

# **Program and Course Structure**

**School of Medical Science and Research** 

MD (Pharmacology) Session:2020-23



#### 1. Standard Structure of the Program at University Level

#### 1.1 Vision, Mission and Core Values of the University

#### **Vision of the University**

To serve the society by being a global University of higher learning in pursuit of academic excellence, innovation and nurturing entrepreneurship.

#### **Mission of the University**

- 1. Transformative educational experience
- 2. Enrichment by educational initiatives that encourage global outlook
- 3. Develop research, support disruptive innovations and accelerate entrepreneurship
- 4. Seeking beyond boundaries

## **Core Values**

- Integrity
- Leadership
- Diversity
- Community

#### 1.2 Vision and Mission of the School

#### **Vision of the School**

To serve the society by being a premier institute that promotes a comprehensive approach to human health through excellence inacademics, research and clinical care

## **Mission of the School**

- Provide a transformative educational experience in Medical Science
- Develop skills and competencies to create global leaders in clinical care
- Promote innovative and collaborative research through intellectual and technological advancement
- Establish a center for excellence in preventive, promotive and curative health care

#### **Core Values**

- Integrity
- Leadership
- Ethics
- Community Health



#### 1.3 Program Educational Objectives (PEO)

#### 1.3.1 Writing Program Educational Objectives (PEO)

Program educational objectives are broad statements that describe the career and professional accomplishments that the program is preparing graduates to achieve.

#### **Program Objectives**

At the end of the MD training programe in Pharmacology, the student should acquire competencies in the following areas:

#### A. Acquisition of knowledge

The student should be able to explain clearly concepts and principles of Pharmacology and therapeutics. The student should also be able to explain the drug development processes. S/he should be able to explain Drugs and Cosmetics Act, in addition to clinical trial procedures

#### B. Teaching and training

The student should be able to effectively teach undergraduate students in medicine (MBBS) and allied health science courses (Dentistry and Nursing) so they become competent healthcare professionals and able to contribute to training of postgraduate trainees.

#### C. Research

The student should be able to carry out a research project (both basic and clinical) from planning to publication and be able to pursue academic interests and continue life-long learning to become more experienced in all the above areas and to eventually be able to guide postgraduates in their thesis work



## **1.3.2** Map PEOs with Mission Statements:

PEO Statements	School Mission 1	School Mission 2	School Mission 3	School Mission 4
The student should be able to explain clearly concepts and principles of Pharmacology and therapeutics. The student should also be able to explain the drug development processes. S/he should be able to explain Drugs and Cosmetics Act, in addition to clinical trial procedures	3	2	2	1
The student should be able to effectively teach undergraduate students in medicine (MBBS) and allied health science courses (Dentistry and Nursing) so they become competent healthcare professionals and able to contribute to training of postgraduate trainees.	2	3	1	2
The student should be able to carry out a research project (both basic and clinical) from planning to publication and be able to pursue academic interests and continue life-long learning to become more experienced in all the above areas and to eventually be able to guide postgraduates in their thesis work	1	1	3	3

#### 1.3.3 Program Outcomes (PO's)

#### 1. Cognitive domain

- PO1. Describe and apply pharmacological principles to explain the mechanism/s of the effects of drugs used in diagnosis, prevention and treatment of diseases of all systems of human body.
- PO2. Explain pharmacodynamics and pharmacokinetics of drugs.
- PO3. Describe mechanisms of drug-drug interactions and their clinical importance.
- PO4. Apply and integrate knowledge of pathophysiology of diseases and its modulation by drugs.
- PO5. Acquire knowledge on pharmacogenetics and pharmacogenomics
- PO6. Acquire knowledge on principles of Pharmacoeconomics
- PO7. Acquire knowledge on pharmacoepidemiology, including drug utilization studies.
- PO8. Aquire knowledge and understanding of principles of Good clinical practice (GCP) and Good laboratory practice (GLP) guidelines
- PO9. Acquire knowledge on essential medicines
- PO10. Acquire knowledge on pharmacovigilance
- PO11. Acquire knowledge and apply the principle of biostatistics in the evaluation and interpretation of drug safety and efficacy studies
- PO12. Describe how to evaluate, analyse and monitor preclinical and clinical data in drug discovery
- PO13. Able to integrate principles of immunology in biochemistry.

ability to use them efficiently to promote learning of pharmacology.

