

***ESTIMATION AND STABILITY STUDIES OF
AMOXYCILLIN TRIHYDRATE IN THE CAPSULE
DOSAGE FORM***



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PAKISTAN

2015

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

Submitted to University of Management and Technology Lahore

in partial fulfillment of the requirements

for the award of degree of

MASTER OF SCIENCE

IN

CHEMISTRY

BY

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SESSION: 2013-2015

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بِسْمِ اللَّهِ الرَّحْمَنِ الرَّحِيمِ

*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 lofty
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.”**

ACKNOWLEDGMENTS

This thesis becomes a reality with the kind support and with the help of many individuals. I would like express my many thanks to all of them.

For most, I want to offer this endeavor to my ALLAH ALMIGHTY for the wisdom he bestowed upon me, the strength, peace of my mind and good health in order to finish this research.

I am highly indebted to my respected and helpful advisor DR. AYESHA MOHYUDDIN for their guidance and continuous supervision as well as for providing necessary information regarding this research and also for their support in completing this endeavor.

Many thanks for our Dean DR. MUHAMMAD AZHAR IQBAL for their best wishes for my research and thesis work.

I am very thankful to DR SAMMIA SHAHID chair person of the Chemistry department for her support and encouragement.

Many thanks for the committee members of the UNIVERSITY OF MANAGEMENT AND TECHNOLOGY for their help in my thesis and research work.

I am extremely thankful to my friend/colleague MR WAQAS BASHIR & MR MUHAMMAD IKRAM who motivated and encourages me to do this work and helped me during my studies and thesis writing.

I am really appreciable to MR ABDUL MANNAN who allows me to do my research work at Pharmagen Ltd and MR SAGHEER who have honestly and cooperatively helped me with my practical work and make this research possible.

I would like to give many thanks to my Uncle MR AMIR RASHEED for giving me the suggestion about my research work and helped me with the permission for doing research in Pharmagen Ltd.

I would like to express my hearty gratitude toward my family for the encouragement which helped me in completion of this paper. My respected and beloved father RANA ASIM RASHEED who was always by my side whenever I need him and my mother who always inspire me for this responsibility.

I am very much thankful to my Uncle MR JAHANGIR ILYAS MIRZA who have guide me allot and gave me bright ideas about my work and studies.

I am really thankful to my all friends for their help and encouragement. They are always in need of any help I always grateful to them. My special thanks for all class members of university of management and technology, Lahore.

My thanks and appreciation also goes to my colleagues and people who have willingly helped me out with their abilities.

Over all I feel very lucky to be in UMT and I always remember that I have studied in such a great and prosperous institute.

MAAZ ASIM

ABSTRACT

A simple, rapid and time saving method for the validation of Amoxicillin 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 (5 μ m)] 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.

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NOMENCLATURE

AMT	Amoxicillin Trihydrate
G ⁻	Gram Negative
G ⁺	Gram Positive

FTIR Fourier Transform Infrared

US United States

6-APA6-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

