

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

**SEMESTER-I**

<b>A. THEORY</b>							
SL. NO.	CODE	THEORY	CONTACTS (PERIODS/WEEK)				CREDITS
			L	T	P	TOTAL	
01	MPT-108(1)	General Pharmacology	4			4	3
02	MBS-101	Bio-Statistics (Common paper)	4			4	2
03	MPT-101	Modern Pharmaceutical Analytical Techniques (Common paper)	4			4	3
04	MPT-108(2)	Advanced Pharmacology	3			3	2
<b>Sessional</b>							
05	MPT-181	Seminar					1
06	MPT-198	Pharmacology Lab			4	4	3
	MPT-191	Pharmaceutical Analysis Lab.			4	4	3
						23	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**

<b>A. THEORY</b>							
SL. NO.	CODE	THEORY	CONTACTS (PERIODS/WEEK)				CREDITS
			L	T	P	TOTAL	
01	MPT-208(1)	Clinical Pharmacology	3			3	2
02	MPT-209	Pharmaceutical Bio-technology	4			4	3
03	MPT-212	Process validation & CGMP (Common paper)	4			4	3
04	MPT-208(2)	Molecular Pharmacology	3			3	2
<b>Sessional</b>							
05	MPT-281	Seminar					1
06	MPT-293	Pharmacology Lab.			4	4	2
						18	13

**SEMISTER-III**

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

**SEMISTER-IV**

<b>A. THEORY</b>							
SL. NO.	CODE	THEORY	CONTACTS (PERIODS/WEEK)				CREDITS
			L	T	P	TOTAL	
01	MPT-493(1)	Thesis					9
02	MPT-493(2)	Defence of Thesis					3
							12

**The Synopsis and presentation of 1<sup>st</sup> semester and Thesis and Defence of Thesis in 4<sup>th</sup> 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

### SEMESTER-I

#### GENERAL PHARMACOLOGY

**Code : MPT-108(1)**

**Contact : 4L**

**Credits: 3**

**Full marks : 100**

#### **GENERAL PHARMACOLOGY (1<sup>st</sup> Sem)**

- Identify drug absorption, distribution, metabolism and elimination potential through the concept of ionization as defined by the Henderson-Hassel-batch equation.
  - Discuss the role of lipid solubility and route of administration relative to drug absorption, distribution, metabolism and elimination.
- Drug discovery process: Principles, Techniques and Strategies used in new drug discovery. Regulations for laboratory animal care and ethical requirements.
  - Bioassays: Basic principles of bioassays, official bioassays, experimental models and statistical design employed in biological standardization. Bioassay of histamine, Insulin, Sexhormone, Oxytocin and acetylcholine.
- Pre-clinical and clinical models employed in the screening of new drugs belonging to following categories: Analgesic - antipyretics, anti-inflammatory, anti-anxiety agents, anti-depressant drugs, anti-convulsants, anti-diabetics, local anesthetics and anti-histaminic.
- Alternative to animal screening procedure. Models of study drug metabolism.
- Adverse drug reactions and drug interactions. Principle of toxicity evaluation and determination of LD<sub>50</sub>, ED<sub>50</sub>, and TD<sub>50</sub>.
- Basic mechanism of membrane transport, membrane transporters in therapeutic drug responses, membrane transporters and adverse drug responses

#### Bio-Statistics

**Code : MBS-101**

**Contact : 4L**

**Credits: 2**

**Full marks : 100**

- 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.
- Probability:*** Definition and probability distributions, normal, binominal and polynominal distributions, continuous data distribution, fiducial limits, pobit and logit analysis.
- Regression:*** Linear regression and correlation, curvilinear regression method of least squares, curve fitting, multiple regression and correlation, significance of correlation and regression.
- 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, LD<sub>50</sub>, ED<sub>50</sub>, 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. <sup>1</sup>H 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. <sup>13</sup>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.

