 98.37%, while in the study of Diclofenac Potassium, the mean percent recovery was 98.31%, while the mean percent recovery was 100.34%.Under varied conditions, both Dicyclomine Hydrochloride and Diclofenac Potassium showed %RSD values within the acceptable range of 2%, demonstrating the robustness and reliability of the method. This study concluded that valuable insight is provided into the use of validated UHPLC methods in this study, which contributes significantly to the evolution of pharmaceutical analytical techniques.

KEY WORDS: Dicyclomine Hydrochloride, Diclofenac Potassium,,UHPLC, Method development, Method validation.

Dr. N. SENTHILKUMAR,
PRINCIPAL,
JKK MUNIRAJAH MEDICAL RESEARCH FOUNDATION
ANNAI JKK SAMPOORANI AMMAL COLLEGE OF PHARMACY,
ETHIRMEDU, KOMARAPALAYAM - 638 183.
NAMAKKAL DISTRICT, TAMILNADU.

ANALYTICAL METHOD DEVELOPMENT AND VALIDATION OF FEXOFENADINE HYDROCHLORIDE AND CETIRIZINE HYDROCHLORIDE IN TABLET DOSAGE FORM BY RP-HPLC

Dissertation submitted to

THE TAMILNADU Dr. M. G. R. MEDICAL

UNIVERSITY CHENNAI 600 032

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

MASTER OF PHARMACY

IN

PHARMACEUTICAL ANALYSIS

submitted by

VIGNESH.S

Registration No.261320507510

Under the guidance of

Dr. P. Kalaiselvi, M. Pharm., Ph.D.,

Associate Professor

DEPARTMENT OF PHARMACEUTICAL ANALYSIS

JKK MUNIRAJAH MEDICAL RESEARCH FOUNDATION ANNAI JKK SAMPOORANI AMMAL COLLEGE OF PHARMACY, KOMARAPALAYAM 638183

April 2023

Dr. N. SENTHILKUMAR,
PRINCIPAL,
JKK MUNIRAJAH MEDICAL RESEARCH FOUNDATION
ANNAI JKK SAMPOORANI AMMAL COLLEGE OF PHARMACY,
ETHIRMEDU, KOMARAPALAYAM - 638 183.
NAMAKKAL DISTRICT, TAMILNADU.

JKKMMRF's ANNAI JKK SAMPOORANI
AMMAL COLLEGE OF PHARMACY,
KOMARAPALAYAM,
NAMAKKAL DT-638183

CERTIFICATE

This is to certify that the dissertation work entitled "**ANALYTICAL METHOD DEVELOPMENT AND VALIDATION OF CETIRIZINE HYDROCHLORIDE AND FEXOFENADINE HYDROCHLORIDE IN TABLET DOSAGE FORM BY RP-HPLC**" is the bonafide work carried out by, **VIGNESH S (Reg. No: 261320507510),** under the guidance and supervision of **Dr. P. KALAISELVI, M.Pharm., Ph.D.,** Associate Professor in the Department of Pharmaceutical Analysis.

This is forwarded to the Tamil Nadu Dr. M.G.R Medical University, Chennai, for the partial fulfillment of requirements for the Degree of Master of Pharmacy in Pharmaceutical Analysis, (2022-2023).

PRINCIPAL **HEAD OF THE DEPARTMENT** **GUIDE**

PLACE : KOMARAPALAYAM

DATE: 01/09/2023

EVALUATOR (1):

Dr. N. SENTHILKUMAR
PRINCIPAL,
JKK MUNIRAJAH MEDICAL RESEARCH FOUNDATION
ANNAI JKK SAMPOORANI AMMAL COLLEGE OF PHARMACY,
ETHIRMEDU, KOMARAPALAYAM - 638 183.
NAMAKKAL DISTRICT, TAMILNADU.

EVALUATOR (2):

1/9/23

DECLARATION

The work presented in the dissertation entitled "**ANALYTICAL METHOD DEVELOPMENT AND VALIDATION OF CETIRIZINE HYDROCHLORIDE AND FEXOFENADINE HYDROCHLORIDE IN TABLET DOSAGE FORM BY RP-HPLC**" was carried out by me, under the guidance of **Dr. P. KALAISELVI, M. Pharm., Ph.D.,** Associate Professor in the Department of Pharmaceutical Analysis, JKKMMRF'S Annai JKK Sampoorani Ammal college of Pharmacy, Komarapalayam.

The work is Original and has not been submitted in part or full for the award of any other degree or diploma of any other university.

VIGNESH S
(Reg.No:261320507510)

Place : Komarapalayam
Date : 01/09/2023

Dr. N. SENTHILKUMAR,
PRINCIPAL,
JKK MUNIRAJAH MEDICAL RESEARCH FOUNDATION
ANNAI JKK SAMPOORANI AMMAL COLLEGE OF PHARMACY,
ETHIRMEDU, KOMARAPALAYAM - 638 183.
NAMAKKAL DISTRICT, TAMILNADU.

JKK Munirajan Medical Research Foundation, TN, India
Annai J.K.K Sampoorani Ammal College of Pharmacy
Komarapalayam 638 183.

ANALYTICAL METHOD DEVELOPMENT AND VALIDATION OF CETIRIZINE HYDROCHLORIDE AND FEXOFENADINE HYDROCHLORIDE IN FORMULATED TABLET DOSAGE FORM BY RP-HPLC

ABSTRACT:

The current investigation created and verified a delicate RP-HPLC technique for analytical method validation of formulated combined tablet dosage form consist of Fexofinadine hydrochloride and Cetirizine hydrochloride using SHIMADZU-I SERIES LC-2030,

On stationary phase Phenomenex Luna C18 100A;150mmX4.6mm with an isocratic mobile phase of ACN: Methanol : Buffer (30: 20: 50) 30%, 20% and 50% pH 3.0, at 1.0 mL per min flow rate and a 10 min total run time with injection volume 20 micolitre at 230nm. Using RP-HPLC, the peak of Fexofinadine hydrochloride and Cetirizine hydrochloride was found well separated within 10 minutes and retention time of Fexofinadine hydrochloride and Cetirizine hydrochloride was found to be 4.121 and 5.715 minutes. The number of theoretical plates of Fexofinadine hydrochloride and Cetirizine hydrochloride was found to be 1751807 and 303378 which indicates efficient performance of the column and resolution was found to be 3.976 and result of analysis for Fexofinadine hydrochloride and Cetirizine hydrochloride was found to be 99.58% and 99.62%.

KEYWORDS: RP-HPLC, Fexofinadine hydrochloride, Cetirizine hydrochloride, Retention time, Run time, Buffer, ACN, Methanol.

Dr. N. SENTHILKUMAR,
PRINCIPAL,
JKK MUNIRAJAH MEDICAL RESEARCH FOUNDATION
ANNAI JKK SAMPOORANI AMMAL COLLEGE OF PHARMACY,
ETHIRMEDU, KOMARAPALAYAM - 638 183,
NAMAKKAL DISTRICT, TAMILNADU.

JKK Munirajah Medical Research Foundation, TN, India
Annai J.K.K. Sampoorani Ammal College of Pharmacy
Komarapalayam
638 183