STRUCTURE FOR THEORY & PRACTICAL PAPERS
WITH CONTACT HOURS PER WEEK AND CREDIT POINTS FOR
MASTER DEGREE IN PHARMACEUTICAL TEHCOLOGY (M. PHARMA) IN PHARMACEUTICAL CHEMISTRY

SEMESTER-I

A. THEORY							
SL. NO.	**CODE**	**THEORY**	**CONTACTS (PERIODS/WEEK)**				**CREDITS**
			L	**T**	**P**	**TOTAL**	
01	MPT-103(1)	Advanced Pharmaceutical Chemistry-I	**4**				3
02	MBS-101	Bio-Statistics (Common paper)	**4**				2
03	MPT-101	Modern Pharmaceutical Analytical Techniques (Common paper)	**4**				3
04	MPT-103(2)	Advanced Pharmaceutical Chemistry-II	**3**				2
Sessional							
05	MPT-181	Seminar					1
06	MPT-193(1)	Pharmaceutical Chemistry 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

SEMISTER-II

A. THEORY							
SL. NO.	**CODE**	**THEORY**	**CONTACTS (PERIODS/WEEK)**				**CREDITS**
			L	**T**	**P**	**TOTAL**	
01	MPT-203(1)	Advanced Pharmaceutical Chemistry-III	**3**				2
02	MPT-209	Pharmaceutical Bio-technology	**4**				3
03	MPT-212	Process validation & CGMP (Common paper)	**4**				3
04	MPT-203(2)	Advanced Pharmaceutical Chemistry-IV	**2**				2
Sessional							
05	MPT-281	Seminar					1
06	MPT-293	Pharmaceutical Chemistry Lab.			**4**		2
							13

SEMISTER-III

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

SEMISTER-IV

A. THEORY							
SL. NO.	**CODE**	**THEORY**	**CONTACTS (PERIODS/WEEK)**				**CREDITS**
			L	**T**	**P**	**TOTAL**	
01	MPT-493	Thesis					9
02	MPT-493(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 CHEMISTRY

SEMESTER –I

ADVANCED PHARMACEUTICAL CHEMISTRY – I

Code : MPT-103(1)
Contact : 4 hr per week
Credits : 3
Full Marks : 100

I. MOLECULAR BASIS OF DRUG ACTION:

A) Receptor: Drug Receptor Interaction.

a) Basic ligand concept, agonist, antagonist, partial agonist, inverse agonist.

b) Receptor Theories - Occupancy, Rate & Activation Theories.

c) Receptor Binding Assays, Determination of B-max and Kd by transforming data with Hill plot and Scatchered plot.

d) Above concepts with special reference to Opioid, Histaminergic, Adrenergic and GABA nergic receptors.

B) Enzyme Inhibition –

a) Enzyme structure: primary, secondary, tertiary and quaternary.

b) Enzyme Kinetics.

c) Enzyme Inhibitors - Kcat inhibitors. Transition state analogs.

d) Enzyme Inhibitors as drugs - ACE, leukotrienes, Lipoxygenase, Cycloxygenase, Aromatase, Xanthine oxidase, DNA Polymerase Inhibitors, HIV - Protease / Reverse Transcriptase, Integrase and Cytochrome P-450 Inhibitors.

C] Drug binding to nucleic acid -- Antimalarial, anti-cancer, antiviral

2) DESIGN AND APPLICATION OF PRODRUGS –

a) Prodrug concept.

b) Prodrugs of various functional groups like carbonyl, hydroxy. amide, amines.

c) Application of Prodrug approach to:

i. Improvement of bioavailability

ii. Prevent first pass metabolism

iii. Reduction of side effects

iv. Prolong duration of action

v. Site specific delivery

3. Physicochemical properties in relation to drug action; metabolic transformation of drugs and its role in development of new drug molecules; Metabolic antagonism.

4. Stereochemical aspects of drug receptor interactions and mechanism of drug interaction. Isosterism and bioisosterism as guides to structural variations; Concepts of conformational analysis and its role in design and development of new drug molecules.

5. Principle of drug design: Analogue synthesis versus rational design; discovery of lead compounds, Pharmacophoric identification, Prodrugs and soft drug.