- PO14. Demonstrate knowledge of basics of research methodology, develop a research protocol, conduct the study, record experimental observations, analyse data using currently available statistical software, interpret results and disseminate these results and to have the potential ability to pursue further specializations and eventually be competent to guide students.
- PO15. Describe the principles of teaching learning technology towards application and take interactive classroom lectures, modules for problem based learning (PBL), case discussions, small group discussions, seminars, Journal club and research presentations PO16. Demonstrate knowledge about computer assisted learning (CAL) softwares and



- PO17. Demonstrate knowledge of principles of Instrumentation.
- PO18. Demonstrate knowledge about recent advances and trends in research in the field of pharmacology and clinical pharmacology.
- PO19. Acquire knowledge on generic drugs and generic prescription.
- PO20. Acquire knowledge on rational use of drugs and prescription auditing
- PO21. Acquire knowledge about antimicrobial stewardship programs and strategies for containment of antibiotic resistance
- PO22. Acquire knowledge on animal toxicity studies
- PO23. Acquire knowledge on common poisoning
- PO24. Acquire knowledge on the legal and ethical issues involved in drug development and research.
- PO25. Acquire knowledge in Biostatistics including use of statistical software's :Estimation Sample size for a clinical trial
  - i. Scales of measurement, data display, measures of central tendency (mean, median, mode)
  - **ii.** Dispersion of data (variance, standard deviation)
  - iii. Selection of tests (of significance) and their applicabilityCorrelation and regression analysis
  - iv. Basics of systematic reviews and meta-analysis

#### Affective domain

- PO26. Effectively explain to patients, the effects and side effects of drugs, including the need for medication adherence.
- PO27. Communicate effectively with pharmacological reasoning with students, peers, staff and faculty, and other members of the health care team on rational use of drugs and improving spontaneous reporting of adverse events.
- PO28. Demonstrate respect in interactions with peers, and other healthcare professionals.
- PO29. Demonstrate ethical behavior and integrity in one's work.
- PO30. Demonstrate ability to generate awareness about the use of generic drugs in patients.



PO31. Acquire skills for self-directed learning to keep up with developments in the field and to continuously build to improve on skills, expertise and perpetual professional development.

#### **Psychomotor domain**

- PO32. Able to predict efficacy and adverse effects associated with use of drugs, along with causality assessment.
- PO33. Demonstrate skills for prescription writing.
- PO34. Perform major in vivo and in vitro animal experiments.
- PO35. Observe and understand basic principles of working of important advanced techniques, like High Performance Liquid Chromatography (HPLC).
- PO36. Demonstrate standard operating procedures of various methods and techniques used in clinical trials and research.
- PO37. Determine levels of common poisons in blood
- PO38. Demonstrate presentation skills at academic meetings, publications and writing research projects for funding agencies.
- PO39. Be able to analyze and evaluate a research paper

## By the end of the course, the trainee should have acquired practical skills in the following

- **1.** *In vivo* and *ex vivo* experiments, like organ bath, analgesiometer, physiography/polygraph, convulsiometer, plethysmograph, learning and memory, models for affective disorders.
- **2.** Administration of drugs by various routes (subcutaneous, intravenous, intraperitoneal) in experimental animals
- 3. Collection of blood samples and oral gavage in experimental animals
- **4.** Preparation and administration of a drug solution in appropriate strength and volume
- **5.** Experiments to show dose response curve of agonists (in the presence or absence of an antagonist) on various biological tissues, like
  - a. Isolated rabbit/rat/ guinea-pig intestine



#### b. Isolated rat uterus

- **6.** Determination of EC50, ED50, pD2 and pA2 values of drugs
- 7. Perform in vivo experiments to study effect of mydiatrics and miotics on rabbit eye
- **8.** Perform *in vivo* experiments to study effect of antiepileptic drugs using animal models of epilepsy
- **9.** Perform *in vivo* experiments to study effect of analgesics using animal models of analgesia
- **10.** Perform *in vivo* experiments to study effects of drugs on learning, memory and motor coordination
- **11.** Estimate toxic drug levels using chemical and biological tests (alkaloids, glycosides, steroids, barbiturates, salicylates) by commonly used methods)
- **12.** Clinical pharmacology
  - (i) Prepare protocol for a clinical trial
  - (ii) Prepare Informed consent form and participant information sheet for research involving human participants
  - (iii) Report Serious Adverse Effect (SAE)
  - (iv) Evaluate promotional drug literature
  - (v) Prepare "Drug Information Sheet" (WHO criteria)
  - (vi) Interpret bioavailability parameters with the help of given pharmacokinetics data
  - (vii) Perform causality assessment and report ADR as per Pharmacovigilance
    Programme of India (PvPI)



