University School of Pharmaceutical Sciences

Study scheme and Syllabus
Batch 2014-16

Programme : Pharmaceutical sciences
Level : Postgraduate
Course : M.Pharm.
Specialization : Pharmacology
## Study Scheme for M.Pharm (Pharmacology)

### Semester: 1st

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Page 2 of 23
## Study Scheme for M.Pharm (Pharmacology)

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- Cumulative credit of 3rd and 4th semester
### M.Pharm (Pharmacology) I Semester Syllabus

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1. **Spectroscopic methods:**
   - Theory, Instrumentations, chemical applications and structural elucidation by UV, IR, $^1$H NMR, $^{13}$C NMR including DEPT, Mass Spectrometry, ESR and Emission spectroscopy.

2. **Separation techniques:**
   - Fundamental principles, theory, instrumentation and application of Gas-liquid chromatography, HPLC, Size Exclusion chromatography, GC-MS, LC-MS, UPLC, HPTLC, Ion Pair & Ion Exchange Chromatography and Supercritical Fluid Chromatography.

3. **Thermal Analysis:**
   - Theory, Instrumentations and applications of Thermogravimetric Analysis (TGA) and Differential Thermal Analysis (DTA).

4. **Calorimetric Analysis:**
   - Theory, Instrumentations, chemical applications and structural Elucidation, Differential Scanning Calorimetry (DSC), Isothermal titration Calorimetry (ITC)

5. **Powder X-ray Diffraction:**
   - Instrumentation and applications.

6. **Electron Microscopy:**

### Recommended Books

10. Introduction to Spectroscopy, 3rd edition, Pavia, Lampman, Kriz, Thomson Publisher.
14. Pharmacopoeia of India.
15. United State Pharmacopoeia
16. British Pharmacopoeia
M.Pharm (Pharmacology) I Semester Syllabus

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1. Principles of Experimental Pharmacology: Common laboratory animals in pharmacological research, limitations of animal tests, alternatives to animal use, anesthetics used in laboratory animals, some standard techniques used in laboratory animals, euthanasia of experimental animals. Care, handling and breeding techniques of laboratory animals. Regulations for laboratory animal care and ethical requirements. Regulations for the care and use of laboratory animals. Knowledge of CPCSEA Perfora for performing experiments on animals. Alternatives to animal studies.

2. Drug Discovery:
   Strategies and approaches employed in drug discovery. Basic concept of combinatorial chemistry, high throughput screening, cell lines, and their application in drug discovery. Transgenic animal models in the development of new drugs.

3. Organization of Preclinical screening programme and safety assessment tests.

4. Preclinical evaluation of following category of drugs:
   a. Sedatives, hypnotics, anxiolitics, antidepressants, antipsychotic, nootropics, antiparkinsonian agents, analgesics, antipyretics
   b. Anti-inflammatory agents, anticonvulsants, local anesthetics, CNS stimulants
   c. Cardiac glycosides, anti-arrhythmic, antihypertensives, anti-atherosclerotic
   d. Anti ulcer agents, laxatives
   e. Bronchodilators, antitussives
   f. Diuretics
   g. Histamine antagonists
   h. Muscle relaxants, Anticholinesterases, anticholinergics, adrenolytics.
   i. Hypoglycemic, anti fertility agents, androgens
   j. Anti-thyroid agents

5. In vitro testing of Drugs: Animal cell lines and their uses, limitations of in vitro testing of drugs.

6. Knowledge of Modern Methods of Pharmacological evaluations including radioligand binding assay, patch clamp, ELISA, and other sophisticated methods

RECOMMENDED BOOKS
M.Pharm (Pharmacology) I Semester Syllabus

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1. Drug Regulatory Affairs:
Harmonization of regulatory requirements including ICH activity. Regulatory requirements of different regions applicable to pharmaceutical developments, manufacturing, quality control on finished products, extended release products, biopharmaceutical and bioequivalence assessment and good clinical practices and Comparison with regulation in India. Filing of INDA, NDA and ANDA for approval and registration.

