## M. PHARM. – PHARMACOLOGY
### COURSE STRUCTURE (w. e. f. 2011-12)

### I SEMESTER

<table>
<thead>
<tr>
<th>Course No.</th>
<th>Title</th>
<th>L(h)</th>
<th>T(h)</th>
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<tr>
<td>MPS1101</td>
<td>Advanced Instrumental Analysis (AIA)</td>
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<td>MPS1131</td>
<td>Biological Standardization and Pharmacological Screening (BSPS)</td>
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### LAB

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<td>Preclinical Studies Lab</td>
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### BREADTH

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**Total Hours**

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### II SEMESTER

### THEORY

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### ELECTIVE(ANY ONE)

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<td>MPSE109</td>
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### LAB

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### III SEMESTER

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### IV SEMESTER

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**Total Credit - 75**

Note:
L: Lecture; T: Tutorial; P: Practical; C: Credit
MPS: M. Pharm. Pharmaceutical Sciences Core
MPSE: M. Pharm. Pharmaceutical Sciences ELECTIVE
MMA: Mathematics
MCR: M.S. Pharmaceutical Sciences Core

Department of Pharmaceutical Sciences, B.I.T. Mesra, Ranchi, 2011
M. PHARM – I SEMESTER

MPS1101 : ADVANCED INSTRUMENTAL ANALYSIS (AIA) (4 CREDITS)

2. Infrared Spectrophotometry: Qualitative uses; Interpretation of I.R. Spectra, Quantitative analysis. 6h
3. NMR-Spectroscopy: The NMR-Signal, Instrumentation practical consideration, chemical shift, spin-spin coupling, Structure elucidation, investigation of dynamic properties of molecules, quantitative analysis. 8h
4. Mass Spectrometry: Theory instrumentation, practical consideration, structure elucidation, detection of impurities, quantitative analysis. Application to determination of structure, the gas chromatograph mass spectrometer combination. 8h
5. Optical Rotatory Dispersion: Terminology Plain Curves, Rotatory dispersion of ketones, The Axial Haloketone Rule, Octant Rule. 3h
6. Recent trends in chromatography with reference to analysis of drugs and related substances: HPLC, UPLC, HPTLC, GC and hyphenated techniques (LC-MS/ LC-MS/MS). 8h
7. Theory, Instrumentation and Applications of: Thermogravimetric Analysis (TGA), Differential thermal analysis (DTA), Differential Scanning Calorimeter (DSC), X ray Diffraction(XRD). 8h

BOOKS RECOMMENDED:
1. Practical Pharmaceutical Chemistry (part II) by Beckett and Stenlake.
2. Optical Rotatory Dispersion by C. Djerassi (For ORD).
3. Indian Pharmaceutical (Biological & Microbiological Assay).
10. Application of NMR Spectra to Organic Chemistry-Jackmann.
11. Instrumental Methods of Analysis- Willard.
13. Pharmaceutical Experiments on isolated preparations by the staff of the Department of Pharmacology, University of Edinburg.
15. Lewis Pharmacology- James Crossland.
17. Indian Pharmacopoeia.
20. Assay of Vitamins by Haskmi
MPS1131: BIOLOGICAL STANDARDIZATION & PHARMACOLOGICAL SCREENING (3 CREDITS)

1. Laboratory Animals 7h.
   a. Commonly used laboratory, transgenic and other genetically prone animal models (viz. nude mice SH rats etc.)
   b. Techniques of blood collection, anesthesia & euthanasia of experiment animals.
   c. Maintenance & breeding of laboratory animals.
   d. Regulation and ethics requirements.
   e. Guidelines & regulatory agencies – CPCSEA, OECD, FDA ICH, FHSA, EPA, EEC, WHO, etc.
   f. Importance of alternative experimental models, its advantages & disadvantages.

2. Principles of Biological Standardization 4h.
   a. Methods of biological assay, principles of biological assays with certain examples as per IP and BP.
   b. Development of new bioassay methods.

