MANAV BHARTI UNIVERSITY

SYLLABUS OF
M. PHARMA
(PHARMACOLOGY)
COURSE STRUCTURE
2009

MANAV BHARTI UNIVERSITY
SYLLABUS OF M.PHARMA (PHARMACOLOGY)

Semester I

No.	Subjects
1	Advanced Pharmaceutical Analysis
2	General Pharmacology
3.	Biopharmaceutics And Pharmacokinetics
4	Advanced Pharmacology
5	Clinical Pharmacology

Semester II

No.	Subjects
1	Advanced Pharmaceutical Analysis
2	Molecular Pharmacology
3.	Biopharmaceutics And Pharmacokinetics
4	Pharmaceutical Bio-Technology
5	Process Validation And Cgmp
6.	Practicals

Semester III & IV

Project and Dissertation work
Every student for the degree of Master of Pharmacy shall be required to undertake a project involing methodical research under the supervision of an guide and submit copies of thesis.

SEMESTER – I

PAPER-1

ADVANCED PHARMACEUTICAL ANALYSIS

1. ULTRAVIOLET AND VISIBLE SPECTROSCOPY :

Brief review of electromagnetic spectrum, UV-Visible range, Interaction of electro-magnetic radiation (UV-Vis) and matter and its effects, Chromophore and their interaction with EMR, Woodward-Fieser rule. Beer-Lambert's Law, Multicomponent analysis, derivative spectroscopy, spectral correlation with structure.

2. SPECTROFLUORIMETRY:

Fluorescence, Phosphorescence - Theory, instrumentation and applications.

3. INFRA-RED SPECTROSCOPY:

Nature of Infra-red radiation, Interaction of IR radiation with organic molecule and effects on bonds. Brief outline of IR instrument

tation and interpretation of spectra, including sample preparation for spectroscopy, Influence of substituents, ring size, hydrogen bonding, vibrational coupling and field effect on frequency, Quantitative methods, FT-NIR and applications, spectral interpretation with example.

4. RAMAN SPECTROSCOPY

Principle, instrumentation and applications.

5. LASER SPECTROSCOPY

Introduction, principle, instrumentation and applications.

6. RADIO IMMUNO ASSAY AND ELISA

Introduction, principle, instrumentation and applications

7. ELECTROPHORESIS

Principle, techniques, instrumentation including detection strategies and applications.

8. HYPHENATED TECHNIQUES

Introduction and applications.

PAPER 2

GENERAL PHARMACOLOGY

1. (a) Drug discovery process: Principles, Techniques and Strategies used in new drug discovery. Regulations for laboratory animal care and ethical requirements.

(b) Bioassays: Basic principles of bioassays, official bioassays, experimental models and statistical design employed in biological standardization. Bioassay of histamine, Insulin, Sexhormone, Oxytocin and acetylcholine.

2. 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.
3. Alternative to animal screening procedure. Models of study drug metabolism.
4. Adverse drug reactions and drug interactions. Principle of toxicity evaluation and determination of LD50, ED50, and TD50.
5. Basic mechanism of membrane transport, membrane transporters in therapeutic drug responses, membrane transporters and adverse drug responses

PAPER-3

BIOPHARMACEUTICS AND PHARMACOKINETICS

1. ABSORPTION OF DRUGS:
Definition, gastrointestinal absorption – Mechanism, Factors affecting drug absorption. Absorption of drugs from non-oral route.
2. DISTRIBUTION OF DRUGS:
Definition, Factors affecting drug distribution, Volume of distribution, Protein binding-factor affecting, significance and kinetics.
3. BIOTRANSFORMATION OF DRUGS:
Definition, Phase I and Phase II reactions and Factors affecting biotransformation.
4. EXCRETION OF DRUGS:
Definition, Renal and non- renal excretion, Concept of clearance- Organ clearance, Total clearance, Hepatic clearance and Renal clearance
5. NON LINEAR PHARMACOKINETICS
Cause of non-linearity, Michalis-Menten equation, Estimation of Km and Vmax.

PAPER- 4

ADVANCED PHARMACOLOGY

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-$\propto$). Identify the target for

immunosuppressive actions of the following drug agents such as Cyclosporine, Tacrolimus, Cortisteroids, Azathioprine, Methotrexate, Cyclophosphamide, Mycophenolate, CD3 antibodies including their mechanisms of action in imunosuppression.

4. Role of Prostaglandins, Bradykinins, Adhesion Molecules and NF κB in various immunological and inflammatory disorders.

5. Emerging concepts and newer therapeutic interventions with special reference to 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 antiangiogenic concept for the treatment of chronic diseases, Solid tumor and Cancer.

PAPER 5

CLINICAL PHARMACOLOGY

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.

SEMESTER – II

PAPER-1

ADVANCED PHARMACEUTICAL ANALYSIS

1. NUCLEAR MAGNETIC RESONANCE SPECTROSCOPY

Introduction of NMR, magnetic nuclear, chemical shift, shielding, relaxation process, chemical & magnetic non equivalence, local diamagnetic shielding and magnetic anisotropy, spin splitting, Pascal triangle, coupling constant, mechanism of coupling. Effect of stereochemistry on the spectrum, shift reagent, application of H^1NMR with some examples. C^{13} NMR introductions and its structural applications.

2. MASS SPECTROSCOPY

Introduction of mass, Essential components of a mass spectrometer, types of ions, molecular ion, fragment ion, rearrangement ion, metastable ion, Isotopic ions and their corresponding peaks, rules of fragmentation, Mc Lafferty rearrangement, Retro Diels Alder and other fragmentation patterns. Chemicals ionization mass spectroscopy (CIMS), field ionization mass spectroscopy (FIMS) , Fast atom bombardment mass spectroscopy (MFABMS). Introduction to LC-MS, GC-MS.

3. CHROMATOGRAPHIC TECHNIQUES

a) Classification of chromatographic methods based on mechanism of separation: paper chromatography, thin layer chromatography, ion exchange chromatography, column chromatography and affinity chromatography – techniques and applications.

b) Theory, Principal and applications of following chromatographic techniques – Gas Chromatography (GC), high performance liquid chromatography (HPLC), RP – HPLC, high performance thin layer chromatography (HPTLC)

PAPER-2

MOLECULAR PHARMACOLOGY

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, IP3, 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.
7. Free Radials Pharmacology : Generation of free radicals,Role of free radicals in etiopatholgy of various diseases, Protective activity of certain important antioxidants

PAPER-3

BIOPHARMACEUTICS AND PHARMACOKINETICS

1. PHARMACOKINETICS:
Basic considerations, Compartment modeling - one compartment open model, I.V. Bolus, I.V. Infusion, extra vascular administration, urinary excretion data. Two compartment model: I.V. bolus, I.V. infusion, extra vascular administration.
2. BIOAVAILABILITY AND BIOEQUIVALENCE STUDIES:
Definition, Objectives, measurement of bioavailabilty, Plasma level-time study, urinary excretion studies, in-vitro dissolution testing models, in-vitro in vivo correlation, Bio equivalence study and methods of enhancing bioavailablity of drug.

PAPER-4

PHARMACEUTICAL BIO-TECHNOLOGY

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..

PAPER-5

PROCESS VALIDATION AND CGMP

1. Basic concepts of quality assurance, Requirements of CGMP/GLP, ISO 9000 series, Qualityn 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

PHARMACEUTICAL ANALYSIS LAB

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.

PHARMACOLOGY LAB –I

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 Physostignine 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.

PHARMACOLOGY LAB –II

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.