ACADEMIC REGULATIONS,
COURSE STRUCTURE
AND DETAILED SYLLABUS

M – PHARMACY (PHARMACOLOGY)

FOR
M.PHARMACY TWO YEAR PG COURSE
(Applicable for the batches admitted from 2014-2015)

SCHOOL OF PHARMACY
ANURAG GROUP OF INSTITUTIONS
(AUTONOMOUS)
Venkatapur, Ghatkesar, Hyderabad – 500088

Academic Regulations - for M. Pharm (Regular)
(Effective for the students admitted into I year from the Academic Year 2014-2015 onwards)
### M. Pharm. (Pharmacology)
#### Course Structure and Syllabus

**I Year I Semester**

<table>
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**I Year II Semester**

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**II Year - I Semester**

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**II Year - II Semester**

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Objective: The course is designed to impart the knowledge in the field of Pharmaceutical Analysis. The various modern analytical techniques like UV-Visible, IR, NMR, Mass, GC, HPLC, different chromatographic methods and other important topics are taught to enable the students to understand and apply the principles involved in the determination of different bulk drugs and their formulation. In addition to the theoretical aspects, the basic practical knowledge relevant to the analysis is also imparted.

UNIT I
Introduction to chromatography and classification of chromatographic methods based on the mechanism of separation:
- Column Chromatography: Adsorption and partition, theory, preparation, procedure and methods of detection
- Thin Layer Chromatography: Theory, preparation, procedures, detection of compounds
- Paper Chromatography: Theory, different techniques employed, filter papers used, qualitative and quantitative detection
- Counter – current extraction, solid phase extraction techniques, gel filtration

UNIT II
b. HPLC: Principles and instrumentation, solvents and columns used, detection and applications
c. HPTLC: Theory and principle, instrumentation, elution techniques and pharmaceutical applications

UNIT III
a. UV-Visible spectroscopy: Introduction, electromagnetic spectrum, absorbance laws and limitations, instrumentation-design and working principle, chromophore concept, auxochromes, Wood-Fisher rules for calculating absorption maximum, applications of UV-Visible spectroscopy
b. IR spectroscopy: Basic principles-Molecular vibrations, vibrational frequency, factors influencing vibrational frequencies, sampling techniques, instrumentation, interpretation of spectra, FT-IR, theory and applications

UNIT IV
Mass spectroscopy: Theory, ionization techniques: electron impact ionization, chemical ionization, field ionization, fast atom bombardment, plasma desorption, fragmentation process: types of fission, resolution, GC/MS, interpretation of spectra and applications for identification and structure determination

UNIT V
NMR: Theory, instrumentation, chemical shift, shielding and deshielding effects, splitting of signals, spin-spin coupling, proton exchange reactions, coupling constant(J), nuclear overhauser effect(NOE), $^{13}$C NMR spectra and its applications, 2D-NMR, COSY and applications in pharmacy

Outcome: The appreciable knowledge will be gained by the students in the Modern Analytical Techniques and can apply the theories in the Analysis of various bulk drugs and their formulations. The students will also be in a position to apply their knowledge in developing the new methods for the determination and validate the procedures.

References:
1) Instrumental Methods of Chemical Analysis by B.K Sharma
2) Organic spectroscopy by Y.R Sharma
3) A Text book of Pharmaceutical Analysis by Kerrenth A. Connors
4) Vogel’s Text book of Quantitative Chemical Analysis by A.I. Vogel
5) Practical Pharmaceutical Chemistry by A.H. Beckett and J.B. Stenlake
6) Organic Chemistry by I. L. Finar
7) Organic spectroscopy by William Kemp
8) Quantitative Analysis of Drugs by D. C. Garrett
9) Quantitative Analysis of Drugs in Pharmaceutical Formulations by P. D. Sethi
10) Spectrophotometric identification of Organic Compounds by Silverstein
11) HPTLC by P.D. Seth
12) Indian Pharmacopoeia 2007
13) High Performance thin layer chromatography for the analysis of medicinal plants by Eike Reich, Anne Schibli
14) Introduction to instrumental analysis by Robert. D. Braun
I Year – I Sem M.Pharm (Pharmacology)

(A41002) ADVANCED BIOSTATISTICS AND RESEARCH METHODS

Objective: The student shall know the introduction, scope of biostatistics and Research work, calculation and present of all data. It also informs the students, how the present research work writing and correlating.

