



**STRUCTURE FOR THEORY & PRACTICAL PAPERS
WITH CONTACT HOURS PER WEEK AND CREDIT POINTS FOR
MASTER DEGREE IN PHARMACEUTICAL TECHNOLOGY (M. PHARMA) IN
PHARMACEUTICAL ANALYSIS & QUALITY ASSURANCE**

SEMESTER-I

A. THEORY							
SL. NO.	CODE	THEORY	CONTACTS (PERIODS/WEEK)				CREDITS
			L	T	P	TOTAL	
01	MPT-101(1)	Quality Assurance of Pharmaceuticals	4				3
02	MBS-101	Bio-Statistics (Common paper)	4				2
03	MPT-101	Modern Pharmaceutical Analytical Techniques (Common paper)	4				3
04	MPT-101(2)	Phytopharmaceutical Analysis	3				2
SESSIONAL							
05	MPT-181	Seminar					1
06	MPT-191(2)	Phytopharmaceutical analysis Lab			4		3
	MPT-191	Pharmaceutical analysis Lab			4		3
							17

FULL MARKS FOR PAPER WITH 2 / 3 CREDIT POINT = 100

FULL MARKS FOR PAPER WITH 1 CREDIT POINT = 50

FULL MARKS FOR PAPER WITH 5 CREDIT POINT = 200

FULL MARKS FOR PAPER WITH 9 CREDIT POINT = 300

SEMESTER-II

A. THEORY							
SL. NO.	CODE	THEORY	CONTACTS (PERIODS/WEEK)				CREDITS
			L	T	P	TOTAL	
01	MPT-201(1)	Advanced Pharmaceutical Analysis-I	3				2
02	MPT-209	Pharmaceutical Bio-technology (Common paper)	4				3
03	MPT-212	Process validation & CGMP (Common paper)	4				3
04	MPT-201(2)	Advanced Pharmaceutical Analysis-II	2				2
SESSIONAL							
05	MPT-281	Seminar					1
06	MPT-291	Advanced Pharmaceutical Analysis Lab			4		2
							13



SEMESTER-III

A. THEORY							
SL. NO.	CODE	THEORY	CONTACTS (PERIODS/WEEK)				CREDITS
			L	T	P	TOTAL	
01	MPT-314	Research Methods & Clinical Trials	3				2
02	MPT-391	Synopsis					5
03	MPT-392	Presentation					3
							10

SEMESTER-IV

A. THEORY							
SL. NO.	CODE	THEORY	CONTACTS (PERIODS/WEEK)				CREDITS
			L	T	P	TOTAL	
01	MPT-491	Thesis					9
02	MPT-491 (1)	Defence of Thesis					3
							12
The Synopsis and presentation of 1st semester and Thesis and Defence of Thesis in 4th Semester should be assessed in presence of External Examiner(s). The Final Credit should be awarded to the student of the above mentioned subjects by both the internal and external examiners.							



M. PHARM. SYLLABUS FOR PHARMACEUTICAL ANALYSIS & QUALITY ASSURANCE

SEMESTER-I

QUALITY ASSURANCE OF PHARMACEUTICALS

Code: MPT-101 (1)
Contact: 4 hr per week
Credits: 3
Full Marks: 100

1. Organization and personnel, responsibilities, training hygiene.
2. Premises: Location, design, plan layout, construction, maintenance and sanitations, environmental control, sterile areas, control of contamination.
3. Equipments: Selection, purchase specifications, maintenance, clean in place, sterilize in place.
4. Raw materials: Purchase specifications, maintenance of stores, selection of vendors, controls and raw materials.
5. Manufacture of and controls on dosage forms: Manufacturing documents master formula, batch formula records, standard operating procedures, quality audits of manufacturing processes and facilities.
6. In process quality control on various dosage forms sterile, biological products and non-sterile, standard operating procedures for various operations like cleaning, filling, drying, compression, coating, disinfection, sterilization, membrane filtration etc. Guidelines for Quality assurance of Human Blood products and Large volume parenterals.
7. Packaging and labeling controls, line clearance and other packaging materials.
8. Quality control laboratory: Responsibilities, good laboratory practices, routine controls, instruments, protocols, non-clinical testing, controls on animal house, data generation and storage, quality control documents, retention samples, records, audits of quality control facilities.
9. Finished products release: Quality review, quality audits, batch release document.