## 1.3.4 Mapping of Program Outcome Vs Program Educational Objectives

	PEO1	PEO2	PEO3
PO1	3	2	1
PO2	3	2	1
PO3	3	2	1
PO4	3	2	1
PO5	3	2	1
PO6	3	2	1
PO7	3	2	1
PO8	3	2	1
PO9	3	2	1
PO10	3	2	1
PO11	3	1	2
PO12	2	1	3
PO13	3	1	2
PO14	2	1	3
PO15	2	3	1
PO16	2	3	1
PO17	3	1	2
PO18	2	1	3
PO19	3	2	1
PO20	3	2	1
PO21	3	2	1
PO22	3	1	2
PO23	3	2	1
PO24	2	1	3
PO25	2	1	3
PO26	2	3	1
PO27	2	3	1



PO29       1       3       2         PO30       2       3       1         PO31       2       3       1         PO32       1       3       2         PO33       2       3       1         PO34       2       1       3         PO35       2       1       3         PO36       2       1       3         PO37       1       2       3         PO38       1       2       3				Beyond Boundaries
PO30       2       3       1         PO31       2       3       1         PO32       1       3       2         PO33       2       3       1         PO34       2       1       3         PO35       2       1       3         PO36       2       1       3         PO37       1       2       3         PO38       1       2       3	PO28	٠٠_٠٠	3	
PO31       2       3       1         PO32       1       3       2         PO33       2       3       1         PO34       2       1       3         PO35       2       1       3         PO36       2       1       3         PO37       1       2       3         PO38       1       2       3	PO29	1	3	2
PO32       1       3       2         PO33       2       3       1         PO34       2       1       3         PO35       2       1       3         PO36       2       1       3         PO37       1       2       3         PO38       1       2       3	PO30	2	3	1
PO33       2       3       1         PO34       2       1       3         PO35       2       1       3         PO36       2       1       3         PO37       1       2       3         PO38       1       2       3	PO31	2	3	1
PO34       2       1       3         PO35       2       1       3         PO36       2       1       3         PO37       1       2       3         PO38       1       2       3         3       3       3       3         4       2       3       3         8       1       2       3	PO32	1	3	2
PO35       2       1       3         PO36       2       1       3         PO37       1       2       3         PO38       1       2       3	PO33	2	3	1
PO36       2       1       3         PO37       1       2       3         PO38       1       2       3	PO34	2	1	3
PO37 1 2 3 PO38 1 2 3	PO35	2	1	3
PO38 1 2 3	PO36	2	1	3
	PO37	1	2	3
<b>PO39</b> 2 1 3	PO38	1	2	3
	PO39	2	1	3

Scho	ool: SMSR	Batch:
Prog	gram: MD	Current Academic Year: 2019-20
PHA	RMACOLOGY	
1	Programme	SMS0701
	Code	



## **Department of Pharmacology**

School of Medical Sciences & Research

# Curriculum MD Pharmacology

#### Introduction

Pharmacology has evolved over the years. Originally a scientific discipline that described the overt effects of biologically active chemicals, pharmacology now explores the molecular mechanisms by which drugs cause biological effects. In the broadest sense, pharmacology is the study of how chemical agents, both natural and synthetic (i.e., drugs) affect biological systems. This encompasses investigation of the derivation, chemical properties, physiological and behavioral effects, mechanisms of action, biological transformations, and the therapeutic and non-therapeutic uses of drugs. Pharmacological studies can determine the effects of chemical agents upon subcellular, systemic, physiological or behavioral processes; focus on the treatment and prevention of diseases; or deal with the potential hazards of pesticides and herbicides.

Pharmacology is often described as a bridge science because it incorporates knowledge and skills from a number of basic science disciplines including physiology, biochemistry and cell and molecular biology. Pharmacologists are able to 'translate' such knowledge into the rational development of therapeutics. As a result of their multidisciplinary training, pharmacologists are able to offer a unique perspective in solving drug-, hormone- and chemical-related problems.

The interdisciplinary nature of the field offers pharmacologists a variety of research opportunities not found in other fields of scientific inquiry. It is this flexibility as well as the potential for the practical application of research that attracts people into becoming pharmacologists.