3. Immunoassay 5h
   a. General principles of immunoassay, Theoretical basis, Optimization of immunoassay, Heterogenous immunoassay system, Homogenous immuno system.
   b. Production of immunoassay reagent: Introduction, receptors or binders, unlabelled ligands Calibrators, Labelled ligands and receptor, Separation technique, buffers.

4. Organization of screening for the Pharmacological activity of new substances with emphasis on evaluation using in-vivo, in-vitro, ex-vivo, in-situ, in silico and other possible animal alternative models. 18h.
   a. General Principles & safety pharmacology procedure.
   b. CVS Pharmacology – Antihypertensive, Anti arrhythmics, Vasodilators, disentail.
   c. CNS Pharmacology – behavioral & muscle co-ordination, CNS stimulants, anti-epileptics, Nootropics.
   d. Drugs for Neurodegenerative diseases, like parkinsonism, Alzheimers, multiple sclerosis.
   e. Drugs acting on ANS.
   f. Respiratory Pharmacology – Anti-asthmatics, COPD, Anti-allergic & Mucoactives.
   g. Reproductive Pharmacology – Aphrodisiacs & antifertility agents.
   h. Analgesics, anti-inflammatory & antipyretics.
   i. G.I.T. – Anti-ulcer, anti-emetics, anti-diarrhoeal & laxatives.
   j. Anti-cancer agents.
   k. Metabolic disorders like anti-diabetics, anti-hyperlipidemid, anti-obesity, hepatoprotective.
   l. Models in drug absorption & metabolism.
   m. Immuno Pharmacology – specific (cell & hormonal mediated) & non-specific methods.
   n. Screening of free radical scavenging activity.
   o. Acute, Sub-acute & Chronic toxicity test.

5. Clinical pharmacology and pharmacodynamics: clinical study design, documentation, presentation and interpretation 2h
6. Clinical trials: definition, phase I – IV studies, design documentation, presentation and interpretation, statistical analysis of clinical data, factorial design, guidelines as per Indian and other regulatory authorities. 5h
7. Importance of alternative experiment models, its advantages & disadvantages. 2h

BOOKS RECOMMENDED:

2. I.P. & B.P.
6. Selected topics on Experiment Pharmacology by Issha G. Kamat, Dadkar, N.K. & Seth, UK.
8. Pharmacological Experiment on intact preparation by Churchill Livingstone
11. Principles & Methods of Toxicology by Hays.
12. CRC Handbook of Toxicology by Derelako & Hollinger.
1. Molecular Pharmacology  
   a. The study of the molecular, biochemical, genetic and cellular mechanisms of action of drugs or endogenous signaling molecules.  
   b. Analysis of cellular signal transduction pathways for drugs and endogenous molecules.  
   c. Study of genetic variations in drug action and drug metabolism including cellular receptors, signal transduction proteins, cellular adhesion molecules, ion channels, drug abuse, second messenger molecules, metal toxicity, oxidant toxicity and drug metabolism.

2. Essential of Toxicology:  
   a. Physicochemical, Biochemical & genetic basis of toxicity, principles of toxicokinetics, mutagenesis & carcinogenesis.  
   b. Behavioural, Inhalation, Cellular & Sub cellular toxicity hypersensitivity, immune response, range finding test.  
   c. Acute, Sub-acute & Chronic toxicity test.

3. Molecular Mechanism of Toxicity:  
   Cellular dysfunction, Cell destruction, Cellular responses to injury  
   Switch points between cell survival and apoptosis or necrosis  
   Receptor mediated toxicity, Mechanism of cell death, calcium mediated toxicity, excitatory amino acid toxicity, NO toxicity and steroid hormone induced toxicity. Mechanism of chemical toxicity, Oxidative stress, Necrosis and significance of toxicity evaluation.