UNIT I

UNIT II
Measures of central tendency: computation of means, median and mode from grouped and ungrouped data. Measure of dispersion: computation of variance, standard deviation, standard error and their coefficients.

UNIT III

UNIT IV
Developing a research question, Resources for research question, Literature Review: Traditional Qualitative Review, Meta-Analysis—A Quantitative Review Preparation of Research Proposal Variables—Definition of Variable, Types of variables (Dependent and Independent variables, Confounded variables), Measurement of variables, Types of measurement scales and their comparison. Reliability and Validity of Measurements.

UNIT V

Outcome: The student will be known the Biostatistics arrangement, presentation and formation of tables and charts. They also know the correlation and regression & application of different methods, analysis of data and also learn how to write dissertation, thesis and Research paper.

Text Books
1. Deepak Chawla Neena Sondhi, Research Methodology Concepts and Cases, Vikas books publishers
2. Donald H. McBurney -Theresa L. White “Research Methods” (Cengage learning India Pvt. Ltd)
**Reference Books**

1. Remington’s Pharmaceutical Sciences
2. Theory & Practice of Industrial Pharmacy by Lachman
3. Statistics for business and economics 3rd edition by Vikas books publications
4. Biostatistics & Computer applications by GN Rao and NK Tiwari
10. Research Methodology by RK Khanna bis and Suvasis Saha
11. Research methods and Quantity methods by G.N.Rao
Objective: This subject will provide an opportunity for the student to learn about the drug with regard to classification, pharmacodynamic and pharmacokinetic aspects, adverse effects, uses, dose, route of administration, precautions, contraindications and interaction with other drugs. In this subject, apart from general pharmacology, drugs acting on autonomic nervous system, cardiovascular system, central nervous system, blood and blood forming agents and renal system will be taught. In addition to theoretical knowledge, the basic practical knowledge relevant to therapeutics will be imparted.

UNIT I
Drugs acting at Synaptic and neuro effector junctional sites.
a. Autonomic & Somatic nervous systems.
b. Muscarinic receptor agonists & antagonists.
c. Anticholinesterases.
d. Agents acting at Neuro Muscular Junction and autonomic ganglia.
e. Sympathomimetic drugs, Catecholamines and Adrenergic antagonists.

UNIT II
Drugs acting on the Central Nervous System.
a. Neurotransmission and CNS.
b. Drugs used in the treatment of
   1. Anxiety & Psychosis
   2. Depression & Mania
   3. Epilepsy
   4. Migraine
   5. CNS degenerative disorders
   6. Parkinson’s Disease
   7. Pain
   c. Drug addiction, dependence and abuse.

UNIT III
Drugs affecting renal and cardiovascular function.
a. Diuretics
b. Drugs used in the treatment of
   1. Myocardial Ischemia
   2. Hypertension
   3. CHF
   4. Hyperlipidemia
   5. Arrhythmias

UNIT IV
Drugs acting on the blood & blood forming organs.
a. Hemopoietics & plasma expanders
b. Anticoagulants, Thrombolytics & antiplatelet drugs.

UNIT V
Dermatological pharmacology, Vitamins & Chelating agents

Outcome: Upon completion of the subject student shall be able to (Know, do, appreciate) –
a. understand the pharmacological aspects of drugs falling under the above mentioned chapters;
b. handle and carry out the animal experiments;
c. appreciate the importance of pharmacology subject as a basis of therapeutics; and
d. correlate and apply the knowledge therapeutically.
I Year – I Sem M.Pharm (Pharmacology)

(A41004) PHARMACOKINETICS AND DRUG METABOLISM

Objective: In current methods of treatment which involves individualization of drug therapy, the student should have sound knowledge in pharmacokinetics and the effects of changes in pharmacokinetic parameters on therapeutic efficacy of the drugs.