#### **Goals & General Objectives**

The overall goal of the course is to develop expertise in the field of Pharmacology. A process of rational thinking and coherent action will be inculcated in an individual so that he/she shall be competent to pursue various activities as demanded by the profession, as a Pharmacologist and to orient the learners towards research in the field of Pharmacology

#### **Competencies**

To achieve this goal, the following objectives must be fulfilled. At the end of course in Pharmacology, the trained specialist shall be able to

- **1.** Acquire sound knowledge of general pharmacological principles, systemic pharmacology and rational use of drugs.
- **2.** Perform common experimental techniques required for evaluation of new drug with competence.
- **3.** Carry out screening of drugs for pharmacological and toxicological profile.
- **4.** Critically review and comment on research papers.
- **5.** Monitor adverse drug reactions, therapeutic drug monitoring, and able to provide drug information service.
- **6.** Preparation of protocols to conduct experimental studies in animals and human drug trials independently.
- **7.** Plan and conduct lecture, practical demonstration, and tutorial classes for students.
- **8.** Plan and carry out both laboratory and clinical research with adherence to scientific methodology and GLP/GCP guidelines
- 9. Be aware of legal and ethical aspects of drug evaluation.
- **10.** Communicate the findings, results and conclusions of scientific research, both verbally and in writings.
- **11.** Be aware of regulatory procedures needed to be carried out prior to the marketing of a new drug in India.
- **12.** Develop the ability for continued self-learning so as to update the knowledge of recent advances in the field of Pharmacology and allied fields.



#### **Learning Methods**

The following self learning sessions for the students will be held

- Post graduate lectures to update knowledge in various aspects of pharmacology.
- Therapeutic club: To critically analyze the day to day development in therapeutics and new drug development including therapeutic exercises.
- Journal club: To familiarize with research methodologies and critical appraisal of results.
- Seminars: To update newer developments in pharmacology/emerging trends/ novel mechanisms of drug action.
- Practical exercises: Once in a week, under the supervision of a faculty, with/without the help of animals, various principles/ mode of drug action/ screening of drugs/ drug analysis using various techniques should be performed to develop practical skills to conduct similar experiments in future.

#### Thesis/ Dissertation

Each PG student will carry out research work under the supervision of a faculty member of the Pharmacology Department. The thesis will be submitted to Sharda University and will be refereed by suitable experts in the field. The acceptance of the thesis/dissertation by the University will be a prerequisite for the candidate to be allowed to appear in the final examination.

#### Thesis/Dissertation Objectives

- 1. To make the post graduate student aware about every aspect of research including finding research topic, searching literature, research methodology, statistics, analysis of results, scientific writing and ethical aspects involved.
- **2.** The topic or project taken need not necessarily bring out /explore something very novel, very big or breakthrough in medical science. the main aim is to train post graduate student for taking up such challenges in the future and learn maximum about the research methodology during their curriculum.

Thesis/Dissertation topic, along with protocol of work, is to be submitted to the university within one year of registration. The study is to be cleared by the institutional ethics committee. [Topics not be repeated for three years].

Required number of copies of completed dissertation with appropriate certificates should be submitted at the end of completion of two year of training.



Four examiners will examine these dissertations and report acceptance or otherwise.

## Eligibility for the course

MBBS with one year of completed internship recognised by MCI.

#### **Course Details**

Duration of the course -36 months

#### **Assessment**

Schedule	Internal (Formative) Assessment				Final (Summative) Assessment		
Examination	1 <sup>st</sup> Year Midterm 6	1st Year 12	2 <sup>nd</sup> Year Midterm 18	2 <sup>nd</sup> Year 24	Pre final	Total	
(Months)					30		
Marks (Theory)	20	20	20	20	20	100	400
Marks (Practical)	20	20	20	20	20	100	300
Marks (G Viva)							100
Grand Total							800

#### **MD Examination**

**Internal Assessment**- Will be based on marks obtained in internal examinations, day to day performance including participation in departmental seminars, journal clubs and other learning-teaching activities.

#### **Final Examination:**

Eligibility criteria for appearing in the final examination- A minimum of 50% marks in internal assessment.



#### Theory examination

There will be **four question papers** of 3-hour duration, **each of 100 marks**.

#### Paper- I

General pharmacological principles and clinical pharmacology

#### Paper-II

Systemic pharmacology, chemotherapy and therapeutics

#### Paper-III

Experimental pharmacology, screening of drugs, research methodology and biostatistics

#### Paper-IV

Recent advances in pharmacology

History of Pharmacology

#### **Practical Examination**

#### Duration: 2 days; Total marks: 300

- 1. Experimental pharmacology exercise on intact animal including handling.
- 2. Experimental pharmacology exercise on isolated organ.
- 3. Chemical pharmacology exercise.
- 4. Clinical pharmacology exercise.