2. Stability Testing:
Role of stability testing, stability test guidelines. Protocol of stability testing including testing under different climatic zones and conditions. Conduct of stability testing. Presentation and recording of stability data, determination of shelf life. Stability test equipment and recent developments in this area.

3. Documentation:
Importance of documentation, statutory requirements and procedure for documentation, critical examination of documents.

4. GMP of Pharmaceuticals:
Current GMP in manufacturing, processing, packaging of drugs. GMP for finished products. General provision, organization and personnel, building and facilities, equipment, control of components and drug product, container and closures, production and process, packaging and labeling, laboratory and control of records and reports.

5. Intellectual property right (IPR):

6. Indian IP Case Studies: The Novaritis Case, Lipitor case, Natco vs Bayer case of compulsory license, Patenting Traditional Knowledge (neem, Basmati, Haldi patent), Patenting of life forms (Diamond vs Chakravartty case)


RECOMMENDED BOOKS
2. Good manufacturing practices for pharmaceuticals: A plan for total quality control from manufacturer to customer, 5th edition, revised and expanded by Sidney H. Willig, Marcel and Dekker.
3. CDSO publications and updates of drug and Cosmetics act and rules (Govt. of India).
4. CDER Publications and Guidance
5. EMEA Publications and Guidance
8. Pharmaceutical Product Dev. IVIVC by Murthy, Sunkara and David
9. USPTO and WIPO Guidelines.
10. Orange Book, ICH guidelines, Indian Patents Act
12. Govt. Publications on issues affecting sales, distribution, manufacturing, excise, etc
M.Pharm (Pharmacology) I Semester Syllabus

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Therapeutic drug monitoring (TDM): criterion for TDM, Clinical significance and its need on Patients associated with narrow therapeutic range of drugs.

Monitoring of drug therapy, patient compliance, principles of pediatric and geriatric pharmacology, drug therapy in pregnant and lactating mothers.

02. Pharmacotherapeutics, Management & Current Good Clinical Practice of following diseases:

- Cardiovascular disorders: Hypertension, congestive heart failure, angina pectoris, myocardial infarction and ischemia, cardiac arrhythmia, atherosclerosis, hyperlipidemia, peripheral vascular disorders and coagulation disorders.

- Gastrointestinal disorders: Peptic Ulcers, emesis, diarrhoea and constipation

- Renal diseases: Acute and chronic renal failure, renal dialysis and transplantation, Drug doses in renal impairment.

- Drug Therapy of Neurological Disorders: Pathophysiology and drug therapy of epilepsy, Parkinson's disease, migraine, and myasthenia gravis.

- Drug Therapy of Psychiatric Disorders: Pathophysiology and drug therapy of anxiety, schizophrenia, Alzheimer’s disease, mood and sleep disorders.

- Drug Therapy of Endocrine Disorders: Pathophysiology and drug therapy of diabetes mellitus, contraception, and infertility.

- Drug Therapy of Metabolic and Sexual Disorders: Pathophysiology and drug therapy of obesity and erectile dysfunction

- Autoimmune and metabolic disorders: Rheumatoid arthritis, Osteoarthritis, gout and hyperuricemia, Diabetes mellitus (DM).

- Respiratory diseases: Asthma, chronic obstructive pulmonary edema. Pulmonary embolism.


- Neoplastic disorders: General principles of cancer chemotherapy, monoclonal antibodies.

- Immunotheraphy: Immunostimulant, Immunomodulators and Immunosuppressant.

- Chemotherapy of Infectuous Diseases: mechanism of antibiotic resistance, antifungal and antiprotozoal, helminthiasis, tuberculosis, Malaria, leprosy, AIDS.