UNIT I


UNIT II


UNIT III

Elimination of drugs: Concept of renal clearance and excretion of drugs – biological half – life, area under curve.

UNIT IV


UNIT V

Pharmacogenetics: Inter racial and individual variability in drug metabolism.

Outcome: Upon completion of the subject student shall be able to (Know, do, appreciate) –
   a. understand various pharmacokinetic parameters
   b. influence of these parameters on efficacy of drugs
   c. identify and resolve drug related problems;
   d. pharmacogenetics
OBJECTIVE: This course is designed to impart knowledge and skills necessary for contribution to quality use of medicines. Chapters dealt cover briefly pathophysiology and mostly therapeutics of various diseases. This will enable the student to understand the pathophysiology of common diseases and their management.

UNIT I
Principles of Pharmacokinetics
a. Revision of basic concepts.
b. Clinical Pharmacokinetics.
   i) Dose – response in man
   ii) Influence of renal and hepatic disease on Pharmacokinetics
   iii) Therapeutics drug monitoring & individualization of drug therapy
   iv) Population Pharmacokinetics.

UNIT II
Adverse Drug Reactions, Drug Interactions, ADR monitoring & Pharmacovigilance.

UNIT III
Pathophysiology and drug therapy of the following disorders.
Schizophrenia, anxiety, depression, epilepsy, Parkinson’s, alzheimer’s diseases, migraine, hypertension, angina pectoris, arrhythmias, atherosclerosis, myocardial infarction.

UNIT IV
Pathophysiology and drug therapy of the following disorders.
TB, leprosy, leukemia, solid tumors, lymphomas, psoriasis, respiratory, urinary, g.i. tract infections, endocarditis, fungal and HIV infection, rheumatoid arthritis, glaucoma, menstrual disorders, menopause.

UNIT V
Drug therapy in
   a. Geriatrics
   b. Pediatrics
   c. Pregnancy & Lactation.
   d. Renal & hepatic insufficiency.

OUTCOME: At completion of this subject it is expected that students will be able to understand –
   a) the pathophysiology of selected disease states and the rationale for drug therapy;
   b) the controversies in drug therapy;
   c) the importance of preparation of individualised therapeutic plans based on diagnosis;
   d) needs to identify the patient-specific parameters relevant in initiating drug therapy, and monitoring therapy (including alternatives, time-course of clinical and laboratory indices of therapeutic response and adverse effects);
   e) summarise the therapeutic approach to management of these diseases including reference to the latest available evidence;
   f) therapy (including alternatives, time-course of clinical and laboratory indices of therapeutic response and adverse effects).
   g) Pathophysiology and applied Pharmacotherapeutics of diseases associated with following system/diseases with of special reference to the drug of choice.
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I Year – I Sem M.Pharm (Pharmacology)

(A41201) MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES LAB

List of experiments

1. Colorimetry / UV / Visible, Spectroscopy, scanning of few compounds for UV-absorption, calculation of Assay / content uniformity / % of drug release (2-3 experiments.)
2. Estimation of multi components formulation by UV of two different methods.
3. Experiment base on HPLC (Isocratic and gradient) Techniques – (2 experiments)
4. Incompatibility studies, identification and functional groups – Determination by FTIR (2 experiments)
5. Separation and calculation of Rf values by using paper chromatography, TLC, HPTLC Technique (2-3 experiments)
6. Interpretation of spectra and structure determination of Mass Spectroscopy
7. Separation of protein drug substances by electrophoresis.
8. Workshop on IR and NMR interpretation
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I Year – I Sem M.Pharm (Pharmacology)

(A41202) ADVANCED PHARMACOLOGY - I LAB

List of experiments

2. Study of use of anesthetics in laboratory animals.
3. To record the dose response curve of Ach using isolated ileum/rectus abdominis muscle preparation.
4. To carry out bioassay of Ach using isolated ileum/rectus abdominis muscle preparation by interpolation method.
5. To carry out bioassay of Ach using isolated ileum/rectus abdominis muscle preparation by three point method.
6. To carry out bioassay of Ach using isolated ileum/rectus abdominis muscle preparation by four point method.
7. Estimation of pA₂ value on isolated tissues
8. Bioassay of 5-HT using rat fundus strip
9. Bioassay of oxytocin using rat uterus
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I Year – II Sem M.Pharm (Pharmacology)

