## M. PHARM. (PHARMACEUTICAL ANALYSIS AND QUALITY ASSURANCE)

### COURSE STRUCTURE AND SYLLABUS

#### I YEAR I SEMESTER

<table>
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MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES  
(PAQT-1.1)  
(Common to All Branches)

Unit I

a. Column Chromatography: Adsorption and partition, theory, preparation, procedure and methods of detection  
b. Thin Layer Chromatography: Theory, preparation, procedures, detection of compounds  
c. Paper Chromatography: Theory, different techniques employed, filter papers used, qualitative and quantitative detection  
d. Counter – current extraction, solid phase extraction techniques, gel filtration

Unit II

b. HPLC: Principles and instrumentation, solvents and columns used, detection and applications

Unit III

a. UV-Visible spectroscopy: Introduction, electromagnetic spectrum, absorbance laws and limitations, instrumentation-design and working principle, chromophore concept, auxochromes, Wood-Fisher rules for calculating absorption maximum, applications of UV-Visible spectroscopy  
b. IR spectroscopy: Basic principles-Molecular vibrations, vibrational frequency, factors influencing vibrational frequencies, sampling techniques, instrumentation, interpretation of spectra, FT-IR, theory and applications

Unit IV

Mass spectroscopy: Theory, ionization techniques: electron impact ionization, chemical ionization, field ionization, fast atom bombardment, plasma desorption, fragmentation process: types of fission, resolution, GC/MS, interpretation of spectra and applications for identification and structure determination

Unit V

NMR: Theory, instrumentation, chemical shift, shielding and deshielding effects, splitting of signals, spin-spin coupling, proton exchange reactions, coupling constant(J), nuclear overhauser effect(NOE), $^{13}$C NMR spectra and its applications, 2D-NMR, COSY and applications in pharmacy
REFERENCES:

1) Instrumental Methods of Chemical Analysis by B.K Sharma
2) Organic spectroscopy by Y.R Sharma
3) A Text book of Pharmaceutical Analysis by Kerrenth A. Connors
4) Vogel’s Text book of Quantitative Chemical Analysis by A.I. Vogel
5) Practical Pharmaceutical Chemistry by A.H. Beckett and J.B. Stenlake
6) Organic Chemistry by I. L. Finar
7) Organic spectroscopy by William Kemp
8) Quantitative Analysis of Drugs by D. C. Garrett
9) Quantitative Analysis of Drugs in Pharmaceutical Formulations by P. D. Sethi
10) Spectrophotometric identification of Organic Compounds by Silverstein
11) HPTLC by P.D. Seth
12) Indian Pharmacopoeia 2007
ADVANCED BIOSTATISTICS & RESEARCH METHODS

Unit-I:
Developing a research question, Resources for research question,
Literature Review: Traditional Qualitative Review
Meta-Analysis—A Quantitative Review
Preparation of Research Proposal

Variables—Definition of Variable, Types of variables—Dependent and Independent variables,
Confounded variables, Measurement of variables, Types of measurement scales and their comparison. Reliability and Validity of Measurements.

Unit-II:
Validity, Types of validity—Internal validity, Construct validity, External validity, Threats to validity.

Control: Subject as own control (Within Subject control), Statistical control.

Unit-III:
Non-experimental Research:
Observational Research: Naturalistic Observation, Participant-Observer Research.
Archival Research: Archival Data Collection and Compilation.
Case Studies: Characteristic of Case Studies.

Non-experimental Research: Survey Research—Designing of Questionnaire, Methods of Administration, Response Rates. Types of Samples—Haphazard Samples, Purposive Samples, Convenience Samples and Probability Samples.

Unit-IV:


Unit V:
Single-Subject Experiments: Advantages and Disadvantages.
Quasi Experiments: The differences between Quasi and True Experiments.
Design without Control Groups—Interrupted Time Series Designs and Repeated Treatment Designs.

Text Books
1. Donald H. McBurney -Theresa L. White “Research Methods” (Cengage learning India Pvt. Ltd)
3. Biostatistics & Computer applications by GN Rao and NK Tiwari

Reference Books
1. Remingtons pharmaceutical Sciences
2. Theory & Practice of Industrial Pharmacy by Lachman
ADVANCED PHARMACEUTICAL ANALYSIS – I

Unit I

An advanced study of the principles and procedures involved in Non-aqueous, Complexometric, Oxidation-reduction and Diazotization methods

Unit II

An advanced study of the principles and procedures involved in the electrometric methods: Conductometry, Potentiometry, and Polarography and Amperometry

Unit III

Detailed study of the principle and procedures involved in the quantitative determination of the organic functional groups: Amines, Aldehydes, Ketones, Ester and Hydroxy

Unit IV

Principles and procedures involved in using the following reagents in pharmaceutical analysis with suitable examples

i. MBTH (3-methyl-2- benzothizolone hydrazone)
ii. F.C. Reagent (Folin-Ciocalteau)
iii. PDAB (Para Dimethyl Amino Benzaldehyde)
iv. 2, 3, 5 – Triphenyl tetrazolium salt
v. 2,6 Dichloroquinone Chlorimide

