

Syllabus for M.Pharm in Pharmacology & Toxicology

**STRUCTURE FOR THEORY & PRACTICAL PAPERS WITH CONTACT
HOURS PER WEEK AND CREDIT POINTS FOR MASTER DEGREE
(M. PHARM) IN PHARMACOLOGY & TOXICOLOGY
SEMESTER-I**

A. THEORY							
SL. NO.	CODE	THEORY	CONTACTS (PERIODS/WEEK)				CREDITS
			L	T	P	TOTAL	
01	MPT-105 (1)	PHARMACOLOGY AND GENERAL TOXICOLOGY	4				3
02	MBS-101	Bio-Statistics (Common paper)	4				2
03	MPT-101	Modern Pharmaceutical Analytical Techniques (Common paper)	4				3
04	MPT-105(2)	MODERN CONCEPTS OF PHARMACOLOGY	3				2
Sessional							
05	MPT-181	Seminar					1
06	MPT-195	PHARMACOLOGY AND TOXICOLOGY LAB –I			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-205(1)	Drug Therapy	3				3
02	MPT-209	Pharmaceutical Bio-technology (Common paper)	4				2
03	MPT-212	Process validation & CGMP (Common paper)	4				3
04	MPT-205(2)	RECENT ADVANCES IN PHARMACOTHERAPEUTICS	3				2
Sessional							
05	MPT-281	Seminar					1
06	MPT-295	PHARMACOLOGY LAB –II			4		2
							13

SEMESTER-III

A. THEORY							
SL. NO.	CODE	THEORY	CONTACTS (PERIODS/WEEK)				CREDITS
			L	T	P	TOTAL	
01	MPT-314	Research Method & 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-495A	Thesis					9
02	MPT-495B	Defense of Thesis					3
							12

The Synopsis and presentation of 1st semester and Thesis and Defense 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.

SYLLABUS FOR M. PHARM IN PHARMACOLOGY & TOXICOLOGY

SEMESTER-I

PHARMACOLOGY AND GENERAL TOXICOLOGY

Code : MPT-105(1)

Contact : 4L

Credits: 3

Full marks: 100

1. a) Discussion of pharmacokinetics aspects of drug action: Absorption, Distribution, Metabolism, Excretion.
b) Concept of histopathology.
2. Bioassays: Basic principles of bioassays, official bioassays like bioassay of histamine, insulin, oxytocin and acetylcholine.
3. Drug Toxicity, Tolerance, Addiction, Habituations, Idiosyncrasy, Allergy, Hypersensitivity, Antagonism, Synergism, Potentiation, Tachyphylaxis, Heavy metal poisoning
4. Basic principles of toxicology; Dose response relationship, LD50, ED50; manifestation of toxicity.
5. Implication of drug interactions and rational combination therapy. Adverse drug reactions.
6. Laboratory Animal care and Ethical requirement as per guidelines of CPCSEA.
7. Screenings of Anti-inflammatory, Analgesic, Antidepressants, Anxiolytics, Anticonvulsant and Gastro Intestinal Drug using animal models.

Books Recommended:

1. Goodman and Gilman's The Pharmacological Basis of Therapeutics, 11th ed. Joel G. Hardman, Lee E. Limbird, Alfred G. Gilman (eds.). International Edition, The McGraw Hill Companies, Inc., 2006
2. H.G. Vogel (ed), Drug Discovery and Evaluation-Pharmacological Assays, 2nd edition, Springer Verlag, Berlin, Germany, 2002.
3. M.N. Ghosh, Fundamentals of Experimental Pharmacology, 2nd edition, Scientific Book Agency, Calcutta, India, 1984.
4. CRC Handbook of Toxicology by Derelako & Hollinger
5. Methods in Pharmacology by Arnold Schwartz.
6. Principles of Biochemical Toxicology, John Timbrell ed 3rd ed.
7. Screening Methods in Pharmacology by R.A. Turner. Vol. I & II Academic Press, New York and London.
8. Principles and Methods of Toxicology by A Wallace Hayes CRC Press

Bio-Statistics

Code : MBS-101

Contact : 4L

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, pobit 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.