RECOMMENDED BOOKS:

1. The International Pharmacopoeia Vol 1,2,3,4, 3rd Edition General methods of analysis and quality specifications for pharmaceutical substances, excipients, dosage forms.
2. Quality Assurance of Pharmaceuticals – A compendium of guidelines and related materials Vol.1 and Vol.2, WHO, (1999)
3. Basic tests for pharmaceutical substances – WHO (1988)
4. Basic tests for pharmaceutical dosage forms – WHO (1991)
5. GMP-Mehra
6. How to Practice GMPs – P.P.Sharma, Vandana Publication
7. The Drugs and Cosmetic Act 1940 – Vijay Malik, Eastern Book Company
8. Pharmaceutical Process Validation by Berry and Nash.
9. Q.A Manual –D H Shah, Business Horizon.
10. SOP Guidelines- D H Shah, Business Horizon.

BIO-STATISTICS

Code: MBS-101
Contact: 4 hr per week
Credits: 2
Full marks: 100

1. An introduction to statistics and bio-statistics collection and organisation of data: Graphical and pictorial presentation of data, measures of central tendency and dispersion, sampling techniques, sample size, coefficient of variation, mean error, relative error, precision and accuracy.
2. Probability: Definition and probability distributions, normal, binominal and polynominal distributions, continuous data distribution, fiducial limits, probit and logit analysis.
3. Regression: Linear regression and correlation, curvilinear regression method of least squares, curve fitting, multiple regression and correlation, significance of correlation and regression.
4. Parametric tests: Testing hypothesis, types of errors, tests of significance based on normal distribution, test of significance for correlation coefficients.



MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES

Code: MPT-101

Contact: 4 hr per week

Credits: 3

Full marks: 100

1. Principles of separation and applications of TLC. Column chromatography. Paper chromatography, Ion exchange chromatography, Counter current chromatography, G.C., DCCC, HPTLC & HPLC and electrophoresis.
2. Infrared spectroscopy
Introduction: The IR absorption process; the modes of vibration bond properties and absorption trends. The Hook's Law & calculations of frequencies for different types of bonds; coupled interactions; hydrogen bonding; radiation source, sample handling, qualitative and quantitative applications and introduction about FT-IR
3. Ultraviolet spectroscopy:
Introduction: The nature of electronic excitation, the origin of UV band structure; principle of absorption spectroscopy; Beer and Lambert's Law, Chromophore $s \rightarrow s^*$, $h \rightarrow s^*$, $p \rightarrow p^*$, $h \rightarrow p^*$, transitions; shifts reagents effects of substituents; effect of conjugation' confirmations and geometry; calculation of Lamda maxima, effect of solvents, qualitative and quantitative applications
4. Nuclear Magnetic Resonance spectroscopy:
A. 1H NMR Spectroscopy: Principle, Instrumentation techniques. Chemical equivalence, spin-spin coupling, The origin of spin-spin splitting, Pascal triangle, the coupling constant chemical shift reagents Pharm. application including interpretation of Proton-NMR spectra.
B. ^{13}C NMR Spectroscopy: Peak assignments, off resonance decoupling, selective proton decoupling, chemical shift equivalence, chemical shifts and spin coupling.
5. Mass Spectrometry:
Basic principle and theory involved, Instrumentation, types of ions, fragmentation, rearrangements; mass spectra of representative compounds, recognition of molecular ion peak, chemical ionization mass spectrometry, field desorption mass spectrometry, mass spectrometry, fast atom bombardment mass spectrometry.
6. Thermal analysis:
Introduction to various thermal methods of analysis, basic principle and theory; differential thermal analysis and differential scanning calorimetry and micro calorimetry. Different types of calorimeters and micro calorimeters.
7. Pharmacological evaluation of drugs in biological fluids: Bioassay.
8. Microbiological assays.
9. Radioimmunoassays.
10. Quantitative microscopy of herbal drugs. Lycopodium spore method, stomatal number, stomatal index, palisade ratio, vein-islet number, and vein-termination number.