(A42001) INTELLECTUAL PROPERTY RIGHTS AND REGULATORY
AFFAIRS

Objective: Various types of Intellectual Property Rights Patentable Subject History of Indian Patent Protection, Patent filing procedure in India, Opposition- pre-grant opposition and post-grant opposition, Patent filing procedure under PCT, advantages, patent search and literature and Salient features of Indian Patents are discussed in detail.

Intellectual Property Rights:

UNIT I

Introduction, Types of Intellectual Property Rights (Patents, Trademarks, Copyrights, Geographical Indications Industrial Designs and Trade secrets), Patentable Subject Matter (Novelty, Non-Obviousness, Utility, enablement and Best mode),

UNIT II


b. Patent filing procedure in India (Patent Prosecution), Specifications (Provisional and Complete), Claims- types of claims and legal importance of claims, Grant of patent, Rights of Patentee and co-owners

c. Opposition- pre-grant opposition and post-grant opposition, Anticipation, Infringement, Compulsory Licensing, revocation of patents, and power of Controller.

d. Patent filing procedure under PCT, advantages, patent search and literature

UNIT III

b. Background, Salient Features and Impact of International Treaties / Conventions like

   i. Paris Convention, Berne convention
   ii. World Trade Organization (WTO)
   iii. World Intellectual Property Organization (WIPO)
   iv. Trade Related Aspects of Intellectual Property Rights (TRIPS)
   v. Patent Co-operation Treaty (PCT), Mandrid Protocol

Regulatory Affairs

Unit IV

a. National Drug Regulatory requirements, National Drug Policy, Drugs and Cosmetics Act and its amendments, overview of schedules, detail study of schedule M and Schedule Y.
b. USFDA, FDA guidelines on IND, NDA and ANDA approvals, and SUPAC changes and understanding on 505 (b) (2) applications

Unit V

a. Requirement of GLP Guidance and recommendation on Dissolution and Bio-equivalence requirement. Types of ANDA filing (Para I, II, III, IV filing). Exclusivities (NCE, NS, NP, NDF, PED, ODE, PC)
b. ICH objectives and Guidelines- stability testing, WHO guidelines, ISOs- Production design, certification. ICH 8(QbD), ICH Q9 and ICHQ10
**Outcome:** The clear information about the patent laws, intellectual property rights and drug regulation in India and abroad is gained by the students.

**Recommended Books:**
1. Deepak Chawla Neena Sondhi, Research Methodology Concepts and Cases, Vikas books publishers
4. Original Laws Published by Govt. of India
5. Protection of Industrial Property rights by P.Das and Gokul Das
6. Law and Drugs, Law Publications by S.N. Katju
7. Laws of drugs in India, Hussain
10. Drugs and Cosmetics act by Vijay Malik
12. fda.org, wipo.int, patentlawlinks.com, hc-sc.gc.ca, ich.org, cder.org
13. Current good manufacturing practices for pharmaceuticals by Manohar A. Potdar
Objective:- The students is going to study about various techniques for screening of drugs for various pharmacological activities and guidelines for handling animals and human and animal ethics for screening of drugs.

UNIT I
Care Handling and breeding techniques of laboratory animals, Regulations for laboratory animals, CPCSEA guidelines, alternatives to animal studies, Good laboratory Practices.

UNIT II
Bioassays: Basic principles of Biological standardization: Methods used in the bio-assay of Rabbis Vaccine, Oxytocin, Tetanus Antitoxin and Diphtheria Vaccine. Test for pyrogens.

UNIT III
Toxicity tests: OECD guidelines, determination of LD50, acute, sub-acute and chronic toxicity studies.

UNIT IV
Organization of screening for the Pharmacological activity of new substances with emphasis on the evaluation cardiac, psychopharmaceutical, anti-inflammatory, analgesic and anti-diabetic.