5. *Non-parametric tests :* Data characteristics and non-parametric procedures, chi-square test, sign test, Wilcoxon sign rank test, goodness of fit Mann-Whitney etc.

6. *Experimental design:* Randomization in completely randomized and latin square designs, factorial design, cross over and parallel design, bio-availability and bio-equivalence.

7. *Techniques:* Bioassay dose effect, relationships, LD50, ED50, probability calculations, Statistical quality control, shewhart control charts, statistical procedures in assay development.

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES

Code : MPT-101

Contact : 4L

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. ¹³C 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.

MODERN CONCEPTS OF PHARMACOLOGY

Code : MPT-105(2)

Contact : 3L

Credits: 2

Full marks : 100

1. a) Pharmacogenetics and its importance in variability of Drug response. Genetic polymorphisms influencing drug response.
b) Basic concepts of mechanism of Antisense therapy.

2. a) Stem cells and its implications in therapeutics.
b) Transgenic Animal Models.
3. Endogenous peptides like Interleukin, TNF, NFκB, PG, Bradykinin and their role in diseases.
4. Action of various Neurotransmitters and their roles in CNS diseases. Antiepileptic,
5. Detailed study of Antiparkinsonian, Antidepressants, Anxiolytics and Antipsychotic Drugs.
6. Concept of Cell Cycle, Angiogenesis and Apoptosis and their role in cancer.
7. Cardiovascular diseases like Hypertension, Ischemia, Congestive Heart Failure, Cardiac arrhythmia and their treatment.

Books Recommended :

1. Goodman and Gilman's The Pharmacological Basis of Therapeutics, 11th ed. Joel G. Hardman, Lee E. Limbird, Alfred G. Gilman (eds.). International Edition, The McGraw Hill Companies, Inc., 2006
2. Harrison's Principles of Internal Medicine, Vol-I And II, 17 th Edition, 2008, Mc Graw-Hill
3. Basic & Clinical Pharmacology, 11 edition Bertram G. Katzung
4. Principles and Methods of Toxicology by A Wallace Hayes, CRC Press
5. Pathologic basis of diseases – Robins SL, W.B. Saunders Publicaton
6. Molecular Biology of the Cell - Alberts - 5th ed New York: Garland Science
7. Molecular Cell Biology, 4th edition Harvey Lodish, W. H. Freeman and Company

PHARMACOLOGY AND TOXICOLOGY LAB –I

Code : MPT-195

Contact : 3L

Credits: 2

Full marks : 100

1. Acute toxicity test: LD50, ED50
2. Subacute toxicity test
3. Hematological tests, TC, DC, Hb, ESR, Blood glucose
4. Bioassay of histamine, insulin, oxytocin and acetylcholine.
5. Effect of papaverine on barium chloride-induced contraction of guinea pig ileum.
6. Evaluation of anti-inflammatory effect of ibuprofen and diclofenac in carrageenan-induced acute inflammation model in rat's paw.

Pharmaceutical Analysis Lab. (4 hr per week)

Code : MPT-191

Contact : 3L

Credits: 2

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.

2. Microbial analysis of Vitamins and Anti-biotics
3. Pharmacological Bioassay of some drugs.

SEMESTER-II

Drug Therapy

Code: MPT-205(1)

Contact: 3L

Credits: 2

Full marks: 100

1. Drug therapy in various stages of life like Pediatric, Pregnancy and Geriatric.
2. Patient Counseling and Monitoring for rational use of drugs.
3. Treatment for poisoning of barbiturates, pesticides, heavy metals etc.
4. Detailed study of anti cancer chemotherapy.
5. Advances in Antimicrobial Chemotherapy like β lactam antibiotics, fluoroquinolones, macrolides and aminoglycosides.
6. Detailed study of antiviral and anti retroviral drug therapy.

