



## Department of Pharmacology

### PG Curriculum Template

1. **Goals:** Pharmacology encompasses all aspects of knowledge about drugs, for effective and safe use of drugs in patient care. The applied nature of the discipline needs integration of curricula with other biomedical and clinical disciplines.

A postgraduate student shall be well versed with the principles of Pharmacology along with the ability to carry out research related to drugs independently. The ultimate goal of teaching pharmacology to postgraduate student is to develop expertise in the field of pharmacology and to expand the scope of pharmacology from bench to bedside. The graduate shall be competent to pursue various activities as demanded by the profession as an efficient pharmacologist in academia and pharmaceutical industry.

2. **Programme outcomes:** At the end of the MD (Pharmacology) training, the postgraduate student shall be able to achieve following learning objectives

#### **2.1 Cognitive:**

- a. To describe and apply pharmacological principles to identify/ explain rational basis of use of drugs in the diagnosis, prevention and treatment of diseases affecting human body
- b. Describe the mechanisms of drug-drug interactions and their clinical importance.
- c. Able to explain the concept of pharmacogenetics and pharmacogenomics, pharmaco economics, Pharmacoepidemiology and its applied aspect.
- d. To understand and apply the principles of Good Clinical Practice (GCP) and Good Laboratory Practices (GLP) as per the regulatory requirements
- e. The graduate will demonstrate the requisite knowledge and apply the principles of rational use of medicine
- f. To explain the concept of essential medicine and to motivate clinicians for the use of generic medicines
- g. Acquire knowledge on pharmacovigilance
- h. Acquire knowledge and apply the principle of biostatistics in the evaluation and interpretation of drug safety and efficacy studies

- i. Describe how to evaluate, analyse and monitor preclinical and clinical data in drug discovery
- j. Able to integrate principles of immunology in biochemistry
- k. 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
- l. 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
- m. Demonstrate knowledge about computer assisted learning (CAL) softwares and ability to use them efficiently to promote learning of pharmacology
- n. Demonstrate knowledge of principles of Instrumentation
- o. Demonstrate knowledge about recent advances and trends in research in the field of pharmacology and clinical pharmacology
- p. Acquire knowledge about antimicrobial stewardship programs and strategies for containment of antibiotic resistance
- q. Acquire knowledge on animal toxicity studies
- r. Acquire knowledge on common poisonings, including their management
- s. Acquire knowledge on the legal and ethical issues involved in drug development and research.
- t. Acquire knowledge in Biostatistics including use of statistical softwares

## **2.2 Psychomotor:**

- I. Able to predict efficacy and adverse effects associated with use of drugs, along with causality assessment & reporting via Vigiflow
- II. Demonstrate skills for prescription writing
- III. To perform major in vivo and in vitro animal experiments including toxicity studies.
- IV. Observe and understand basic principles of working of important advanced techniques, like High Performance Liquid Chromatography (HPLC).

- V. Demonstrate standard operating procedures of various methods and techniques used in clinical trials and research
- VI. Determine levels of common poisons in blood
- VII. Be able to analyze and evaluate a research paper
- VIII. Write a research protocol, conduct the study, record experimental observations, analyze data using currently available statistical software and interpret results
- IX. Demonstrate presentation skills at academic meetings, publications and writing research projects for funding agencies
- X. Write protocols to conduct experimental studies in animals and clinical trials in human beings.
- XI. Write and publish research papers in peer reviewed journals

### 2.3 Affective

- a. Effectively explain to patients, the effects and side effects of drugs, including the need for medication adherence.
- b. 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 event
- c. Demonstrate respect in interactions with peers, and other healthcare professionals
- d. Demonstrate ethical behaviour and integrity in one's work.
- e. Demonstrate ability to generate awareness about the use of generic drugs in patients.
- f. 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

## 3. Syllabus

### 3.1 Theory

System/Section	List of topics
1. General Pharmacological principles	1. Principles of drug action, agonist, antagonist, partial agonist, inverse agonist, spare receptors and types of antagonism. 2. Molecular mechanisms of drug action including drug receptor interactions, transducer mechanisms, second messenger systems