#### **Oral Examination (100 marks)**

- 1. Thesis presentation and discussion
- 2. General viva voce
- **3.** Microteaching session

#### **Criteria for Award of Degree**

- **1.** Minimum 50% marks in theory and practical separately
- **2.** A candidate obtaining more than 80% marks in theory and practical examinations including viva voice separately, shall be declared to have passed the subject with honours.
- **3.** Thesis to be submitted at the end of two years of training.
- **4.** One research publication ( published/accepted/communicated)
- **5.** One poster/ oral presentation in state/national/international conference.



#### **Course Contents**

#### Paper-I (Theory)

#### **General and Clinical Pharmacology**

Pharmacokinetics: Absorption, Distribution, Biotransformation and Elimination

Basics of pharmacokinetics, calculation of pharmacokinetic estimates (C-max, Tmax, T1/2, AUC(0-n),  $AUC(0-\mu)$ , (Vd, Ke, Ka etc.) Compartment models used in pharmacokinetics (oral and intravenous).

Compartment fitting (one comp & two comp). Pharmcodynamic /pharmacokinetic (PK/PD) correlation.

Practical skills: Calculation of Pharmacokinetic estimates from given concentration vs time data.

**Drug Delivery Systems** 

**Pharmacodynamics:** Mechanisms of Drug Action, Drug Receptors, Interactions, antagonism, Therapeutic index.

#### **Toxicology**

Drug toxicity, LD 50, AD50, TD50, Monitoring of ADRs, Antidotes in the management of poisoning. Applied analytical toxicology and toxicovigilance.

#### **Molecular Pharmacology**

Gene expression, Pharmacogenomics, Proteomics, techniques involved in studying receptor dynamics.PCR, Northern blot, Southern blot and Western blot. Protein purification. Mono, poly clonal antibodies.Molecular biology in receptor identification. Antisense oligonucleotides, molecular targets of drug action.

#### **Pharmacogenetics**

#### **Drug regulations**

Drugs and Cosmetics Act, Drug Price Control order, Application for Investigational New Drug (IND),

Application for New Drug Discovery (NDD) according to Indian Control Authority & USFDA guidelines.

Conducting bio-equivalence studies. Ethical considerations in utilizing human subjects for drug discovery process. Helsinki's declaration. ICH-GCP Guidelines. Ethical guidelines in utilizing animals for experimental purposes.

Practical skills: Draft an IND and NDD application for the approval of a numbered compound

#### **Pharmacoepidemiology**

Pharmacoeconomics, Essential drug listing

Pharmacovigilance

Therapeutic audit: Drug utilization studies, essential drug concept, rational

Prescribing, Concept of P drugs, Drug Information

#### **Drug development process**



Methods involved in the development of new drugs. Preclinical toxicological studies. Calculation of LD50 & ED50

Acute, subacute and chronic toxicity studies. Irwin profile test, Pre-clinilcal pharmacokinetic and dynamic studies. Lipinski's rule for drug like molecule, High throughput screening (invitro and invivo) for pre-clinical pharmacokinetic and pharmacodynamic studies.

#### Clinical Trials

Types of clinical trials, clinical trial for a new investigational drug in India. Methods involved in the assessment of drugs in human volunteers and bioequivalence studies. Key points in drafting protocol for a large scale multicentric drug trial in India. Practical skills: Draft a protocol to conduct phase II clinical trial for a newly discovered drug.

#### Therapeutic drug monitoring

Basic principles of TDM. Therapeutic index. Trough level monitoring and dosage adjustments.

Drug delivery systems: sustained release, enteric coated formulations and liposome etc.

#### Paper-II (Theory)

#### Systemic Pharmacology, Chemotherapy and Therapeutics

#### **Autonomic nervous System**

Neurotransmission

Cholinergic transmission

Muscarinic and nicotinic receptor and subtypes

Adrenergic receptors and subtypes

Muscarinic receptors agonists and antagonist

Anti-cholinergic agents

Drugs acting on Autonomic Ganglia

Adrenergic agonists and antagonist

#### Peripheral nervous System

Drugs acting on neuromuscular junction

Local anesthetics

#### **Central nervous system**

Neurotransmission and central nervous system

General anesthetics

Therapeutic gases

Hypnotics and Sedatives:

Anti-Anxiety

Anti-psychotics and anti-maniac drugs

Anti-depressant drugs

Drug used in the treatment of epilepsy

Drugs used in the treatment of Neurodegenerative disorders (Parkinson's disease,

Alzheimer's disease, Huntington's disease, Amyotrophic Lateral Sclerosis) and therapy of migraine

Opioid analgesics and antagonists

Drug addiction and drug abuse - Tobacco and Alcohol



#### Cardiovascular system

Diuretics and ADH antagonists

Drugs affecting renal renin-angiotensin system

Calcium channel blockers

Drug treatment of hypertension

Drug treatment of myocardial ischemia

Drug treatment of congestive cardiac failure

Anti-arrhythmic drugs

Lipid lowering agents

Drug therapy of shock

#### **Gastro intestinal system**

Drug treatment of peptic ulcer and gastro-esophageal reflux disease.

**Antacids** 

Anti- Diarrheal drugs

Laxatives and purgatives.

Drug used in the treatment of disorder of bowel motility and water flux, inflammatory Bowel

Disease.
Anti-emetic drugs

#### **Endocrines, Autacoids, Hormones**

Pituitary hormones

Corticosteroids

Insulin and oral hypoglycaemic agents

Thyroid and parathyroid hormones and antagonists

5HT agonist and antagonists

**Prostaglandins** 

Lipid Derived Autocoids:- Eicosanoids and Platelat Activating factor

Estrogens and Anti-Estrogens

Progestin and Anti-progestins

Androgens and Anti-androgens

Estrogen and progesterone receptor modulators

Female and male contraception

Tocolytic agents

Histamine & Anti-histamine

Analgesic, Anti-pyretic & Anti-Inflammatory agent, Treatment of Rheumatoid arthritis and Gout

#### **Hematopoietic System**

Iron and Iron salts

Erythropoietics

Myeloid Growth factors (CSFs)

Thrombopoietics growth factors

Vitamin<sub>B12</sub>, Folic acid, and treatment of megaloblastic of anemia.

Oral and parenteral anti-coagulants

Fibrinolytic agents



Anti-platelets drugs Procoagulants

#### Pharmacotherapy of Bronchial Asthma, COPD and Cough.

#### **Antimicrobial Chemotherapy**

General consideration and principal of antibiotics therapy

Sulfonamides, Quinolones, and agents for UTI

Penicillins, cephalosporins and other  $\beta$ -Lactam antibiotics.

Protein synthesis inhibitors (Aminoglycosides, Tetracyclines, Macrolides).

Miscellaneous anti-bacterial agents

Chemotherapy of tuberculosis, MAC disease, and leprosy.

Anti-fungal agents

Anti-viral agents

Anti-retroviral agent and treatment of HIV infection.

#### Chemotherapy of parasitic infection

Protozoal infection.

Chemotherapy of malaria

Chemotherapy of helminthic infection

#### **Chemotherapy of neoplastic diseases**

Anti-neoplastic agents

#### Immunosuppressant and immunomodulators.

#### Misc. topics

Drug management of osteoporosis

Dermatological Pharmacology

Ocular pharmacology

Chelating agents

Diagnostic agents

Complementary and Alternative Medicine (CAM)

#### Paper III

#### **Experimental Pharmacology and Biostatistics**

**Drug Discovery Process: -** Principles and strategy used in new drug discovery, regulation, laboratory animal care and additional requirements, Drug Development.

#### **Bioassay**

Basic principles

Types of bioassay

Experimental models and statistical designs employed in biological standardization

Preclinical and clinical models employed and screening models for new drugs

Screening of: Analgesic and anti-pyretic, Anti-inflammatory agent, Anti-anxiety agents,

Anti-depressants, Anti-diabetics, Anti-convulsants, Local anesthetics,



Anti-arrhythmic drugs, Anti-hypertensive agent, Anti-anginal drugs, Drugs use in treatment of congestive of cardiac failure, Screening of Anti-Diabetics, Screening of anti epileptic drugs

#### **Isolation of compounds from herbal sources**

Basic constituents of plants (chemical classification). Isolation of active constituent from plant materials. Percolation and maceration. Qualitative constituent characterisation techniques. Utilisation of HPLC for the constituent analysis. Estimation of marker compound in biological fluid after crude plant material administration.

#### **Biostatistics**

Calculation of basic statistical parameters (mean, median, mode, standard deviation, standard error etc.). Null hypothesis, parametric and non parametric tests (Student 't test, Wilcoxon, ANOVA etc.). Meta-analysis.