PHYTOPHARMACEUTICAL ANALYSIS

Code: MPT-101 (2)

Contact: 3 hr per week

Credits: 2

Full Marks: 100

1. Methods of systematic phytochemical analysis including extraction and identification of plant constituents using chromatographic techniques.
2. Quality control of crude drugs : proximate analysis including ash and extractive values, crude fibre content, U.V. and fluorescence analysis of powdered drugs.
3. Qualitative & quantitative microscopy and microchemical tests.
4. Detection of common adulterants and insects infestation in whole and powdered drugs.
5. Analysis of official formulations derived from crude drugs including some Ayurvedic preparations.
6. Brief study of quality control of plant-products and their high-throughput screening.
7. Microbiological screening methods for antimicrobial activity.
8. WHO guidelines for the quality control of raw materials used in herbal formulations.



RECOMMENDED BOOKS:

1. Pharmacopoeia of India
2. Textbook of Pharmacognosy by Trease & Evans.
3. Textbook of Pharmacognosy by Tyler, Brady & Robber.
4. Phytochemical Methods by J.B.Haroborne
5. Instrumental methods of Analysis by Willard, Merrit, Dean
6. Pharmacopoeal standards for Ayurvedic Formulation (Council of Research in Indian Medicine & Homeopathy)
7. Application of Absorption spectroscopy in Organic compounds by J.R.Dyer.
8. The Quantitative Analysis of Drugs by D.C.Garrat.

PHYTOPHARMACEUTICAL ANALYSIS PRACTICAL

Code: MPT-191(2)
Contact: 4 hr per week
Credits: 3
Full Marks: 100

1. Spectrophotometric determination of caffeine from tea powder.
2. The Estimation of curcumin from curcuma longa by spectrophotometric methods.
3. Determination of sugars by descending paper chromatography.
4. Determination of bitterness value of crude drugs.
5. Determination of extractive values of crude drugs.
6. Fluorimetric analysis of iso-quinoline alkaloids.
7. Determination of Rf values of different amino acids and alkaloids.
8. Antimicrobial activity of some plant extracts using different pathogenic and non-pathogenic organisms.
9. Colorimetric analysis of some plant drugs.

PHARMACEUTICAL ANALYSIS PRACTICAL

Code: MPT-191
Contact: 4 hr per week
Credits: 3
Full Marks: 100

1. Practical based on instrumental methods of analysis. A sufficient training will be given through exercises using different kinds of spectral analysis.
Microbial analysis of Vitamins and Antibiotics.
Pharmacological Bioassay of some drugs.



SEMESTER-II

ADVANCED PHARMACEUTICAL ANALYSIS - I

Code: MPT-201(1)
Contact: 3 hr per week
Credits: 2
Full Marks: 100

1. Preparation of drug samples for analysis: Pharmaceutical samples, fundamental theories controlling preparation techniques, specific sample preparation techniques.
2. A detailed study of the principles, instrumentations and applications in drug analysis of: GC-MS, LC-MS with reference to drug metabolism, toxicologic and forensic studies, diagnosis of disease state, quantification of drugs in biological samples, Super critical fluid chromatography and size exclusion chromatography
3. Brief study of the theory, instrumentation and application of the following analytical techniques: atomic force microscopy, plasma atomic emission spectroscopy, photon correlation spectroscopy, atomic absorption spectroscopy.
4. Interpretation of spectral data of Infrared spectroscopy, ^1H N.M.R & ^{13}C N.M.R and MASS spectroscopy for structural elucidation of organic molecules.