4. Toxic Response to foreign compounds  
   Direct toxic action: tissue lesions  
   Pharmacological, Physiological and biochemical effects  
   Teratogenesis  
   Immuno toxicity  
   Genotoxicity

5. Organ Toxicity  
   Liver toxicity  
   Kidney toxicity  
   Respiratory toxicity

6. Carcinogenicity of drugs  
   Benign & Malignant tumors and their classification  
   Mechanism of Carcinogenicity  
   Assessment of the potential Carcinogenicity of drug.

7. Pharmacovigilance

Reference:

1. Pharmaceutical Toxicology, edited by Gerard Mulder and Lennert Deanokr ULLA, Ph.P.


*Department of Pharmaceutical Sciences, B.I.T. Mesra, Ranchi, 2011*
3. Invitro Toxicity Testing.
5. General and Applied Toxicology by Bryan Ballantyne.
MPS1112 MODERN ANALYTICAL TECHNIQUES LAB (2 Credits)

1. Determination of $\lambda_{\text{max}}$. Of given sample using Spectrocolorimeter and validity of Lambert-Beer’s Law.
3. Assay of Quinine Sulphate using UV-Spectrophotometer.
5. Assay of Riboflavin Tablets using Fluorescence Spectrophotometer.
7. Determination of of Na$^+$ & K$^+$ using Flame Photometer.
10. Assay of Paracetamol in the sample using HPLC.
11. Demonstration of functional groups of the given samples I.R.Spectrophotometer.
12. Assay of Paracetamol in the sample using HPTLC.

MPS1132: PRECLINICAL STUDIES LAB (2 Credits)

1. Experimental Techniques to evaluate the various classes of drugs (in vivo studies) (at least 10-12 experiments).
   A. Drugs acting on GIT: - General screening methods of ulcer activity, intestinal motility, & anti-diarrhoeal
   C. Experiments on Analgesic & Antipyretic drugs.

Reference:

2. I.P. & B.P.
6. Selected topics on Experiment Pharmacology by Issha G. Kamat, Dadkar, N.K. & Seth, UK.
7. Fundamental of Experiment Pharmacology – M.N. Gl.
8. Pharmacological Experiment on intact preparation by Churchill Livingstone
9. Drug Discovery & Evaluation by Vogel HG.
11. Principles & Methods of Toxicology by Hays.
12. CRC Handbook of Toxicology by Derelako & Hollinger.
I. BIOPHARMACEUTICAL CONSIDERATIONS IN DRUG PRODUCT DESIGN

1. Factors Influencing Dosage Form Design:
   i) Rate-Limiting step in Drug Absorption
   ii) Biopharmaceutical Aspects
   iii) Patient Considerations
   iv) Manufacturing Considerations

2. Factors Influencing Drug Dissolution/Bioavailability:
   i) Physico-Chemical
   ii) Pharmaceutical, and
   iii) Formulation

3. Rate-Limiting Step in Bioavailability:
   i) Disintegration – in vitro, in -vivo
   ii) *in-vitro* Dissolution Testing
   iii) *in-vitro* Dissolution to *in-vivo* Absorption correlation including its failure.
   iv) Dissolution Testing in lieu of Bioavailability Studies.

II. BIOAVAILABILITY & BIOEQUIVALENCE

1. Definitions of Related Terms (*UG)
2. Purpose of Bioavailability Studies (* UG)
3. Relative & Absolute Bioavailability
4. Bioavailability Assessment
5. Bioequivalence Studies
   i) Design of Study  ii) Statistical Evaluation
6. Waiver of *in-vivo* Bioavailability & Bioequivalence
7. Ranking of Drugs and Several Formulations of the Drug

III. DRUG DISTRIBUTION & ELIMINATION

1. Physiological Factors Influencing Drug Distribution
2. Protein Binding
3. Volume of Distribution
4. Physiological Approach to Drug Elimination
5. Clearance Concepts
6. Dependence of Drug Elimination Kinetics on Clearance & Distribution