Practical skills: Calculation for statistical significance in the given data for Student paired and unpairedt test. Applying ANOVA to the given set of concentration vs time data of two drug formulations to comment about their bio-equivalence.

Introduction of Bio-statistics, graphical representation (histogram line diagram) data collection, measure of central tendency, dispersion sample size, coefficient of variation, relative errors, probit . Definition and probability, by using Binanial passion and normal distribution continuous data distribution logistic analysis . Correlation and regression, rank-correlation, method of least square cure fitting. Introduction of multiple correlation, Test of signification type I&II errors, level of significance t-test, Z-z-test,  $x^2$ -test (chi-square), and significance for correlation coefficient .

#### Paper IV

Recent advances in molecular, basic and clinical pharmacology. Medicine

Evidence based

Newer trends in pharmacotherapeutics.

History of Pharmacology

#### **Practical**

#### **Experimental Pharmacology**

#### On Isolated tissues

Bioassay of histamine

Bioassay of 5-HT, Angiotensin, Oxytocin, Acetylcholine, Adrenaline

#### **Intact animals**

- i Bioassay of Diuretics (Rat)
- ii. Rat BP
- iii. Lagendroff's Prepration

Effect of various drugs on dog blood pressure respiration and other parameters and also detections and unknown drugs (Demonstration).

Effect of antiinflammatory agents on caraagennan induced rat paw edema.

Evaluation of analgesic activity of morphine using tail flick latency test.



Evaluation of cardiotonic drugs on isolated rabbit heart (Langendroff isolated heart preparation). Demonstration of Dale's vasomotor reversal and nicotinic effect of acetylcholine on dog blood pressure.

Effect of autonomic drugs on rabbit intestine.

Demonstration of bronchodilation on guinea pig tracheal chain.

Effect of sedatives on rodents (rotarod test). Four point assay of histamine and acetylcholine on guinea pig ileum.

Four point assay of 5HT on rat uterus.

Estimation of PA2 value of atropine.

Identification of unknown by evaluating its action on dog haemodynamic parameters. Assay of acetylcholine using rat fundus.

Estimation of pressor agents on rat blood pressure.

#### **Chemical Pharmacology**

Extraction of active principle, from medicinal plants.

Qualitative testing, titrimetric analysis. Beer and Lambert's law. Basis and working principle of colorimeter, ultraviolet, atomic absorption spectrometers, Fluorescence spectroscopy, NMR and Mass Spectroscopy.

Basics of Chromatography.

Partition, adsorption and ionexchange chroma tography.

Column chromatography, thin layer chromatography, paper chromatography, immunoabsorbant chromatography, high performance thin layer chromatography, high performance liquid chromatography and gas Chromatography.

Radioimmunoassay.

Processing of biological materials for drug analysis.

Calculations in drug analysis.

Good laboratory practice.

Validation of analytical procedure.

Practial skills: Spectrophoto & fluorimetric estimations of drugs in biological fluids.

#### **Clinical/human experiments:**

To study the effect of following activities in healthy human volunteers:

To demonstrate the use of any model as an experimental tool on human subjects without administration of any drug/beverage for evaluation of analgesic activity, psychomotor function, cardiac parameters (HR, BP),

Physical stress, Mental stress

To determine lung volumes

To perform:

EEG

Spirometry

ECG

Treadmill test/Bicycle ergometry/Master's Step test

Psychomotor tests



#### **Psychomotor Skills**

The candidates should be conversant with the following techniques:

Weighing technique (chemicals & animals)

Handling of equipment

Handling of small animals including various anaesthetic techniques.

Recording of blood pressure (In vivo and Computer Assisted Learning program)

Administration of drugs/chemicals to animals (parenteral and enteral routes)

Screening of drugs using appropriate models

Isolated tissue preparations for log dose response curve and bioassay

Use of various methods to evaluate drug effects in humans

Elementary principles of common chemical techniques such as

colorimeter, spectrophotometer, flame photometer etc.

Use of appropriate statistical techniques to analyze the result.

#### **Teaching and Communication Skills**

Delivering lectures, conducting practical/demonstrations for undergraduate and postgraduate students.

Maintenance of records of practical exercise. Techniques to retrieve relevant information from various sources.

Methodology of preparing research manuscripts. Research presentation in scientific deliberations.

Practical skills: Post graduate teaching of recent developments in pharmacology and therapeutics.