RECOMMENDED BOOKS

1. Burger: Medicinal Chemistry (John Wiley & Sons N.Y.)
2. Foe: Principles of Medicinal Chemistry (Varghese & Co.)
3. Ledinicer: Organic Drug synthesis Vol. 1, 2, 3, 4 (John Wiley & Sons N.Y.)
4. Ariens: Medicinal Chemistry Series
5. Ellis and West: Progress in Medicinal Chemistry Series
6. Bunerworther Progress in Medicinal Chemistry Series
7. Wilson & Gisvold - Text book of Medicinal Chemistry (J.B. Lippincoff cam)
8. Stuart Warren: Organic Synthesis- The Disconnection, approach (John Wiley & Sons)
9. Stuart Warren : Designing Organic Syntheses: A Programmed Introduction to the Synthon Approach
10. Comprehensive Medicinal Chemistry - Series –I – VI (Academic Press)
11. Text Book of Bio-chemistry
12. Text Book of Bio-chemistry - Leminger
13. Molecular biology - Walson & Crick

ADVANCED PHARMACEUTICAL CHEMISTRY – II

Code : MPT-103(2)
Contact : 3 hr per week
Credits : 2
Full marks : 100

1. Combinatorial Chemistry:

• Introduction

• Combinatorial approaches

• Chemical Peptide and small molecule libraries

• Applications, methodology

• Combinatorial Organic Synthesis

• Assays and Screening of Combinatorial libraries

• Introduction to High Throughputs Screening (HTS)

2. Chiral Technology:

Introduction to Chirality and Techniques used asymmetric synthesis of
Diltiazem, Timolol, Vitamin C, Ampicillin, Dextrapropoxyphen,
Thienamycin, Citrenalol, Propranolol, Atenolol, and Naproxen.

3. Microorganisms in Drug Synthesis and Development-
Microbial conversions of drugs like steroids, prostaglandin, antibiotics,
enzyme immobilization Techniques (micro-organism & animal enzymes)

4. Agents used in Neurodegenerative diseases: like Alzheimer's and
Parkinsonism

5. Agents used in treatment of AIDS: Life cycle of HIV and Drugs used.

6. Proteins and Peptide drugs:
Chemistry, structure and stability, Reactivity of proteins and peptides.
Different ways to synthesize these drugs - study of Insulin, Relaxin,
Somatostatin, DNAse Interferon

RECOMMENDED BOOKS

1. Burger: Medicinal Chemistry (John Wiley & Sons N.Y.)
2. Foye: Principles of Medicinal Chemistry (Varghese & Co.)
3. Ledinicer: Organic Drug synthesis Vol. 1,2,3,4 (John Wiley &. Sons N.Y.)
4. Ariens : Medicinal Chemistry Series
5. Ellis and West : Progress in Medicinal Chemistry Series
6. Butterworther: Progress in Medicinal Chemistry Series
7. Wilson and Gisvold: Text book of Medicinal Chemistry (J.B. Lippincoff cam)
8. Stuart Warren : Organic Synthesis – The Disconnection Approach (John Wiley & Sons)
9. Comprehensive Medicinal Chemistry - Series -I-VI (Academic Press)
10. Combinatorial Chemistry by Arup Mukherjee

Pharmaceutical Chemistry Practical

Code : MPT-193(1)
Contact : 4 hr per week
Credit : 3
Full marks : 100

1. Study and applications of enzymes Kinetics, Inhibition and Immobilization.
2. Determination of pKa value.
3. Synthesis of drugs using basic operations like Molecular distillation, fractional crystallization, and purification by column chromatography. Preparative TLC.
4. Mixture analysis of 2/3 organic compounds.
5. Application of partition coefficient, pKa. Stearic factors, electronic factors in QSAR studies with example. Use of statistical regression analysis.

RECOMMENDED BOOKS

1. Organic Synthesis; Fieser and William Son (CBS Publishers)

2. Mann and Saunders. Practical Organic Chemistry (Orient Longman)

3. A. l. Vogel, Practical Qualitative and Quantitative Organic Chemistry

(Orient Longman)

PHARMACEUTICAL ANALYSIS LAB. (4 HR PER WEEK)

Code : MPT-191
Contact : 4 hr per week
Credit : 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.

