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

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For the award of degree of

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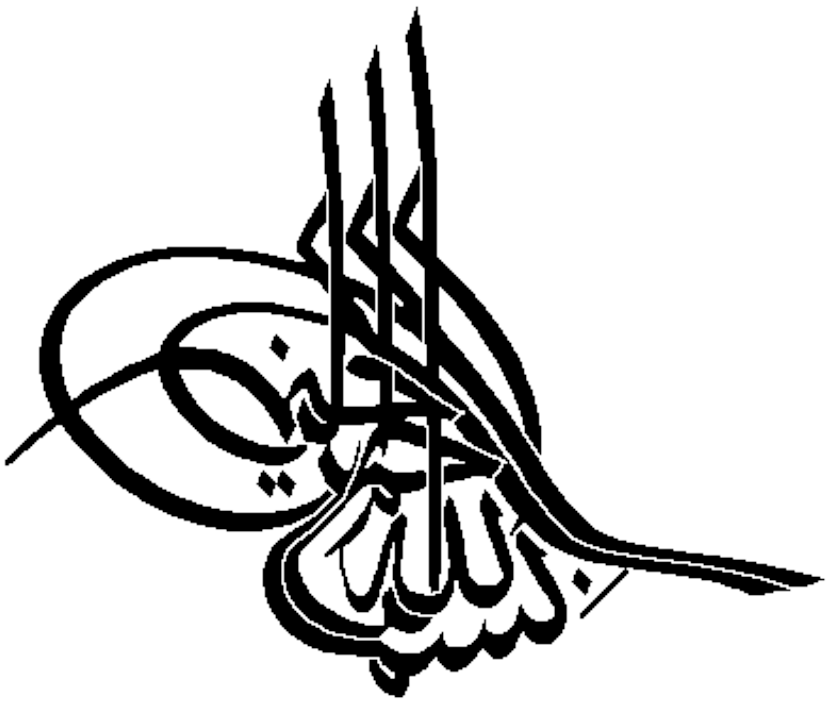

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Certified that the research work contained in this thesis titled, "**Development and Validation of Analytical Method of Silymarin by RP-HPLC with UV Detector**" has been carried out and completed by **, ID: 13001140045**. The quantum and the quality of the work contained in this thesis is adequate for the award of Degree of MS/M.Phil.

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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.

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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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