IV. PHARMACOKINETICS (based on Plasma & Urinary Excretion Data of Intact Drug)

1. Compartmental Approach:
   i) One Compartmental Model
   ii) Two Compartmental Model
2. Nonlinear (Dose Dependent) Pharmacokinetics:

i) Michaelis-Menten Concept
ii) Pharmacokinetics of Drugs under Such Situations
   (one compartment model – single dose):
   a) Intravenous Administration, and
   b) First-Order Absorption
iii) Time-Dependent Pharmacokinetics
iv) Nonlinear Pharmacokinetics due to Protein Binding
v) Pitfalls in Pharmacokinetic Modelling

BOOKS RECOMMENDED

MPS2131: CLINICAL PHARMACOLOGY & PHARMACOTHERAPEUTICS
(3 CREDITS)

Pathophysiology & applied Pharmacotherapeutic management of diseases associated with following system / diseases.

1. Nervous System 6 h
   Pain and Pain Management, Pathophysiology to inflammation and repair, Pain pathways,
   Anaesthesia and Neuromuscular block
   Epilepsy, Parkinsonism, schizophrenia, depression, migraine, Alzheimer’s disease

2. Cardiovascular System 9h
   Hypertension, Congestive cardiac failure, Ischemic heart disease (Angina, Myocardial infarction),
   Arrhythmias, Hyperlipidemias, atherosclerosis, Endocarditis, Thromboembolic disorder.
   Haemostasis, Anaemia, Blood Substituents, Drug induced haematological disorders.

3. Respiratory System 4 h
   Pulmonary function tests, bronchial asthma, Chronic obstructive airways diseases, Drug induced
   pulmonary diseases.

4. Renal & Endocrine System 11 h
   Diuretic therapy, Potassium depletion, Hyperkalaemia, Acute Renal failure, Chronic renal failure,
   Drug induced renal diseases.
   Adrenal corticoids, antagonists, Thyroid hormones & antithyroid drugs, Diabetes Mellitus, thyroid
   and parathyroid diseases, Hormone replacement therapy,

5. Gastrointestinal System 4 h
   Ulcer diseases, Inflammatory Bowel Diseases, Hepatitis, cirrhosis, Jaundice, Diarrhoeas &
   Constipation,

6. Bone and joint disorders 4 h
   Osteoporosis, rheumatoid arthritis, Osteoarthritis, gout, Paget’s diseases of bones. Geriatric,
   Paediatric & Perinatal Pharmacology.

7. Neoplastic disorders & infections 6h
   Acute leukemias, Hodgkins disease and carcinoma of breast etc.
   Various infectious diseases including Tuberculosis, urinary tract infections, enteric infections,
   upper respiratory tract infections, sexually transmitted diseases and AIDS.

References:

4. Davidson’s Principle and Practice of Medicine, Eds. Christopher R. W., Edwards & Ian A.D.
   and Aronson J., Oxford University Press
7. Principles of Pharmacology, the Pathophysiologic Basis of Drug Therapy, Lippincott, Williams & Wilkins.
8. CRC desk reference of Clinical Pharmacology, Manuchair Ebadi.
# MPS2133: ADVANCED PHARMACOLOGY (3 CREDITS)

1. **Emerging Trends & Recent Advances in:** 8 h  
   a. Receptor and G-protein  
   b. Cyclic nucleotides  
   c. Ion channel regulators  
   d. Gene therapy  

2. **Neurohormonal transmission in central and Automatic Nervous System**  
   Mechanism of Neurohormonal transmission in CNS and ANS, Adrenergic, Choline, dopaminergic  
   Serotoninergic, Histaminergic, GABAergic and excitatory amino acid receptors and their subtypes. 10 h  

3. **Autacoid Pharmacology** 10 h  
   Eicosanoids (Prostaglandins, leukotrienes, thromboxanes and related compounds) Nitric oxide oxygen free radicals, Role of Endothliam in vascular function, cytokines, opioid autacoids, Cox – 2 selective Inhibitors.  