03. Drug interaction and rational for drug combinations: Various mechanisms of drug interaction, drug-food interaction and drug - drug interaction

04. Drug Toxicity and its prevention: Principles of toxicology, abnormal action of drugs such as tolerance, addiction, habituation, idiosyncracy, allergy, hypersensitivity, antagonism, synergism, potentiation, tachyphylaxis. Adverse drug reactions and its monitoring.

05. Novel Target Sites for drug action: Physiological functions, pharmacological implications and therapeutic potential of the following target sites: Poly (ADP-ribose) polymerase (PARP) Caspases Peroxisome proliferator activator receptors (PPAR)- α and γAMP activated protein kinases Protein kinases Phosphodiesterases
RECOMMENDED BOOKS:
6. Davidson’s Principle of Internal Medicine, Mc Graw-Hill companies.
7. Herfindal ET and Gourley DR. Text Book of Therapeutics: Drug and Disease management. Lippincott Williams & Wilkins, USA.
9. Katzung BG. Basic and Clinical Pharmacology, Lange Medical Publisher, USA.
# M.Pharm (Pharmacology) I Semester Syllabus

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1. **Principles of Experimental Pharmacology:**
   a) Common laboratory animals in pharmacological research
   b) Alternatives to animal use
   c) Anesthetics used in laboratory animals
   d) Some standard techniques used in laboratory animals
   e) Methods for euthanasia, dosing (i.v., oral, i.p., s.c., i.m.) and blood collection by various techniques, IAEC-CPCSEA Form B, Procedure & maintenance of records as per CPCSEA Guidelines.
   f) 6. Computer simulation of following animal experiments through softwares such as X-pharma and X-cology
   g) 7. Study of Animal Behavior, Normal physiology and biochemical parameters of laboratory animals, maintaining records of animal food & water intake.

2. Experiments to study pharmacology of receptors (competitive and non-competitive antagonists)

3. Experiments to calculate pA2 using isolated, vas deferens, uterus of rat, rat colon, and rat fundus preparations.

4. **Experiments in intact animals to evaluate following therapeutics agents using appropriate animal model:**
   a) Local anesthetics
   b) Mydriatics and miotics
   c) Analgesics
   d) Anti-inflammatory agents,
   e) Hypnotics,
   f) Antianxiety agents,
   g) Antiepileptic agents,
   h) Antidepressants,
   i) Antipsychotics,
   j) Antiparkinsonian agents,
   k) Nootropics, and
   l) Antiulcer agents

## RECOMMENDED BOOKS

M.Pharm (Pharmacology) I Semester Syllabus

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1. Combination Drug Analysis (Any Five)

2. Illustrations of theoretical principles using assay of drugs official in various pharmacopoeias (Any 10). This should cover titrimetric, spectrophotometric (including flame photometric) methods, HPLC etc. The titrimetric methods should include argentometric, conductometric, and potentiometric end-point determination.

The students should be exposed to handling of as many instruments as possible by themselves or under the guidance of a teacher.

3. Interpretation of UV, IR, NMR spectra of some unknown intermediates and drugs. (Any two)

RECOMMENDED BOOKS
Same as Given in PS6101
M.Pharm (Pharmacology) II Semester Syllabus

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1. Molecular mechanism of drug action: Receptor occupancy and cellular signaling systems such as G-proteins, cyclic nucleotides, calcium and calcium binding proteins, phosphatidylinositol. Ion channels and their modulators.
2. Endogenous bioactive molecules: Cytokines, neuropeptides and their modulators, neurosteroids, nitric oxide, phosphodiesterase enzyme and protein kinase C, arachidonic acid metabolites, COX-2 regulators and their role in inflammation, endothelium derived vascular substances (NO, endothelins) and their modulators. Pharmacology of atrial peptides, reactive oxygen intermediates, antioxidants and their therapeutic implications.
3. Recent trends on different classes of receptors and drugs acting on them:
   a. Angiotensin receptors
   b. Excitatory amino acid receptors
   c. Kinin receptors
   d. Adrenoceptors
   e. Low molecular weight heparins, hirudins and GP II/IIIa receptor antagonists
   f. Cholinergic receptors
   g. Dopamine receptors
   h. Serotonin receptors
   i. Hormone receptors
   j. GABA and Benzodiazepine receptors
   k. Opiod receptors
   l. Purinergic receptors
   m. Glutamate receptors