	<p>in transmembrane signalling, G – protein coupled receptors, tyrosine kinase linked receptors, ion channel linked receptors, nuclear receptors, P-glycoprotein.</p> <p>3. Pharmacokinetic principles: Factors governing transport of drugs across biological membranes; basis of selective distribution of drugs in the body; biotransformation and elimination of drugs; drug elimination kinetics and its clinical importance; bioavailability and bioequivalence</p> <p>4. Drug interactions, fixed dose combinations and combined use of drugs.</p> <p>5. Adverse effects of drugs including drug toxicity, hypersensitivity, idiosyncrasy, tolerance, dependence, teratogenicity, mutagenicity and carcinogenicity.</p> <p>6. Dose-response relationships, variation in drug response and factors governing it.</p> <p>7. Physiological processes and biochemical mechanisms relevant to the understanding of drug action.</p> <p>8. Ethnopharmacology.</p> <p>9. Essential drugs, P drug concept and list, rational prescribing.</p> <p>10. Structure – activity relationships in drug action.</p> <p>11. Molecular biology in Pharmacology: pharmacogenomics, proteomics, epigenetics, gene expression, PCR, antisense oligonucleotides, molecular targets of drug actions etc.</p>
<p>2. Systemic Pharmacology</p>	<ol style="list-style-type: none"> <li>1. Autonomic nervous system</li> <li>2. Central nervous system ((Sedative, Hypnotics, Antiepileptics, General Anesthetics, Local Anesthetics, Skeletal Muscle Relaxants, Antipsychotic, Antidepressants, Drugs used in Parkinson’s disease and other neurodegenerative disorders, opioid agonists and antagonists, Drugs of abuse)</li> <li>3. Autacoids and related pharmacological agents (NSAIDs) and drugs used in Rheumatoid arthritis and Gout</li> <li>4. Drugs modifying renal function</li> <li>5. Drugs acting on cardiovascular system and haemostatic mechanisms (Antihypertensives, Antianginal, Antiarrhythmics, Drugs used in heart failure, Drugs used in dyslipidaemias, Fibrinolytics, Anticoagulants, Antiplatelets)</li> <li>6. Pharmacology of drugs affecting the respiratory system (drugs used in Bronchial Asthma and COPD)</li> <li>7. Gastrointestinal drugs</li> </ol>

	<ol style="list-style-type: none"> <li>8. Pharmacology of drugs used in endocrine disorders (drugs used in diabetes mellitus, hypothalamic and pituitary hormones, thyroid and antithyroid drugs, adrenocorticoid hormones and their antagonists, gonadal hormones and their inhibitors)</li> <li>9. Reproductive Pharmacology</li> <li>10. Agents effecting calcification and bone turnover</li> <li>11. Antimicrobial, antiviral, antiparasitic agents, disinfectants &amp; antiseptics</li> <li>12. Chemotherapy of neoplastic disease</li> <li>13. Immunomodulators</li> <li>14. Drugs used in Autoimmune disorder and Graft versus Host Disease</li> <li>15. Dermatological pharmacology</li> <li>16. Ocular pharmacology</li> <li>17. Use of drugs in pregnancy</li> <li>18. Perinatal and Paediatric Pharmacology</li> <li>19. Geriatric Pharmacology</li> <li>20. Dietary supplements and herbal medicines</li> <li>21. Miscellaneous</li> </ol>
<ol style="list-style-type: none"> <li>3. Experimental Pharmacology</li> </ol>	<ol style="list-style-type: none"> <li>1. Principles governing animal experimentation and their limitations in drug evaluations.</li> <li>2. General screening and evaluation of: Analgesic, anticonvulsant, antipyretic, antipsychotic, antidepressant, hypnotic, antiparkinsonian, anti-inflammatory, skeletal muscle relaxant, local anaesthetic, antihistaminic, hypoglycemic, antifertility, antitussive, antiulcerogenic, antitumor, diuretic, antiemetics. Antihypertensive, antianginal, antiarrhythmic, cardiotonic drugs.</li> <li>3. General principles of bioassay of drugs, methods of bioassay.</li> <li>4. Toxicity studies including acute, sub-acute and chronic toxicity studies including special toxicity studies (teratogenicity, carcinogenicity and mutagenicity)</li> <li>5. Basics of cell cultures techniques and in vitro cell culture based on drug toxicity testing.</li> <li>6. Evaluation of addicting liability of drugs, methods of studying intestinal absorption of drugs, methods of studying biotransformation and excretion of drugs.</li> </ol>