RECOMMENDED BOOKS:

1. Pharmaceutical Analysis by Ohannason
2. Chemical Analysis by Settle
3. Pharmaceutical Analysis Modern Methods by Munson
4. Chemical Analysis – Modern Instrumentation methods and techniques by Wiley.
5. Instrumental methods of analysis by Willard Dean & Merrit.
6. Hand book of Instrumental techniques for analytical chemistry edited by Frank settle pub. by Prentice Hall Inc.
7. A text book of Pharmaceutical analysis by K.A.Conners (John Wiley)

PHARMACEUTICAL BIO-TECHNOLOGY

Code: MPT-209
Contact: 4 hr per week
Credits: 3
Full marks: 100

1. Systems and methods of molecular biology: Introduction to genetic engineering and biotechnology, genes and gene expression, bacteria, bacteriophage, yeasts, animal cells, use of mutants, genetic analysis of mutants, genetic recombination, complementation.
2. Gene cloning: Nucleic acid isolation cloning vectors (some examples), enzymes used in molecular cloning, cloning methods (some examples)
3. Gene expression: Gene expression, some examples in E. coli in baculovirus in mammalian cells.
4. Fermentation technology: Design, operation and characteristics of fermentation processes, cell growth and production regulation, product biosynthesis and accumulation, instrumentation and bio-process control.
5. Industrial enzymes in drug development: Penicillin amidase, carbohydrase enzymes, chymosin from calf stomach, future directions.
6. Antibiotic biosynthesis genes and their use in developing new antibiotic from micro organisms. Methods for isolating new antibiotics, genetic systems and molecular tools for analysis of antibiotic, bio-synthesis, cloning and analysis of antibiotic biosynthesis genes, genetically engineered hybrid antibiotics.
7. Second generation molecules via site-specific gene alteration, second generation protein program design, examples of engineered proteins of therapeutic potential, methods of protein drug delivery future perspective.
8. Prospects in gene therapy, Potential approach to gene therapy, somatic cell gene transfer, prospects and limitations.
9. Biotechnology in pharmaceutical industry: Major areas for biotechnology in the pharmaceutical industry such as antibiotics, sexual re-combination, recombinant DNA technology, monoclonal antibody, regulatory proteins



(human insulin, interferon, therapeutic peptides) commercial aspects, priorities for future biotechnological research.

10. Sterilization and sterility testing: principle, validation of different sterilization processes, methods, industrial sterilizer, air handling unit and sterility testing of different types of dosage form.

RECOMMENDED BOOKS:

1. J.D.Watson, "Molecular Biology of the cell".
2. J.D.Watson and Tooze, "Recombinant DNA techniques" : A short course.
3. Benjamin Levin, "Genes V".
4. Pepler, "Microbial Technology" I & II.
5. Old & Primrose, "Genetic Manipulations"
6. I.P. 1996, Vol.-I & II

PROCESS VALIDATION AND CGMP

Code: MPT-212

Contact: 4 hr per week

Credits: 3

Full marks: 100

1. Basic concepts of quality assurance, Requirements of CGMP/GLP, ISO 9000 series, Quality audits etc.
2. Precision, accuracy and biases, sampling and operating characteristic curves, sampling plans, statistical inference in estimation of hypothesis testing, statistical procedure in assay development.
3. Development of new analytical method and its validation.
4. In-process quality control tests for various dosage forms including packaging and labeling operations.
5. Brief introduction to general requirements of health regulatory agencies such as US FDA, WHO etc. Preparation of documents for new drug application and export registration.
6. History and various phases of drug development and drug approval, Investigational New drug (IND), New Drug Application (NDA) (Phase I-IV): content and format, Abbreviated new drug application (ANDA), Content, development flow sheet and format, exclusivity, concept of paragraph I to IV, Clinical study and basic concepts of Good clinical practice.
7. Concepts in validation, validation of manufacturing and analytical equipment. Process validation in production of pharmaceuticals. Electronic records (21CFR11)
8. Introduction to orange book, freedom of information (FOI), inactive ingredient guide (IIG), Drug master file (DMF), open part of DMF, codes of therapeutic equivalency, CDER, CBER.