4. Ion channel and their modulators: calcium, potassium, sodium and chloride channels
5. Apoptosis: Basic functions, mechanisms and role of caspases, Pharmacological and clinical implications
6. Cardiac and vascular remodeling
7. Basic Concepts of Chronopharmacology and their implications to Drug Therapy.
10. Techniques for the study of Molecular Pharmacology: Western Blotting, Immunostaining, RT-PCR,

**Recommended Books:**
1. Katzung, B.G; Basic and Clinical Pharmacology, Lange Medical Publisher, USA
7. Grollman Pharmacology and Therapeutics, Lea and Tebiger, Philadelphia
8. Bacq Z.M., Cepek, Fundamentals of Biochemical Pharmacology
10. Goodman and Gilman; Pharmacological Basis of Therapeutics, Mc Graw Hill
M.Pharm (Pharmacology) II Semester Syllabus

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1. Definition and scope of safety pharmacology
2. Regulatory requirements for the new drug safety assessment: Important guidelines such as ICH, OECD, USFDA, EMEA, Japan MHFW
3. Principals and study design of safety evaluation: Repeated dose studies (sub acute and chronic), Analysis of safety pharmacological data
4. Preclinical safety pharmacology: In vitro and in vivo studies including genotoxicity, mutagenicity, carcinogenicity, reproductive and ocular toxicity, Safety testing for dermatological product
5. Clinical Safety pharmacology: Definition, data collection, reporting methods and assessment and analysis of adverse event (AE) monitoring during clinical trials
7. Pharmacovigilance: Definition, scope and aims of pharmacovigilance, Adverse drug reactions-Classification, mechanism, predisposing factors and causality assessment, Role of clinical pharmacist in reporting, evaluation, monitoring, prevention and management of ADRs. collection of data, reporting, assessment of Post marketing surveillance, periodic safety update reports,

Recommended Books:
## M.Pharm (Pharmacology) II Semester Syllabus

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1. **Introduction to clinical Trial:** History, terminologies, types of clinical research, phases of clinical research, role of clinical trial in new drug developments. Clinical Research Organizations in India and Schedule “Y” as per D&C Rules
2. **Regularly affairs in clinical trials:** IND, NDA, ANDA- Parts and contents, Safety monitory boards, FDA in various countries including India
3. **Ethical issues in clinical trials:** Principal, responsible conduct, supervision of ethics, (Informed Consent, Institutional Review Board (Role responsibility, members and auditing), Protection of participants, The Nuremberg Code, The Declaration of Helsinki, The Belmont Report
4. **Clinical trial design:** Designs used in clinical trials with their advantages and disadvantages, hypothesis, risks and benefits, subject selection, inclusion and exclusion criteria, randomization, blinding and controls
5. **Clinical trial protocol Development:** Required Documentation including Investigator's Brochure, Case Report Forms, Serious Adverse Event (SAE) Reports, Laboratory Certification, data collection and quality control of data, closing out of clinical trial
6. **Good Clinical Practice:** Concept, importance, and GCP guidelines including ICH guidelines
7. **Management of Clinical trials:** Role and responsibilities of Stakeholders of clinical trials (FDA, CRO, Sponsor, Physicians, Nurses, Health professionals, Hospitals, Patient), monitoring of clinical trials, Publications of clinical trials
8. **Bioavailability, bioequivalence and Therapeutic Drug Monitoring:** Concept, organization, advantages, special issues, applications, bioequivalence.
9. **Data analysis issues in Clinical Trials:** Monitoring of data, computer applications, statistical tests used, interpretation, survival analysis, sub-group analysis, Quality control of clinical trials