Unit V

Principles and procedures involved in quantitative determination of various pharmaceutical preparations and dosage forms of the Alkaloids, Antibiotics, Vitamins, Glycosides, Steroids and Diuretics drugs included in the IP

REFERENCES
1) Remington’s Pharmaceutical Sciences by Alfonso and Gennaro
2) Pharmaceutical Chemistry by Becket and Stanlake
3) Quantitative Analysis of Drugs in Pharmaceutical Formulations by P.D. Sethi
4) Pharmaceutical Analysis by Higuchi, Bechmman and Hassan
5) Theory and Practice of Industrial Pharmacy by Lieberman and Lachman
6) Indian Pharmacopoeia 1996
7) Instrumental Methods of Chemical Analysis By B.K. Sharma
8) A Text Book of Pharmaceutical Analysis by Kerrenth A. Conners
9) Journals (Indian Drugs, IJPS etc.)
GOOD MANUFACTURING PRACTICES AND AUDITS

Unit I
GMP general considerations and definitions, Aims & Objectives of GMPs, GMP requirements for activities of manufacturing/ packaging/ labeling, testing

Unit II
Introduction to GMPs-MHRA, GMPs-HPFBI, GMPs-MCC, GMPs-EDQM, etc.
ICH Q7A, GMPs for APIs

Unit III
Audits: GMP compliance audit, Definition Summary, Audit policy, Internal and External Audits, Second Party Audits, External third party audits

Unit IV
Preparation for Audit, Conducting audit, audit analysis, audit report, audit follow up,

Unit V
A typical internal Audit Report (First party), External (Second party) Audit Report Third party audit report

TEXT BOOKS
1. How to practice GMP, 1st Edition, P.P. Sharma
2. Good Laboratory Practices, Selier, Jurg P
3. Good Pahrm. Manufacturing Practice Rational and Compliance, John Sharp

SUGGESTED REFERENCES:
1. The Gazette of India, Extra ordinary, New Delhi
2. A Text book of Forensic Pharmacy by Mithal
4. Quality Assurance of Pharmaceuticals
EVALUATION OF PHARMACEUTICAL DOSAGE FORMS

Unit I
Detailed study of the principles and procedures involved in various physicochemical methods of analysis of Pharmaceutical dosage forms belong to the following classes of drugs.

A. Sulphonamides    B. Antibiotics    C. Anti- histamines    D. Vitamins

Unit II
A detailed study on the principles and procedures involved in the determination of the dosage forms of the following group of drugs

A. Adrenergics    B. Anti- malarials    C. Steroids    D. Analgesics and antipyretics

Unit III
Official methods of determination for the mentioned below pharmaceutical dosage forms of the following group of drugs

A. Local anesthetics    B. Barbiturates    C. Anti-diabetics    D. Diuretics

Unit IV
Various in process Quality Control tests carried on the following of Dosage Forms

A. Tablets    B. Capsules    C. Injectables    D. Liquid Orals

Unit V
A detailed study on the biological evaluation of the following dosage forms

A. Rabbis Vaccine    B. Oxytocin    C. Tetanus Antitoxin

Unit VI
Microbiological evaluation of the following dosage forms

A. Neomycin Sulphate    B. Cyanocobalamin    C. Diphtheria Vaccine

Recommended Books:
1) Remington’s Pharmaceutical Sciences by Alfonso and Gennaro
2) Microbiological Assays by Barton J. Wright
3) Pharmaceutical Chemistry by Becket and Stanlake
4) Quantitative Analysis of Drugs in Pharmaceutical Formulations by P.D.Sethi
5) Pharmaceutical Analysis by Higuchi, Bechmman and Hassan
6) Theory and Practice of Industrial Pharmacy by Lieberman and Lachman
7) Indian Pharmacopoeia 1996
1. Use of spectrophotometer for analysis of Pharmacopoeial compounds and their formulations
2. Simultaneous determination of combination formulations (Minimum of 04 experiments)
3. Effect of pH and solvent on UV spectrum of certain drugs
4. Experiments of Chromatography
   a. Thin layer chromatography
   b. Paper chromatography: Ascending, Descending, circular and two-dimensional techniques
5. Experiments based on HPLC and GC
6. IR, NMR and mass spectra: Interpretation for the structural elucidation of organic compounds
7. Any other relevant experiments

ADVANCED PHARMACEUTICAL ANALYSIS - I

1. Determination of official compounds by Non-aqueous titrations
2. Determination of drugs containing di and trivalent metal ions by complexometric titrations
3. Determination of sulfa drugs by diazotization
4. Determination of Vitamin C by redox titration
5. Conductometric, potentiometric and polarographic & amperometric titrations
6. Quantitative determination of functional groups present in drugs
7. Quantitative determination of suitable drugs using the reagents mentioned in Unit IV
8. Quantitative determination of pharmaceutical dosage forms belonging to alkaloids, antibiotics, vitamins, glycosides, steroids and diuretics