	<p>7. Basic principles and applications of simple analytical methods</p> <p>8. Principles of quantitative estimation of drugs, endogenous compounds and poisons using Colorimetry, Spectrophotometry, flame photometry, High Performance Liquid Chromatography (HPLC) and enzyme-linked immunosorbent assay (ELISA).</p>
<b>4. Biostatistics</b>	<ol style="list-style-type: none"> <li>1. Estimation Sample size for a clinical trial</li> <li>2. Elements of data collection and presentation of data</li> <li>3. Measures of central tendency and dispersion</li> <li>4. Non-parametric tests</li> <li>5. Parametric test</li> <li>6. Correlation and regression</li> <li>7. Meta-analysis</li> </ol>
<b>5. Clinical Pharmacology</b>	<ol style="list-style-type: none"> <li>1. The scope of clinical pharmacology and its relevance to optimum use of drugs.</li> <li>2. Preclinical data needed by regulatory authorities before undertaking clinical trial of a new drug.</li> <li>3. Clinical trials: GCP, protocol designing, placebos, phases of clinical trial – their purpose and methodology.</li> <li>4. Ethical aspects of clinical trials and studies of drugs in human beings. Get an exposure on the working of Institutional Ethics Committee</li> <li>5. Drug regulations: Drug regulatory requirements for clinical trials in India, drugs and cosmetic act, drug price control order</li> <li>6. Pharmacovigilance.</li> <li>7. Therapeutic drug monitoring: Dosage strategies, influence of hepatic, renal, cardiovascular, hormonal, gastrointestinal diseases and ageing on pharmacokinetics of drugs.</li> <li>8. Drug utilization studies, pharmacoconomics, rational prescribing and concept of essential drugs.</li> <li>9. Recent advances in the understanding of drug action and their future therapeutic relevance.</li> </ol>

### 3.2 Practical/ Skills (wherever applicable)

1. *In vivo* and *ex vivo* experiments in experimental animals using various instruments like organ bath, analgesiometer, physiography/ polygraph, convulsimeter, plethysmograph, learning and memory etc. as per CPCSEA guidelines.
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
  - ✚ Isolated rabbit/rat/ guinea-pig ileum/chicken ileum
  - ✚ Isolated rat uterus
6. Determination of EC<sub>50</sub>, ED<sub>50</sub>, pD<sub>2</sub> and pA<sub>2</sub> values of drugs
7. Perform *in vivo* experiments to study effect of mydriatics 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. Proficiency in using computer aided learning (CAL) programme for demonstration of effects of drugs on animals.
12. Demonstration of effect of various drugs on blood pressure in anaesthetized animal and demonstration of various phenomenon like vasomotor reversal of Dale, Tachyphylaxis, Potentiation, Nicotinic action of acetyl choline using CAL.
13. Estimation of drugs in plasma using HPLC/LCMS
14. Clinical pharmacology
  - a. Draft a protocol for different phases of clinical trials
  - b. Draft an IND and NDA application
  - c. Prepare Informed consent form and participant information sheet for research involving human participants
  - d. Writing a research proposal involving humans for IEC approval.
  - e. Evaluate promotional drug literature
  - f. Prepare “Drug Information Sheet” (WHO criteria)
  - g. Interpret bioavailability parameters with the help of given PK data
  - h. Report Serious Adverse Effect (SAE)
  - i. Perform causality assessment and report ADR to NCC, as per the norms of pharmacovigilance Programme of India (PvPI)
  - j. Estimation of drug concentration in serum under Therapeutic drug monitoring (TDM) and its clinical correlation