### Recommended Books:
1. Dipiro, Joseph L.; Pharmacotherapy: A Pathophysiologica
4. Roger and Walker; Clinical Pharmacy and Therapeutics, Churchill, Livingston, London
5. Herfindal, E.T. and Hirschman, J L.; Clinical Pharmacy and Therapeutics
2. Pharmacology of the Autonomic Nervous System: Physiology of autonomic nervous system, Muscarinic receptor agonists and antagonists, Anticholinesterase agents, Agents acting at neuromuscular junction and autonomic ganglia, Adrenergic agonists and antagonists, 5-Hydroxytryptamine receptor agonists and antagonists
3. Pharmacology of Autacoids: Histamine, bradykinin, and their antagonists, Lipid derived autacoids: Eicosanoids and platelet activating factor
4. Drugs Acting on the Central Nervous System: Neurotransmission in central nervous system, General anesthetics, Local anesthetics, Hypnotics and sedatives, Opioid analgesics, Pharmacology of ethanol, Drug addiction and drug abuse, Analgesic, Antipyretic, and Anti-inflammatory Agents
5. Drugs Affecting Renal and Cardiovascular Function: Diuretics, Vasopressin and other agents affecting the renal conservation of water, Renin, angiotensin, and their modulators, Calcium channel blockers
6. Pharmacology of Chemotherapeutic and Antimicrobial Agents: General considerations of antimicrobial therapy, Sulfonamides, trimethoprim, quinolones, other related agents, Penicillins, cephalosporins, and other beta-lactam antibiotics, Aminoglycosides, Protein synthesis inhibitors and miscellaneous antibacterial agents, Antifungal agents, Antiviral agents (Non-retroviral), Antineoplastic Agents.
7. Hormones and Their Antagonists: Pituitary hormones and their hypothalamic releasing factors, Thyroid and antithyroid drugs, Estrogens and progestins, Androgens, Adrenocortical steroids and their synthetic analogs, inhibitors of synthesis and actions of adrenocortical hormones, Agents affecting mineral ion homeostasis and bone turnover
8. Drugs Acting on the Blood and Blood-Forming Organs: Hematopoietic agents: Growth factors, minerals, and vitamins, Blood coagulation and anticoagulant, thromboiytic, and antiplatelet drugs,
9. Pharmacology of Dermatological Agents
10. Ocular Pharmacology
11. Immunosuppressants, Tolerogens, and Immunostimulants

Recommended Books
4. Ion channel and their modulators: calcium, potassium, sodium and chloride channels.
5. Apoptosis: basic functions, mechanisms and role of caspases, pharmacological and clinical implications
6. Adhesion therapy and cardiac and vascular remodelling.
7. Basic Concepts of Chronopharmacology and their implications to Drug Therapy.
A. Research Methodology
1. Research:
Meaning and objective of research, types of research (basic, applied and patent oriented research), selecting a problem & preparing a research proposal for different types of research as mentioned above.

2. Literature survey and documentation:
Methods of Literature survey, Use of library, books, journals, e journals, thesis, chemical abstracts and patent data base, techniques of documentation, importance of documentation, uses of computer packages in documentation.

3. Technical writing:
Self study & Practice: Research report, paper, thesis writing [Title, abstract, key words, methodology, results, discussion, conclusion, acknowledgement, references, errata, foot notest], types of research paper [review article, research papers and short communications and meeting report], detailed study of ‘Instruction to Authors’ of IJPS journal, a thorough understanding of steps involved in submitting articles electronically to IJPS [registration, new article submission, tracking the process, submitting revised articles]. Impact factor, Rating, Indexing and citation etc.