### **ADVANCED PHARMACOLOGY**

**Code : MPT-108(2)**  
**Contact: 3L**  
**Credits : 2**  
**Full Marks : 100**

1. Gene therapy: Central concept of gene therapy, gene therapy for hereditary diseases, gene therapy for cancer, gene therapy for HIV. Antisense therapy, basic concept, mechanism of antisense therapy, examples of antisense therapy for the treatment of different diseases.
2. The role of Nitric oxide in various physiological functions and its importance in pharmacotherapy of disorders like hypertension, Angina and Erectile dysfunction.
3. Role of Cytokines as a biological response modifiers (a) Interleukins, (b) Colony Stimulation Factors (c) Tumor Necrosis Factors Alpha (TNF- $\alpha$ ). Identify the target for immunosuppressive actions of the following drug agents such as Cyclosporine, Tacrolimus, Corticosteroids, Azathioprine, Methotrexate, Cyclophosphamide, Mycophenolate, CD3 antibodies including their mechanisms of action in immunosuppression.
4. Role of Prostaglandins, Bradykinins, Adhesion Molecules and NF  $\kappa$ B in various immunological and inflammatory disorders.
5. Emerging concepts and newer therapeutic interventions with special reference to atherosclerosis and obesity.
6. Neuropharmacology: Molecular and cellular mechanisms, Glutamate receptors, GABA and its receptors, catecholamine receptors, Serotonin receptors, the opioid receptors, strokes, neurodegeneration, antiepileptic drugs.
7. Physiological and Pathological Angiogenesis, Stimulator and Inhibitors of Angiogenesis, Modern anti-angiogenic concept for the treatment of chronic diseases, Solid tumor and Cancer.

### **PHARMACOLOGY LAB –I**

**Code : MPT-198**  
**Contact: 4p/week**  
**Credits: 3**  
**Full Marks : 100**

1. Effect of Anti-depolarizing agents like pancuronium on acetylcholine-induced contraction of frog rectus abdominis muscle.
2. Identification of unknown sample of drug using frog rectus muscle.
3. Effect of papaverine on barium chloride-induced contraction of guinea pig ileum.
4. Identification of unknown sample of drug using guinea pig ileum.
5. Effect of Physostigmine on regular pendular movement of rabbit intestine.
6. Identification of unknown sample of drug using of rabbit intestine.
7. Histopathological study of liver isolated from mice.
8. Histopathological study of pancreas isolated from mice.
9. Histopathological study of kidney isolated from mice.
10. Histopathological study of small intestine isolated from mice.

### **Pharmaceutical Analysis Lab. ( 4 hr per week )**

**Code : MPT-191**

**Contact : 4p/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 Anti-biotics

Pharmacological Bioassay of some drugs.

### **SEMESTER-II**

#### **CLINICAL PHARMACOLOGY**

**Code : MPT-208(1')**

**Contact : 3L**

**Credits: 3**

**Full marks : 100**

1. Definition and scope of clinical pharmacology, Evaluation of drugs in man, Official regulation of medicines, Classification and naming of drugs.
2. Drug therapy monitoring in special situations such as pediatric geriatric, pregnancy etc.
3. Racial gender and ethnic differences in drugs response.
4. Patient counseling and interviewing techniques, Improving patient compliance and patient monitoring.
5. Application to therapeutic drug monitoring (TDM), Pharmacist interventions in case of renal impairment, hepatic impairment and anti-coagulant therapy.
6. ADR monitoring, management and reporting of drug interactions and adverse drug reactions.
7. Discuss and identify appropriate chemotherapeutic agents for the major tissue sites of cancer.

#### **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.

### **MOLECULAR PHARMACOLOGY**

**Code : MPT-208(2)**

**Contact : 3L**

**Credits: 2**

**Full marks : 100**

1. Introduction of Molecular Pharmacology. Techniques for the study of Molecular Pharmacology such as Western Blotting, Immunostaining, RT-PCR, Cloning, RIA, Cell Cultures etc.
2. Recombinant DNA technology and it's application in the production of Insulin.
3. Drug receptor interactions and second messenger systems. Signal transduction and termination of receptor activity. G - proteins and receptor structures, cAMP pathway, Phospholopase C, IP<sub>3</sub>, DAQ pathway.
4. Molecular Oncobiology: Causes of cancer, genetic of cancer, oncogenes, tumor suppressor genes.
5. Contrast the use of therapeutic agents for cancer chemotherapy versus immunosuppression in terms of dosage and degree of elective toxicity.
6. Molecular Neurobiology:  
Molecular genetics of Alzheimer's disease, Myasthenia gravis and parkinsonism. Molecular mechanism and regulation of behavior.

### **PHARMACOLOGY LAB –II**

**Code : MPT-293**

**Contact : 4p/week**

**Credits: 2**

**Full marks : 100**

1. Effect of CNS stimulants on mice.
2. Effect of CNS depressants in mice.
3. Evaluation of local anesthetic activity of lignocaine hydrochloride on rabbit cornea
4. Evaluation of anti-inflammatory effect of ibuprofen in carrageenin-induced acute inflammation model in rat's paw.
5. Evaluation of anti-inflammatory effect of unknown drug sample in carrageenin-induced acute inflammation model in rat's paw.
6. Determination of SGOT and SGPT value of blood sample of rabbits.
7. To study the effect of paracetamol treatment on the value of SGOT and SGPT of blood sample of rabbits.
8. Determination of cholesterol and triglyceride level in blood sample of rabbits
9. Determination of blood sugar and hemoglobin level in blood sample of rabbits.
10. Determination of ED50, LD50 and TD50 value.



## 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