UNIT V
Clinical evaluation of new drugs, Phases of clinical trial, protocol design, Ethics in human research.

Outcome: - The expected outcomes are student will know how to handle animals and know about various techniques for screening drugs for different pharmacological activities and guidelines and regulations for screening new drug molecules on animals and human volunteers.

Text Books:
5. Principles of clinical research edited by Giovanna di ignazio, Di Giovanna and Haynes

Reference Books:
1. ICH of technical requirements for registration of pharmaceuticals for human use, ICH harmonized tripartite guidelines - Guidelines for good clinical practice, E6, May 1996.
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I Year – II Sem M.Pharm (Pharmacology)

(A42003) ADVANCED PHARMACOLOGY – II

**Objective:** This subject will provide an opportunity for the student to learn about the drug with regard to classification, pharmacodynamic and pharmacokinetic aspects, adverse effects, uses, dose, route of administration, precautions, contraindications and interaction with other drugs. In this subject, apart from general pharmacology, drugs acting on autonomic nervous system, cardiovascular system, central nervous system, blood and blood forming agents and renal system will be taught. In addition to theoretical knowledge, the basic practical knowledge relevant to therapeutics will be imparted.

**UNIT I**

Autacoids : Drugs therapy of Inflammation.
   a. Histamine, Bradykinin & their antagonists
   b. Eicosanoids & PAF (Platelet Activating Factors)
   c. Anti-inflammatory, analgesic & antipyretic agents.
   d. Antiasthamatic agents.

**UNIT II**

Drugs affecting gastro intestinal function.
   a. Agents for control of acidity and antiulcer drugs.
   b. Emetics & anti emetics.

**UNIT III**

Antimicrobial agents
   (i) Sulphonamides, quinolones
   (ii) Cephalosporins and others newer agents.
   (iii) Antifungal & antiviral drugs including anti HIV drugs.

Chemotherapy of
   (i) Malaria & protozoal infections
   (ii) Leishmaniasis & filariasis

**UNIT IV**

Insulin, Oral hypoglycemic agents, Thyroid and Anti-Thyroid agents, Estrogens, Progestins and Androgens

**UNIT V**

a. Neoplastic diseases
   b. Immunomodulators

**Outcome:** Upon completion of the subject student shall be able to (Know, do, appreciate) –
   a. understand the pharmacological aspects of drugs falling under the above mentioned chapters;
   b. handle and carry out the animal experiments;
   c. appreciate the importance of pharmacology subject as a basis of therapeutics; and
   d. correlate and apply the knowledge therapeutically.
Objective: The students shall know about new drug discovery process, bioassay methods, preclinical models employed in the screening of new drugs, alternative to animal screening. They also know about toxicology principles and poisons and their treatments.

UNIT I


Bioassay methods for autacoids, vasopressin, oxytocin, acetylcholine, adrenaline, insulin, d-tubocurarine, HCG, hyaluronidase, corticotrophine, pertussis, rabbis and plague.

UNIT II

Preclinical models employed in the screening of new drugs belonging to following categories. Antifertility agents, sympathomimetics, parasympathomimetics, muscle relaxants (both central and peripheral), sedatives, hypnotics, antiarrhythmic agents, cardiac stimulants, bronchodilators, antihistaminics, eicosanoids. Antipsychotic agents, antianxiety agents, nootropic drugs, antidepressant drugs; antiparkinsonian agents, antiepileptics; antiulcer agents; infarction; antiatherosclerotic drug; antimalarials; anthelminitics models for status epilepticus drugs/ cerebroventricular and other newer techniques of drug administration and development; transgenic animals and other genetically prone animal models.

UNIT III

Alternatives to animal screening procedures, cell-line, patch–clamp technique, In-vitro models, molecular biology techniques.