4. **CVS function:** 5 h  
   Renin Angiotensin system, Applications in clinical cardiology  
   Current perspective in Lipid Lowering Strategies.  

5. **CNS Disorders** 5 h  
   Neuroprotective role of Melatonin  
   Parkinson’s and Alzheimer’s disease: current and future therapies.  

6. **G.I.T. Disorders** 2h  
   Treatment of GIT disease with melatonin.  

7. **Chemotherapy of Microbial disease** 4 h  
   Recent development of chemotherapy agents, Antiretroviral therapy for HIV infected Adults & Adolescents.  

References:  
3. Harrisons Principles of Internal Medicine. Medical Toxicology (Ellen Horns)  
5. Principles of Pharmacology, the Pathophysiologic Basis of Drug Therapy,Lippincott, Williams & Wilkins.  
MPS2141: CLINICAL RESEARCH – ETHICS & DESIGN (3 CREDITS)


2. Drug Development – Discovery, Screening, Formulation, Preclinical, Various Phases (Phase I to Phase IV) of Clinical Study, Clinical & Product Registration 3h

3. BA/BE Studies 1h

4. Investigational New Drug & New Drug Application 1h


6. Study Participants – Sponsor, Investigator, Volunteer, Contract Research Organization, Data Safety & Monitoring Board 3h


8. Study Setup – Feasibility assessment, Site selection, Budget proposal 2h

9. Study Monitoring – Monitoring Responsibilities: Type of monitoring visits, Site Initiation, Interim Monitoring, Site close out, monitoring activities, Monitoring methods, Problem solving, Writing monitoring reports 8h

10. Investigational Product Management – Accountability, Distribution 2h

11. Study Design & Planning – Design, Study Protocol, Case Report Form, Quality of Life, Study Plan, Study Flow Chart, Investigator Selection, Clinical Trial Application 5h

12. Organization – Contracts & Agreements, Liability & Insurance, Financial Disclosure, Clinical Trial Committees, Logistics & Clinical Laboratory 3h

13. Study Conduct – Essential Documents, Subject Recruitment, Randomization & Blinding, Investigational Product Management, Clinical Trial Supplies 3h

14. Safety Reporting – Adverse Events, Serious Adverse Events, Adverse Drug Reactions, Patient Care in Clinical Research, Pharmacovigilance 2h

15. Study Report – Interpretation, Report & Retention of data/report 2h

Books Recommended

1. Principal and practice of Pharmaceutical Medicine edited by Andrew j Fleteher, Lionel D Edwards, Anthony W Fox, Peter Stonier Published by John Wiley & sons Ltd.
1. Pharmacovigilance –
   i) Drug related problems in health care
      Types and mechanisms of ADRs, Risk factors for ADRs, Drug – drug interactions, Other causes
      of drug related problems, Drugs in pregnancy and lactation, Management of patients affected by
      ADRs, Medication errors 5h
   ii) Clinical manifestations of ADRs 5h
      Drug related diseases affecting different organ systems (Brief Overview since covered in Clinical
      Pharmacology)
   iii) Spontaneous reporting 5h
      Organization, Setting up and running a PhV centre, Patient reporting, Managing individual case
      report forms, Terminologies, Feed back to reporters, Case assessment, Signal analysis and follow
      up, Root cause analysis of medication errors
   iv) Epidemiological Methods 5h
      Drug utilization studies, Cohort event monitoring, Cohort studies,
      Case control studies, Longitudinal databases of patient records
   v) Collection and management of safety data during clinical trials: 5h
      Need for good quality safety information, Definition of good safety information, Differing
      regulations concerning safety data collection requirements, Designing a system to collect good
      quality information
   vi) Post-marketing drug safety: Differences in clinical and post-marketing drug safety 4h
   vii). Reporting to the Regulatory Authorities: 5h
      Individual case safety reports, Periodic safety update reports, Answering queries from regulatory
      authorities, Updating product labelling – emphasis on safety changes, Safety reporting
      requirements, Safety report sources, Follow up of safety reports, Electronic safety reporting –
      Oracle & other software program available, Safety file retentions
   viii) Global pharmacovigilance and safety standards 3h
      • Background and introduction to pharmacovigilance
      • The WHO and safety reporting
      • CIOMS – function and purpose
      • ICH – composition and guidelines
      • MedRA
   ix) Understanding signals and benefit-risk determinations 3h
      • Definition of a signal
      • Type of signal
      • Who should be involved in signal detection process?
      • Conducting signal detection in clinical and post-marketing surveillance
      • Defining the signal in relation to risk/benefit
      • Definitions of risk/benefit – FDA and EU perspective
      • Risk/benefit assessments – who does this and where does the information go?
• Safety assessments and risk/benefit – frequency and reporting
• Changes in risk/benefit – how to manage and review existing profile

