

DEVELOPMENT AND VALIDATION OF ANALYTICAL
METHOD OF SILYMARIN BY RP-HPLC WITH UV
DETECTOR



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PAKISTAN

2015

DEVELOPMENT AND VALIDATION OF ANALYTICAL
METHOD OF SILYMARIN BY RP-HPLC WITH UV
DETECTOR

Submitted to University of Management and Technology Lahore

In partial fulfillment of the requirements

For the award of degree of

MASTER OF PHILOSOPHY

IN

CHEMISTRY

BY

SOHAIL ASLAM

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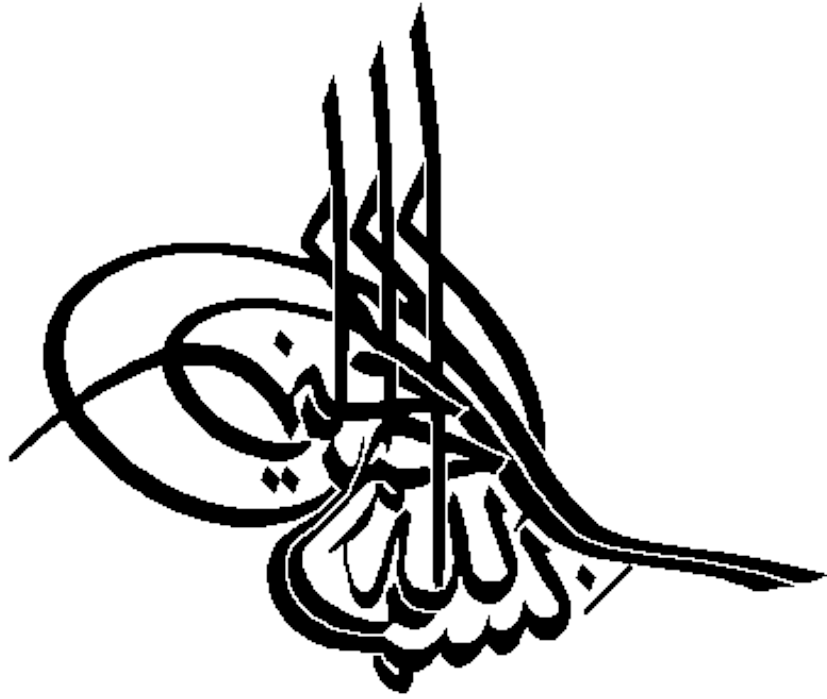
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In the name of

Allah,

The most Compassionate,

The most merciful



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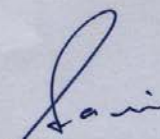
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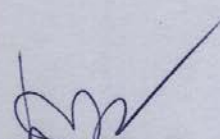


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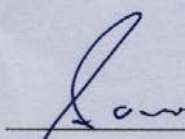
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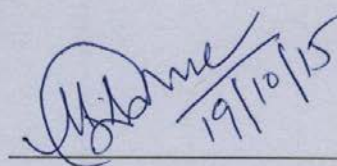
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DEDICATION

Affectionately Dedicated to
My Parents, Teachers and Family
due to whom Prayers and Cooperation
I am able to reach this status.



ACKNOWLEDGEMENT

It gives immense pleasure to say my genuine gratitude to Almighty Allah for all the blessings for the accomplishment of this research project. This acknowledgement is an intention to thank all those who remained concerned in my research project directly and indirectly.

When gratitude articulated in words, feelings of appreciation is partially conveyed so my sincere appreciation to my research advisor Dr. Sammia Shahid, Chairperson Department of Chemistry for her encouraging attitude, precious guidance and devoted interest during my present work. Her inspiring behavior and supportive nature during research and even in compilation of this thesis is commendable. Many thanks to all my other faculty members for their great help.

I am also thankful to my parents, family and colleagues for their valuable support. I would also like to acknowledge my wife as she was always with me during the happy and hard moments to push and motivate me to accomplish this work. I extend my gratitude to my kids for sharing their time in conducting this project.

I am also grateful to the Chaudry Ashfaq Ahmad, Chairman Medisave Pharmaceuticals 578-579 Sundar Industrial estate Lahore Pakistan for his co-operation and allowing me to work in quality control lab to utilize their resources.

Last but not the least, my special gratitude to Dr. Muhammad Naeem, SSO of PCSIR laboratory Lahore for his great support. Once again, thanks to all concerned who participated even a little in completion of this work.



SOHAIL ASLAM

ABSTRACT

Milk Thistle (*Silybum marianum*) is a wild, herbaceous plant. Generally the extract of *Silybum marianum* is expressed as total Silymarin. Silymarin is composed of flavonolignans, silybin, silydianin and silychristin. Out of these compounds, silybin is considered the most vital as it plays an important role for the treatment of liver disorder. Silymarin is very important natural drug which is widely used for the treatment of variety of diseases, especially for hepatic disorders. A novel, reliable and a sensitive method to determine the amount of Silymarin was developed by using reversed phased HPLC method with isocratic solvent delivery. Silymarin was separated using Hypersil ODS C18 column maintaining temperature at 40°C in the column oven and detector was set at wavelength 288 nm with mobile phase in a ratio Methanol:Water:Phosphoric acid (46:54:0.1 v/v/v). The silymarin was tested with respect to silybin which is the most vital and pharmacological active substance. For this purpose the retention time of the silybin among all flavonolignans were determined by injecting silybin standard. Then the silymarin standard and silymarin raw material sample were injected and successfully determined the assay of silymarin. The developed method was then validated as per ICH guidelines. Linearity, accuracy, precision and robustness are the key parameters used to validate the method. This method could easily be used for the determination of silymarin for routine analysis of raw material to maintain its quality and to check the efficacy of the incoming consignments of raw material.



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