ESTIMATION AND STABILITY STUDIES OF AMOXICILLIN TRIHYDRATE IN THE CAPSULE DOSAGE FORM

By:

MAAZ ASIM

ID: 13001140008

ADVISOR:

Dr. AYESHA MOHYUDDIN

DEPARTMENT OF CHEMISTRY

SCHOOL OF SCIENCE

UNIVERSITY OF MANAGEMENT AND TECHNOLOGY, LAHORE, PAKISTAN

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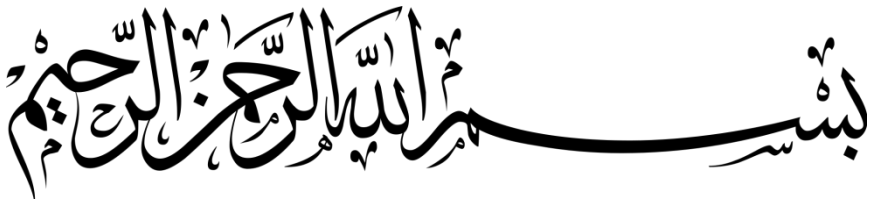

Then let man look at his food, for that We pour water in abundance; and We split the earth in fragments, and produce therein corn, and grapes and nutritious plants and olives and dates, and enclosed gardens dense, with lefty trees, and fruits and fodder, for us and convenience to you and your cattle.

(Al-Quran)

Lord Muhammad (peace be upon him) said,

"The Calamity of Knowledge is forgetfulness; and to lose knowledge is this, to speak of it to the unworthy.

Who are the learned? Those who practice what they know".

DEDICATION

“I dedicate this thesis to my Parents, Brothers and sister who have supported me, friends, and my advisor and who taught me to be creative, attentive, and courageously lead me and make me done this work.”

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ABSTRACT

A simple, rapid and time saving method for the validation of Amoxillin Trihydrate in capsule dosage form has been developed. Recovery studies was achieved by HPLC for this chromatographic separation was achieved by phenomenex [250x4.6 mm with octadecylisily silica gel for chromatograph (5µm)] column on binary mode and mobile phase (A) contain 6.8g of potassium dihydrogen phosphate buffer (adjust to pH 5.0 by sodium hydroxide solution) containing Acetonitrile with ratio of 99:1 and mobile phase (B) containing Buffer and Acetonitrile with ratio of 80:20. The flow rate was 1 ml/min with 8% concentration of mobile phase (B) and was monitored at 254 nm. Retention time was found to be near 7.1 for Amoxicillin Trihydrate. The regression value obtained was 0.9999 with 3.0011 Limit of Detection and 9.0943 Limit of Quantization. Residual solvents were also validated for AMT by using GC-FID and observed that there is no presence of any solvent in it. Other parameters like FTIR, pH, Optical rotation and Moisture contents were also performed for further analysis and all results were satisfactory and was meeting the require values. The projected methods are accurate, exact, selective and rapid for the estimation of Amoxicillin Trihydrate in pharmaceutical dosage forms.

Key words: Amoxicillin Trihydrate, Acetonitrile, Mobile phase, Validation.

CONTENTS

LIST OF FIGURES

CONTENTS

Preface Page No.

LIST OF TABLES

CONTENTS

Preface Page No.

LIST OF CHROMATOGRAMS OF HPLC & GC

CONTENTS

NOMENCLATURE

AMT	Amoxicillin Trihydrate
G^-	Gram Negative
G^+	Gram Positive

FTIR	Fourier Transform Infrared
US	United States
6-APA	6-Amino Penicillanic Acid
PG	Phenyl Glycine
PBP	Penicillin Binding Proteins
HPLC	High Performance Liquid Chromatography
LOD	Limit of Detection
LOQ	Limit of Quantization
SD	Standard Deviation
RSD	Relative Standard Deviation
M.P	Mobile Phase
H^+	Hydrogen Ion
OH^-	Hydroxyl Ion
pH	Power of Hydrogen
ASTM	American Society of Testing and Materials
mV	Milli Volt
ORP	Oxidation Reduction Potential

FID	Flame Ionization Detector
GC	Gas Chromatography
UV	Ultra Violet
CL	Chemiluminescence
FIA	Flow Injection Analysis
µg	Micro Gram
mL	Mille Liter
mg	Mille Gram
NMT	Not More Than
R.P	Reverse Phase
ACN	Acetonitrile
Nm	Nano meter
M	Molar
λ	Wavelength
r^2	Regression value