x) Standard operating procedures (SOPs) in relation to pharmacovigilance 3h
• Types of SOPs required
• Production and sign off of SOPs
• SOP maintenance
• SOP training

xi) The role of the qualified person (QP) 3h
• Contract versus permanent.
• Essential attributes of the QP
• The duties of the QP
• What the QP must do
• Internal audits of the company pharmacovigilance activities

xii) Audit 3h
• Contracting out pharmacovigilance
• Preparation for a regulatory inspection
• Scope of the pharmacovigilance inspection
• Conduct of the pharmacovigilance inspection
• The pharmacovigilance inspection report
• When things go wrong
• Corrective actions following a pharmacovigilance inspection

Books
2. Pharmacovigilance from A to Z - Barton L. Cobert & Pierre Biron, Blackwell Science
3. Good Pharmacovigilance Practice – MHRA
6. An Introduction to Pharmacovigilance – Waller, Patrick; John Wiley & Sons
8. Pharmacovigilance from A to Z - Barton L. Cobert & Pierre Biron, Blackwell Science
9. Good Pharmacovigilance Practice – MHRA
12. An Introduction to Pharmacovigilance – Waller, Patrick; John Wiley & Sons
1. Introduction to Clinical Pharmacy.  
Clinical laboratory tests used in the evaluation of disease states, and interpretation of tests results.  
Haematological, Liver function, Renal function, Tests associated with Cardiac disorders, Fluid and  
electrolyte balance, Common test in urine, Sputum, faeces, CSF.  
Identifying the Pathogen and selection of appropriate microbial therapy.  
Drug interference with diagnostic tests, mechanism and interpretation.

2. Patient communication in Clinical Pharmacy Practice: The patient case history, its structure and  
use in evaluation of drug therapy.  

3. Prescription auditing and review.  
Drug Therapy Monitoring: Application to therapeutic drug monitoring (TDM) Pharmacist interventions  
(Interpretation of drug concentration data) of Theophylline, Gentamicin, Lithium, Carbamazapine,  
Phenobarbitone, Primidone, Valproic acid, Vigabatrin, Cyclosporin etc.

4. ADR and ADR monitoring, Management and reporting of drug interactions and adverse drug  
reactions.  

5. General Nutrition:  
General Nutrition guideline, Specific Nutritional considerations (Pregnancy, Diabetes Mellitus, patient  
with high blood pressure, Geriatric population, Obesity). Nutritional and their status in clinical medicine.

6. Drug information system: Introduction to information resources available, Drugs and Poisons  
Information, Design of literature searches. Development of a drug and poison information  

7. Pharmacoepidemiology, Pharmacovigilance, Pharmacoeconomics: Types of Health Economic  
Evaluations. Decision analysis Technique.

Wherever possible Discussion should be made with case studies.