UNIT IV

Principles of Toxicology, Test for mutagenicity, carcinogencity, teratogenicity, special tests. Techniques for toxicity studies in man, Toxicogenomics

UNIT V

Poison
   a. Classification of Poisoning
   b. Diagnosis of poisoning
   c. Physical signs of poisoning
   d. Principles of management of acute poisoning, treatment of poisoning
   e. Common poisoning agents

Outcome: the students will have knowledge about techniques used for the development of new drugs, regulation for laboratory animal care and ethical requirements, bioassay methods, preclinical methods for screening of drugs. They also know the toxicology and poison and their control.
(A42005) ADVANCES IN PHARMACOTHERAPY

Objective: In this subject students would gain sound knowledge in novel approaches in drug therapy like CADD, HTS, QSAR, prodrug concepts etc.

UNIT I
Pharmacokinetics approach to New Drug Discovery : Basic concepts and Definition, importance of ADME parameters in disposition, therapeutics and development – their implications on drug discovery,

UNIT II
Overview on computer aided Drug design (CADD) including QSAR, QSPR, Combinational Chemistry, High Throughput screening (HTS), Molecular Basis of Drugs Action.
Drug Latentiation: Basic concepts, Prodrugs of functional groups, Bio-precurssor prodrugs, chemical delivery system.

UNIT III

UNIT IV
Herbal Neutraceuticals as new source for medicines.

UNIT V
Study of Advanced drugs from natural sources of following groups.
Anticancer, Anti AIDS, Hepatoprotectives, Antidiabetics, Antiarthritic, Adaptogenic, Cardiotonic, Antipyretic, antimalarials, Diuretics, Hypnotics, Brain Tonic, Urolithiasis, Antifilarial, AntihyperlipidemicRecent trends in study of authentic and controversial drugs of above mentioned groups. Modern Phytochemical screening techniques and evaluation of Herbal. Drugs, their extracts and formulations-concept of Reverse Pharmacognosy

Outcome: After completing the subject the students would know
a) Implications of pharmacokinetics on drug discovery
b) Computer aided drug design
c) Molecular basis of drug action
d) Role of biotechnology in drug discovery
e) Nutraceuticals
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I Year – II Sem M.Pharm (Pharmacology)  

(A42201) ADVANCED PHARMACOLOGY – II LAB  

List of Experiments  

1. To record the dose response curve of Histamine using isolated guinea-pig ileum preparation.  
2. Study of agonistic and antagonistic effects of drugs using isolated guinea-pig ileum preparation.  
3. To carry out bioassay of Histamine using isolated guinea-pig ileum preparation by interpolation method.  
4. To carry out bioassay of Histamine using guinea-pig ileum preparation by three point method.  
5. To carry out bioassay of Histamine using guinea-pig ileum preparation by four point method.  
6. Effect of drugs on chick/rat mean arterial blood pressure (MABP) by using Condon's mercury manometer.  
7. Effect of drugs on perfused frog heart.
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I Year – II Sem M.Pharm (Pharmacology)

(A42202) ADVANCED SCREENING METHODS & TOXICOLOGY LAB

List of Experiments

Study of theory, principle, procedure involved and interpretation of given results for the following experiments:

1. Analgesic property of drug using analgesiometer.
3. Anticonvulsant activity of drugs using maximal electroshock and pentylene tetrazole methods.
4. Antidepressant activity of drugs using pole climbing apparatus and pentobarbitone induced sleeping time methods.
5. Locomotor activity evaluation of drugs using actophotometer and rotorod.
6. Cardiotonic activity of drugs using isolated frog heart and mammalian heart preparations.
7. Antidiabetic activity using rats / mice.
8. Hepatoprotective activity
9. Anti ulcer activity
10. Antioxidant activity
11. Toxicity studies as per OECD guidelines.
Books Recommended
1. Drug Discovery and Evaluation: Pharmacological Assays Ed by H.Gerhard VOGE
2. T.B.of Therapeutics: Drug & Diseases Management Ed by Eric Harfindal, Dick R Gourley
3. Drug Interaction Ivory H Stackely
4. Biopharmaceutics Clinical Pharmacokinetics by Hilo Gibaldi and Donald Perrier
5. Biopharmaceutics Clinical Pharmacokinetics by E Notari
6. Drug Metabolism by Berhard Tests and Peter Jenner.
7. Principles of Drug action by Goldstein, Aranow and Kolman
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