RECOMMENDED BOOKS:

1. S. H. Willig, M.M.Tuckeman and W.S.Hitchings, "Good Manufacturing Practices for Pharmaceuticals", Drugs and Pharm. Sci. Series, Vol. 16, Marcel Dekker Inc., N.Y.
2. B.T.Loftus & R.A.Nash, "Pharmaceutical Process Validation", Drugs and Pharm Sci. Series, Vol. 23, Maarcel Dekker Inc., N.Y.
3. S. Bolton, "Pharmaceutical Statistics : Practical & Clinical Applications", Drugs and Pharm. Sci. Series, Vol. 25, Marcel Dekker Inc., N.Y.
4. G.S, Banker & C.T.Rhodes, "Modern Pharmaceutics", Drugs and Pharm. Sci. Series, Vol. 7, Maracel Dekker Inc., N.Y.

ADVANCED PHARMACEUTICAL ANALYSIS - II

Code: MPT-201(2)

Contact: 2 hr per week

Credits: 2

Full Marks: 100

1. A detailed study of the principles, instrumentation and applications of the following Instrumental analysis: X-ray fluorescence spectrometry, X-ray diffraction, Scintillation counter, Inductively coupled plasma-atomic emission spectroscopy, Electron spin resonance spectroscopy (ESR)
2. A detailed study of the various principles and procedure involved in the quantitative analysis of pharmaceutical preparations and dosage forms containing the following groups of drugs included in I.P. (Biological and microbiological methods excluded)



- (a) Analgesics and Antipyretics (b) Sedatives & Tranquillizers
(c) Antihypertensives (d) Antibiotics & Antibacterials
(e) Cardiovascular drugs (f) Vitamins (g) Antihistaminics (h) Antidiabetics
3. A detailed study of the principles and procedures involved in the qualitative and quantitative analysis of pharmaceutical preparations and dosage form using the following reagents and reactions.
- (i) Oxidative coupling reactions using MBTH (3-methyl-2-benzothiazolinone hydrazone hydrochloride)
 - (ii) Diazotization followed by coupling
 - (iii) Oxidation followed by complexation.
 - (iv) Oxidation followed by charge transfer reaction.
 - (v) Condensation reactions using the reagents Para Dimethyl Amino Benzaldehyde (PDAB), Para Dimethyl Amino Cinnamaldehyde (PDAC), Folin's reagent and Gibb's reagent.

RECOMMENDED BOOKS:

1. Instrumental methods of analysis by Scoog and West.
2. Chemical Analysis – Modern Instrumentation methods and techniques by Wiley.
3. Instrumental methods of analysis by Willard Dean & Merrit.
4. Hand book of Instrumental techniques for analytical chemistry edited by Frank settle pub. by Prentice Hall Inc.
5. A text book of Pharmaceutical analysis by K.A.Conners (John Wiley)
6. Spectrometric identification of organic compounds by silver stein (7th Edition) 1981.
7. Pharmaceutical analysis edited by Higuchi and Brochmann.
8. Organic Spectroscopy by William Kemp

ADVANCED PHARMACEUTICAL ANALYSIS PRACTICAL

Code: MPT-291
Contact: 4 hr per week
Credits: 2
Full Marks: 100

Practical based on instrumental method of analysis. Importance should be given in various chromatographic techniques.

SEMESTER - III

RESEARCH METHODOLOGY AND CLINICAL TRIALS

Code: MPT-314
Contact: 3 hr per week
Credits: 2
Full marks: 100

Information technology: subject classification and cataloguing, literature searches, data bases electronic and libraries, referencing and bibliographies, electronic communications.

- Good clinical practice.
- Good Laboratory Practice
- Ethics including consent and insurance
- Adverse drug reaction surveillance
- Randomization
- Clinical trial design
- Data management/statistics
- Protocol preparation
- Case record forms
- Evaluation of Reports and Report Writing
- International guidelines for Clinical Research
- Use of unregistered medicines for Research