REFERENCES:

R. Gourley ed.
3. Relevant Review articles from recent medical & pharmaceutical journals.
MPS2132: BIOCHEMICAL PHARMACOLOGY LAB (4 CREDITS)

1. Determination of LD$_{50}$ value.
2. Estimation of AST activity in serum.
5. Estimation of Glucose level in serum.
8. Estimation of Urea in urine.
15. Estimation of GSH levels.
17. Isolation of DNA from Blood
18. Estimation of Lactate dehydrogenase in serum

Reference:

2. I.P. & B.P.
6. Selected topics on Experiment Pharmacology by Issha G. Kamat, Dadkar, N.K. & Seth, UK.
7. Fundamental of Experiment Pharmacology – M.N. Gl.
8. Pharmacological Experiment on intact preparation by Churchill Livingstone
9. Drug Discovery & Evaluation by Vogel HG.
11. Principles & Methods of Toxicology by Hays.
12. CRC Handbook of Toxicology by Derelako & Hollinger.
Experiments on Isolated preparations

1. To calculate PA2 value of atropine using acetylcholine as an agonist employing rabbit intestine.
2. To calculate PA2 value of atropine using acetylcholine as an agonist employing guinea pig ileum.
3. To calculate PA2 value of d-tubocurarine using acetylcholine as an agonist employing frog rectus abdomens muscle.
4. To calculate PA2 value of diphenhydramine using histamine as an agonist employing guinea pig ileum / rabbit jejunum.
5. To calculate PA2 value of cyproheptadine using serotonin employing guinea pig ileum / rabbit jejunum.
6. To record the CRC of 5-HT using rat fundus strip preparation.
7. To record the CRC of noradrenaline using rat anococcygeus muscle preparation.
8. To record the CRC of acetylcholine and it's modification by using rat colon preparation.
9. To record the CRC of oxytocin using uterus preparation.
10. To record the concentration dependent contractile responses of phenylephrine on the isolated rat vas deference preparation.
11. To record the CRC of acetylcholine on the guinea pig tracheal chain.
12. To determine the strength of unknown solution of acetylcholine by 3-point / 4- point bioassay using rabbit intestine / guinea pig ileum. Calculate the test of significance.
13. To determine the strength of unknown solution of histamine by 3-point / 4-point assay method using rabbit intestine / guinea pig ileum. Calculate the test of significance.
14. To determine the strength of unknown solution of histamine by 3-point / 4-point assay method using rat uterus.

Cardiovascular System

15. To study the effect of drug on normal and hypodynamic frog heart.
16. To record the effect of acetylcholine and noradrenaline on the blood pressure and electrocardiography of an anaesthetized rats.

*Results should be expressed with statistical analysis.
M. PHARM III SEMESTER (15 CREDITS)

MPS3131: Thesis:
  • Thesis Seminar

M. PHARM IV SEMESTER (20 CREDITS)

MPS4131: Thesis:
  • Presentation, Submission and Viva-Voce
MMA1101: BIOSTATISTICS (3 Credits)

1. **Introduction:** 1h
   Relevance and the scope of Statistics.
   Difference between ‘Descriptive’ and ‘Inferential’ Statistics; Relationship between them

2. **Sampling Methods** 4h
   Introduction of sampling, probability and non probability sampling, sampling procedures – simple random, stratified, systematic, cluster and multistage sampling, concept of sampling distribution.

3. **Statistical Inference** 6h
   Statistical estimation – point and confidence interval estimations, Introduction of statistical hypothesis and testing, comparison of population mean with sample means, comparing two sample means, comparison of population proportion with sample proportions, comparing two sample proportions, comparison of more than two samples, introduction of non parametric statistical tests.

4. **Correlation and linear regression** 6h
   Introduction of correlation & regression concepts, estimation of correlation coefficient, regression coefficients, assumption of tests of hypothesis in linear regression, variance of sample estimates of the parameters, confidence intervals in regression analysis, non linear regressions, weighted and transformations in regression analysis, application of linear regressions - standard curves in drug analysis and drug stability studies, analysis of covariance.