#### 4. PG activity programme

S. No	Activity	Frequency
1	Seminar	Once a week
2	Journal club	Once a week
3	Practical	Once a week
4	Case discussions	Once a month
5	Drug review	Once a month
6	Theory classes by faculty	Once in 2 months

**Note:** The above will be in addition to routine departmental activities and undergraduate teachings (details of teaching methods may be given as annexure if applicable)

#### 5. Rotations/postings

S. No	Department (Internal/External)	Duration & timing	Rotation objectives
A	<b>Internal</b>		
1	Medicine (Internal)	15 days (3-5 pm)	<ol style="list-style-type: none"> <li>To learn/exposure regarding how to carryout prescription analysis for the rationale use of drugs</li> <li>To learn about gaps in theory &amp; practice of medicine especially regarding medication use process</li> <li>To learn how to identify, collect, &amp; report an ADR or any other drug related problems</li> </ol>
2	Surgery (Internal)	15 days (3-5 pm)	<ol style="list-style-type: none"> <li>To learn regarding the practical aspect of drugs used in perioperative period</li> <li>To follow/learn the rationale for the use of different antimicrobials as a surgical prophylaxis</li> </ol>
3	Microbiology	7 days	<ol style="list-style-type: none"> <li>To learn the concepts of Bacteriological sensitivity testing</li> <li>To learn principles and application of Antibiotic stewardship programme</li> </ol>
4	Hospital drug store	2 months	<ol style="list-style-type: none"> <li>To learn about the practical aspects of drug store management (Inventory policy, storage, policy &amp; procedures for the storage of <b>high-risk medicines</b>, emergency</li> </ol>

			<p>medicines</p> <ol style="list-style-type: none"> <li>To learn regarding the policies &amp; procedures for the use &amp; disposal of Narcotic medicines</li> <li>To have an exposure on stock audit, drug recall &amp; near expiry drugs handling related procedures</li> </ol>
<b>B</b>	<b>External</b>		
1	Pharma industry/CRO- Internship program	2 months	<ol style="list-style-type: none"> <li>To know about the various aspects of conducting clinical trials</li> <li>To get familiarize with the roles &amp; expected competencies of medical pharmacologist in an industry</li> <li>To learn/have an exposure on various submission timelines with regarding to the IND</li> </ol>

## 6. Dissertation

Activity	January admission	July admission
Selection of topic in consultation with PG Guide	March / April	September / October
Approval by Department PG Committee		
Institute Scientific Committee approval	May / June	November / December
Institute Ethics Committee approval		
Final approval letter by Academics Section	30 <sup>th</sup> June	31 <sup>st</sup> December
Final submission to academic section	At least six months prior to the scheduled examination	

## 7. Assessment plan

7.1 **Six monthly reports:** as per standard format. Format to be attached as annexure

7.2 List of certifiable skills:

Sl. No	Certifiable skills
1	Critical appraisal of published journal article
2	Evaluate promotional drug literature
3	Write a scientifically sound & ethically correct protocol for a clinical study
4	To fill, assess and report an ADR by using the format designed by NCC

5	Comment on the rationality of various fixed dose combination used in therapy
6	To design an informed consent form for the proposed study
7	Audit of prescriptions for the various components as per norms
8	Interpretation & calculation of bioassay tracing given by using both methods
9	To choose a drug for the given condition by using P drug concept

### 7.3 Formative Assessment

#### 7.3.1 Theory

S.N.	Schedule	Marks
1.	At end of First year	100 (1 Paper)
2.	At end of Second year	100 (1 Paper)
3.	Pre-professional	400 (4 Papers of 100 marks each)
	Total	600 Marks

#### 7.3.2 Practical

S.N.	Schedule	Marks
1.	At end of First year	100
2.	At end of Second year	100
3.	Pre-professional	400 (Practical 300 + Viva 100)
	Total	600 marks

#### **Eligibility for Professional assessment:**

- Candidate should secure a minimum of 40% marks in Theory and Practical separately in formative assessments, in order to be eligible to appear for Professional Examination
- At least four out of six-monthly progress report should be satisfactory
- Acceptance of Dissertation is mandatory
- Successful completion of Research Methodology programme at induction
- The post graduate students would be required to present one poster presentation, to read one paper at a national/state conference and to submit one research paper for publication/ during period of their postgraduate studies.