Microteaching

#### **Teaching Schedule**

Following is the suggested departmental teaching schedule:

#### Item Frequency

1. Thesis work	Once a week
2. Journal club/Drug review	Once a week
3. Practical (Experimental/Chemical/Human)	Once a week
4. Seminar	Once a week
5. Statistical exercise	Once a fortnight
6. Pharmacokinetic exercise	Once a fortnight
7. Theory test	Once a month

#### Note:

All PGs are supposed to attend the sessions.

All the teaching sessions shall be assessed by the faculty members at the



end of each session and marks should be given out of 10 (for participant) & 100 (for presenter) and kept in the office for the purpose of calculation of internal assessment

Attendance of the residents at various sessions (including central sessions) should be at least 80%

#### Logbook

**Logbook write-ups**: (To be filled by student as provided in the format)

Main purpose of the log book should be to document the work done (Experiments, journal, thesis work, seminars)

The content of the logbook work to be signed ONLY by the Guide/ PG teaching in charge /HOD.

#### **Logbook Format:**

Personal Biodata

Posting Record

S.No. From To Place of posting Remarks Signature Of I/C

Seminars presented

Journal clubs presented

Topic Date Remarks of guide

Experiments (both basic and clinical pharmacology) conducted by the candidate

No. Name of the experiments Date Results Remarks of guide

Conferences/workshops attended

Publications, if any

Signature of Guide Signature of HOD

#### **Recommended Reading**

#### **Journals**

- Annual review in Pharmacology Annual Review in Medicine
- British Journal of Clinical Pharmacology
- British Journal of Pharmacology
- Clinical Pharmacology & Therapeutics
- Drugs
- ICMR bulletin
  - Indian Journal of Experimental Biology
  - Indian Journal of Pharmacology
  - Lancet
  - New England Journal of Medicine



- Pharmacological Reviews
- Trends in Pharmacological Sciences
- WHO Reports & Bulletin
- Indian Journal of Medical Research

#### **Books**

- 1. Goodman & Gilman's The Pharmacological Basis of Therapeutics. HardmanJG & Limbird LE(Ed), Publisher: McGraw-Hill, New York.
- 2. Basic & Clinical Pharmacology. Katzung BG (Ed), Publisher: Prentice hall International Ltd., London.
- 3. Avery's Drug Treatment. TM Speight & NHG Holford (Eds), Adis International.
- 4. Principles of Drug Action. The Basis of Pharmacology. WB Pratt & P Taylor (Eds), Churchill Livingstone, Edinburgh.
- 5. Pharmacology & Pharmcotherapeutics. Satoskar RS, Bhandarkar SD(Ed), Publisher: Popular Prakashan, Bombay.
- 6. Principles of Pharmacology. Sharma HL & Sharma KK (Ed), Publisher: Paras Medical Publishers. New Delhi.
- 7. Clinical Pharmcology. Bennet PN, Brown MJ (Ed). Publisher: Churchill Livingstone
- 8. A Textbook of Clinical Pharmacology. Roger HJ, Spector RG, Trounce JR (Ed), Publisher: Hodder and Stoughton Publishers.
- 9. Harrison's Principles of Internal Medicine. AS Fauci, JB Martin, E Braunwald, DL Kasper, KJ Isselbacher, SL Hauser, JD Wilson, DL Longo (Eds), McGraw Hill, New York.
- 10. Guides to Good Prescribing. TPGM de vries, RH Henning, HV Hogerzeil, DA Fresle, Who Geneva.
- 11. Critical appraisal of epidemiological studies and clinical trials- Mark Elwood. Oxford Press.
- 12. Pharmacology. Rang HP, Dale M, Ritter JM. Edinburgh, Churchill Livingstone, 1999.
- 13. Essentials of Medical Pharmacology, Tripathi KD, Jaypee Brothers Medical Publishers, New Delhi
- 14. Oxford Textbok of Clinical Pharmacology
- 15. Martindale The Complete Drug Reference, Sweetman SC. Pharmaceutical Press; London.
- 15. Indian Pharmacopoeia

#### Evaluation of Drugs

- 1. Drug Discovery and Evaluation-Pharmacological Assays. H. Gerhard Vogel, Springer-Verlag .Berlin
- 2. Selected Topics in Experimental Pharmacology. UK Sheth, NK Dadkar & UG Kamat. Kothari Book Depot, Mumbai.
- 3. Burn's Screening Methods
- 4. Fundamentals of Experimental Pharmacology. MN Ghosh (Ed), Scientific Book Agency, Calcutta.