5. **Concepts of Inferential Statistics** 4h
   Basics of Statistical Inference
   Sampling distribution
   Estimation – Point estimation, Interval estimation
   Parameter, Statistic, Concept of a hypothesis, Research Hypothesis, Null Hypothesis, Level of Significance, Comparison of means of two samples, Comparison of sample proportion with population proportion, Comparison of two sample proportions,
   Degrees of Freedom, Critical Value, Table value, Type I and Type II errors, Rules for rejection & acceptance of Null Hypothesis, Standard Error

6. **Inferential Statistics - Parametric Test:** 4h
   ‘t’ test – Comparison of sample mean with the population mean, Comparison of means of two independent samples, Comparison of two correlated samples
   ‘Z’ test – different applications
   Annova – one way annova: ‘F’ test

7. **Quality control:**
   Introduction, control charts, acceptance sampling and operating characteristic curves, statistical procedures in Assay.Department, establishing in-house limits, some statistical aspects of quality and the “Barr Decision”.

8. **Inferential Statistics - Non-parametric test:** 2h
Chi square test - Testing of goodness of fit, testing of independence, Test of homogeneity; Wilcoxon signed rank test; McNemar test

9. **Computer Applications & Practicals:**
   Introduction of statistical software – SPSS with practical exercises

**BOOKS RECOMMENDED:**


**Text Books**

1. Pharmaceutical Statistics
1. **Drug design** – Introduction, Definition, Rational,
   - Drug discovery & development, Definition, outline, achievements in the field of Pharmaceuticals & Medicinals.
   - Parameters involved in drug design, Physicochemical, Ionization, Hydrogen, bonding, Chelation, surface active agents Redoxpotential
   - Drug distribution: Oral, Systemic, Protein binding, Tissue depots.

2. **Receptors and drug receptor theories**-
   - Drug target binding forces – Electrostatic, Hydrophobic, Hydrogen bonding, Vanderwaals forces.
   - Drug receptor, interaction – Molecular biology of receptors – Protein coupled, Ion channel linked receptors, Nuclearreceptors, GPCR,.
   - Receptorial theories – Occupancy, theory, Rate theory, Induced fit theory, Macromolecular perturbation theory

3. **Isosterism & bioisosterism**-
   - Concepts of isosterism in drug design
   - Classical and non classical isosterism
   - Application of bioisosterism
   - Basic approaches in QSAR – Hansch equation, Free Wilson Model, Topliss Tree, Craig plot.

4. **Metabolite antagonism & drug design, Definition, Historical development**-
   - Wood fields antimetabolite theory
   - Mechanism based enzyme inhibition
   - Transition state analogs

5. **Concepts of drug discovery in Natural products** –
   - Natural Leads : its identification and optimization using CADD techniques with few case studies.

6. **Basic concepts of chemoinformatics** –
   - Introduction to chemoinformatics
   - Molecular file formats and their conversions: smiles, smirks & smarts
   - Database search: sub structure search and similarity search

7. **Basic concepts of ADMET** –
   - Introduction, General principles of ADMET & basic approaches in drug discovery & development.
BOOKS RECOMMENDED:

1. Manfred E. Wolff and Burger’s, Medicinal Chemistry and Drug Discovery- Vol.1, Principles and Practice, Vth Ed, John Wiely & Sons.
3. Progress in Medicinal Chemistry, Series by Ellis & Wert.
13. Chemistry of Alkaloids by S.W. Pelletier
15. Physiology by Dieter Hess.
17. Organic Chemistry by I.L. Finar Vol. II.
18. Chemistry of Natural Products by K.W. Bentley.

Journals.

1. Phytochemistry
2. Planta Medica
3. Phytotherapy Research, Fitoterapia etc.
4. Journal of Medicinal Chemistry
7. Drug Discovery today.