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, LD_{50}, ED_{50}, 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 ® s*, h®s*,p® p*, h® 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.

SEMESTER - 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

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.

ADVANCED PHARMACEUTICAL CHEMISTRY – III

Code : MPT-203(1)
Contact : 3L
Credit : 2
Full marks : 100

1. Drug Discovery –

i. Historical perspective

ii. Drug Discovery Strategies in Direct Drug Design (Structure

based) and Indirect drug design

iii. Target selection and lead identification

a. Natural product sources

b. Fermentation / Microbial sources

c. Synthetic

iv. Introduction to Pharmacogenomics

2. QSAR

Parameters - Lipophilicity, electronic, Stearic factors

b. Quantitative Models –

i. Hansch analysis

ii. Free Wilson Analysis

iii. Mixed approach

c. Other QSAR Approaches

d. Applications of Hansch Analysis, Free Wilson Analysis.

3. Enzymes, Peptides in Drug Design

4. Molecular Modeling in Drug Design

i. Introduction to Molecular Modeling: Concepts and Methods

a. Molecular Mechanics - force fields (Potential energy function).

b. Energy Minimization Methods - Steepest, descent. Conjugate

gradients, Newton methods (Non mathematical)

c. Conformational Analysis

i) Systematic search

ii) Monte Carlo simulations

iii) Molecular dynamics simulations

d. Ligand design based on 3D structure of receptor /enzyme

3. Antidiabetic and Antihypertensive Drugs - A modern approach
   Antihistaminics – Proton pump inhibitors

RECOMMENDED BOOKS

1. Hugo Kubingi - QSAR, Hansch Analysis and Related approaches Vol I

2. Poul Krogsgaand Larsen: A textbook of Drug Design and Development

First Edi.

3. Thomas J. Penim, C.L-Propst - Computer Aided Drug Design

4. Pandi Veerapandian - Structure Based Drug design

5. Paul S. Charifson - Practical Applications of Computer Aided Drug Design

(Marcel & Dekkar Inc. New York)

6. Paul Leff-Receptor Based Drug Design

7. Bernard Testa, Walter Fuh rer – Perspectives in-Medicinal Chemistry

8. C. Hansch Comprehensive Medicinal Chemistry Vol.-IV

Pharmaceutical Chemistry Lab:

Code : MPT-293
Contact : 4 hr per week
Credit : 3
Full marks 100

1. Application of partition coefficient, pKa, Stearic factor, electronic factor in QSAR studies with example. Use of statistical regressional analysis.
2. Microbial conversions for drug synthesis.
3. Resolution of racemic mixture.

Synthesis of compounds using 3/4 steps,

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. Peppler, “Microbial Technology” I & II.
5. Old & Primrose, “Genetic Manipulations”
6. I.P. 1996, Vol.-I & II

Advanced Pharmaceutical Chemistry-IV

Code : MPT-203(2)
Contact : 3L
Credits: 2
Full marks : 100

1. Agents for Diagnostic Imaging

Introduction, Biological effects of Radiation
Radionuclides and Radiopharmaceuticals for organ Imaging
Radionuclide Production
Technetium Radiochemistry
Fluorine Radiochemistry
Gallium Radiochemistry
Iodine Radiochemistry
Indium Radiochemistry

Thallium Radiochemistry
Xerox Radiochemistry
Radiologic Contrust agents
Paramagnetic compounds
Radiologic Procedures

2. Metabolic changes of Drugs and related organic compounds, Microsomal and non-microsomal mechanism; Role of C ytochrome P-450 Monoxygenases in Biotransformations, oxidative, reductive, hydrolytic reactions; classification of the CYP450 multigene family with examples of classes of compounds, biotransformed by each class.

   Induction and inhibition of cytochrome P450 isoforms with examples
   Drug conjugation pathways: Glucoronic acid, sulfate aminoacids, conjugations, glutathione conjugation and mercapturic acid synthesis, methylation, acetylation and cyanide conjugation.

3. Large-scale Synthesis :
   Introduction, scale-up : synthetic strategy, bench-scale, experimentation, scale-up from Bench to Pilot Plant, commercial-scale operations including validation, chemical safety in production, environmental controls. One case study as per example; Nevirapine or any other convenient synthesis.

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