Books Recommended :

1. Clinical Pharmacy & Therapeutics. By Roger Walker and Clive Edwards.
2. Basic & Clinical Pharmacology, 11e Bertram G. Katzung, Lange publication
3. Goodman and Gilman's The Pharmacological Basis of Therapeutics, 11th ed. Joel G. Hardman, Lee E. Limbird, Alfred G. Gilman (eds.). International Edition, The McGraw Hill Companies, Inc., 2006
4. Rang, H.P., Dale, M.N., Pharmacology, Churchill Livingstone, UK
5. Lippincott's Illustrated Reviews: Pharmacology, 4th Edition, Lippincott Williams & Wilkins

Pharmaceutical Bio-technology

Code : MPT-209

Contact : 4L

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.

Books Recommended :

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 : 4L

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

Books Recommended:

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.

RECENT ADVANCES IN PHARMACOTHERAPEUTICS

Code : MPT-205(2)

Contact : 2L

Credits: 1

Full marks : 100

1. Signal Transduction: Concept of Receptors and Cytoplasmic second messenger system, Regulation of receptors.
2. Ion channel and their Modulators; drugs acting on sodium, potassium, calcium and chloride channels.

3. Mechanism of membrane transporters and drug response for drugs like diuretics and SSRIs
4. Immune Response, cell mediated immunity, humoral immunity and immunosuppressive drugs.
5. Study of neurodegenerative diseases like Alzheimer's disease, Huntington's disease and Amyotrophic lateral sclerosis
6. Drug resistance and role of drug efflux proteins.

Reference:

1. Lippincott's Illustrated Reviews: Pharmacology, 4th Edition, Lippincott Williams & Wilkins
2. Basic & Clinical Pharmacology, 11e Bertram G. Katzung, Lange publication
3. Goodman and Gilman's The Pharmacological Basis of Therapeutics, 11th ed. Joel G. Hardman, Lee E. Limbird, Alfred G. Gilman (eds.). International Edition, The McGraw Hill Companies, Inc., 2006
4. Molecular Biology of the Cell - Alberts - 5th ed New York: Garland Science
5. Kuby Immunology, W. H. Freeman Biology

PHARMACOLOGY LAB –II

Code : MPT-295

Credits: 2

Full marks : 100

Contact hour : 60 hr per semester

1. Determination of blood sugar and hemoglobin level in blood sample of rabbits
2. Evaluation of local anesthetic activity of lignocaine hydrochloride on rabbit cornea
3. Effect of CNS depressants and stimulants drugs.
4. Toxicity study of CCl₄ and Paracetamol in rabbits by determination of SGOT and SGPT value
5. Toxicity study by histopathological study of liver, pancreas, kidney etc.

SEMESTER – III

Research Methodology and Clinical Trials

Code : MPT-314

Credits: 2

Full marks :

Contact hour : 3 hr per week

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

INSTRUCTIONS

1. Each Semester will consist of a minimum of 15 weeks instructions :
2. Internal assessment of Theoreticals (30%) will be based on two class tests of 10 marks in each of the theory subject during each semester and 10 marks for class attendance of student in each subject.
3. Internal assessment of practicals (30%) will be based on day to day attendance, viva, laboratory record etc. There will be no separate class test in practicals. The question papers of university examinations shall be set by both the internal and external examiners. The choice in question papers shall be restricted to 25% only. Complete coverage of prescribed syllabus in university question papers is desired.
4. A minimum of 75% attendance in theory and practical classes is compulsory.
5. A student has to get minimum 45% mark in theory and 50% marks in practical separately to pass the subject.
6. Pass mark in aggregate will be 50% of the total marks.
7. A student will secure 1st class if he/she obtains 60% of total marks and 1st class with honours, if he/she obtains 75% of the total marks.
8. A student will be promoted to next higher semester with a maximum of two back papers (including practical).
9. A student will get a maximum of 4 yrs. time from the date of admission to complete the degree course.