4. Presentation:
Importance, types different skills, contained, format of model, introduction & ending, posture, gestures, eye contact, facial expressions, stage, fright, volume, pitch, speed, pause & language, visual aids & seating, questionnaire.

5. Project [cost] management :
Cost analysis of the project- cost incurred on raw materials, procedure, instrumentations & clinical trials.

6. Research organizations and procurement of research grants:
Introduction to various research organization (DST, DBT, AICTE, UGC, CSIR, DRDO, ICMR) along with their function in India, sources for procurement of research grants.

B. Biostatistics
1. Basic Definitions and Concepts:
Variables and variation [continuous variables and discrete variables], sample and population [population parameters and sample statistics, random sampling], precision, accuracy and bias; significant figures.

2. Experimental design:
Meaning, need, features, basic principle and important concepts of experimental design different types of research designs [before-and-after without control design, after-only with control design, before-and-after with control design, completely randomized design, randomized block design, latin square design, factorial design], crossover design and bioavailability / bioequivalence studies.
3. Descriptive Data Analysis:
What is statistics?, parametric and non-parametric data, descriptive and inferential analysis, the organization of data (grouped data distributions), statistical measures (measures of central tendency & measures of spread or dispersion), normal distribution (normal & non-normal distribution, interpreting the normal probability distribution, practical applications of the normal curve), measures of relative position (standard scores: the Z score, the T score, the percentile rank), measures of relationship [pearson’s product-moment coefficient of correlation (r), rank order correlation (ρ), phi correlation coefficient (ϕ)], interpretation of a correlation coefficient [outliers, misinterpretation of the coefficient of correlation, prediction], standard error of estimate. Application of linear regression and correlation to analysis of standard curves and drug analysis.

4. Inferential Data Analysis:
Statistical inference, the central limit theorem, parametric tests, testing statistical significance [the significance of the difference between the means of two independent groups, the null hypothesis (H0), the level of significance], decision making [two tailed and one tailed tests of significance, degrees of freedom], a one sample Z test, student’s distribution (t) [significance of the difference between two small sample independent means], homogeneity of variance [significance of the difference between the means of two matched of correlated groups (non-independent samples), statistical significance of coefficient of correlation], one way and two way analysis of variance (ANOVA), multiple regression and correlation, nonparametric tests [the chi square test (X²), the mann-whitney test], outliers and missing data, multiple comparisons [Bonferroni t-test, Student newman keuls, tukey test, dunnets test, dunn’s test].
Comparison of dissolution various tablet formulations by two way ANOVA, comparison of three drug treatments at three sites by two way ANOVA.

Recommended Books:
1. Research In Education- John V. Best, John V. Kahn 10th edition
2. Presentation skills - Michael Hallon- Indian Society for Institute education
5. Writing a technical paper- Donald Menzel
6. Protection of industrial Property rights- P. Das & Gokul Das
7. Preparation for publication – King Edward Hospital Fund for London
9. Manual for the preparation of industrial feasibility studies
12. Research in Education by john W. Best and James V. Kahn, 11th edition
13. Instruction to Authors of journals.
M.Pharm (Pharmacology) II Semester Syllabus

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**Suggested Practicals Based on Core-II and Core-II offered in II semester**

1. Bio assays of Ach, Histamine, Oxytocin, Adrenaline
2. Monitoring of any one marketed drug in biological fluids
3. Determination of pA2 values of any one antagonist.
4. Evaluation of antidepressant agents
5. Effect of various pharmacological agents on heart rate, coronary flow rate, and force of contraction on isolated mammalian heart.
6. Exercises to calculate pharmacokinetic parameters, bioavailability and bioequivalence using serum/plasma and urine excretion data.
7. Calculation of LD50, therapeutic index and experiments related to toxicity.
8. Study and analysis of clinical problems including case history and drug therapy, pharmacovigilance studies, exercises on effective pharmacist-patient communication.
11. Any other relevant practical

**Books Recommended**

As given in PY6201 and PY6202