## 7.4 Final Professional Assessment

A	Theory	4 Papers each of 100 marks = 400 marks
B	Practical	Practical/ Clinical Case + Viva = 400 marks

### **Note:**

(A) Minimum 40% marks in each paper and aggregate of 50% marks in order to be declared pass in theory exam

(B) Minimum 50% marks required in Theory & Practical separately, in order to be declared successful in summative exam

## 8. Recommended Reading

### 8.1 Books (Latest edition)

1. Brunton LL, Hilal-Dandan R, Knollmann BC. Goodman & Gilman's The Pharmacological Basis of Therapeutics; 13<sup>th</sup> Ed, McGraw-Hill Education: New Delhi, 2018.
2. Katzung BG, Vanderah TW. Basic and Clinical Pharmacology; 15<sup>th</sup> Ed, McGraw-Hill Education: New Delhi, 2021 (ISBN: 978-1-264-25863-5)
3. Shargel L, Andrew B.C. Yu. Applied biopharmaceutics and pharmacokinetics; 7<sup>th</sup> Ed, McGraw-Hill Education: New Delhi, 2016
4. Ghosh MN. Fundamentals of experimental pharmacology; 7<sup>th</sup> Ed, Hilton & Company: Calcutta, 2019 (ISBN: 9788190296507)
5. Tripathi KD. Essentials of Medical Pharmacology; 8<sup>th</sup> Ed, Jaypee Brothers Medical Publishers (P) Ltd: New Delhi, 2019 (ISBN: 978-93-5270-499-6)
6. Satoskar RS, Rege NN, Tripathi RK, Kamat SK. Pharmacology and Pharmacotherapeutics; 26<sup>th</sup> Ed, Elsevier India: Mumbai, 2020
7. Ritter JM, Flower R, Henderson et.al. Rang and Dale's Pharmacology; 9<sup>th</sup> Ed, Elsevier, 2020
8. Vogel HG. Drug Discovery and Evaluation: Pharmacological Assays; 3<sup>rd</sup> Ed, Springer International Publishing AG: Berlin, 2007 (ISBN: 3540714200)
9. Gupta SK. Drug Screening Methods; 3<sup>rd</sup> Ed, Jaypee Brothers Medical Publishers (P) Ltd: New Delhi, 2016 (ISBN: 9789351529828)
10. Medhi B, Prakash A. Practical Manual of Experimental and Clinical Pharmacology; 2<sup>nd</sup> Ed, Jaypee Brothers Medical Publishers (P) Ltd: New Delhi, 2017 (ISBN: 9386150727)
11. Brown M, Sharma P, Bennett P. Clinical Pharmacology; 12<sup>th</sup> Ed, Elsevier India, 2018
12. Jameson JL, Fauci AS, Kasper DL, Hauser SL, Longo DL, Loscalzo J. Harrison's Principles of Internal Medicine; 21<sup>st</sup> Ed, McGraw-Hill Education, 2021
13. Sarkar S, Srivastava V, Mohanty M. Postgraduate Pharmacology; 1<sup>st</sup> Ed, Paras Medical Publisher, 2020 (ISBN: 9788181915214)
14. Maiti R. Postgraduate Topics in Pharmacology; 3<sup>rd</sup> Ed, Paras Medical Publisher, 2020
15. Sharma HL, Sharma KK. Principles of pharmacology; 3<sup>rd</sup> Ed, Paras Medical Publisher, 2017

## **8.2 Journals**

1. Annual Review of Pharmacology and Toxicology
2. British Journal of Pharmacology
3. British Journal of Clinical Pharmacology
4. Clinical Pharmacology and Therapeutics
5. Drugs
6. European Journal of Clinical Pharmacology
7. Fundamental and Clinical pharmacology
8. Indian Journal of Pharmacology
9. Indian Journal of Physiology & Pharmacology
10. Journal of Pharmacology and Experimental Therapeutics
11. Pharmacological Reviews
12. The new England journal of Medicine
13. Trends in Pharmacological Science