

## **COURSE CURRICULUM( MD Pharmacology)**

The purpose of PG education is to create specialists who would provide high quality health care and advance the cause of science through research & training. Pharmacology consists of both the experimental (basic) and clinical sciences. Experimental pharmacology is essential to understanding of drug action in diseases as well as for the pharmaceutical industry for drug discovery and development. Clinical pharmacology is essential for prescribing practice in medicine, adverse drug reactions, clinical trial and pharmacovigilance. The job prospects for a medical pharmacologist are in academics, pharmaceutical industry/clinical research organization, government research institutions, in regulatory bodies and as scientific writer or science manager. Accordingly, a post graduate (MD) student in Pharmacology should be competent to meet the job requirements at all these places.

### **SUBJECT SPECIFIC LEARNING OBJECTIVES**

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

#### **1. 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.

#### **2. 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.

#### **3. 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.

### **SUBJECT SPECIFIC COMPETENCIES**

The student during the training program should acquire the following competencies:

#### **A. Cognitive domain**

1. 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.
2. Explain pharmacodynamics and pharmacokinetics of drugs.
3. Describe mechanisms of drug-drug interactions and their clinical importance.
4. Apply and integrate knowledge of pathophysiology of diseases and its modulation by drugs.
5. Acquire knowledge on pharmacogenetics and pharmacogenomics
6. Acquire knowledge on principles of pharmacoeconomics
7. Acquire knowledge on pharmacoepidemiology, including drug utilization studies.
8. Acquire knowledge and understanding of principles of Good clinical practice (GCP) and Good laboratory practice (GLP) guidelines
9. Acquire knowledge on essential medicines
10. Acquire knowledge on pharmacovigilance
11. Acquire knowledge and apply the principle of biostatistics in the evaluation and interpretation of drug safety and efficacy studies
12. Describe how to evaluate, analyse and monitor preclinical and clinical data in drug discovery

13. Able to integrate principles of immunology in biochemistry.
14. 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.
15. 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
16. Demonstrate knowledge about computer assisted learning (CAL) software and ability to use them efficiently to promote learning of pharmacology.
17. Demonstrate knowledge of principles of Instrumentation.
18. Demonstrate knowledge about recent advances and trends in research in the field of pharmacology and clinical pharmacology.
19. Acquire knowledge on generic drugs and generic prescription.
20. Acquire knowledge on rational use of drugs and prescription auditing
21. Acquire knowledge about antimicrobial stewardship programs and strategies for containment of antibiotic resistance
22. Acquire knowledge on animal toxicity studies
23. Acquire knowledge on common poisoning
24. Acquire knowledge on the legal and ethical issues involved in drug development and research.
25. Acquire knowledge in Biostatistics including use of statistical softwares : ☐ Estimation Sample size for a clinical trial ☐ Scales of measurement, data display, measures of central tendency (mean, median, mode) ☐ Dispersion of data (variance, standard deviation) ☐ Selection of tests (of significance) and their applicability ☐ Correlation and regression analysis ☐ Basics of systematic reviews and meta-analysis

## **B. Affective domain**

1. Effectively explain to patients, the effects and side effects of drugs, including the need for medication adherence.
2. 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.
3. Demonstrate respect in interactions with peers, and other healthcare professionals.
4. Demonstrate ethical behaviour and integrity in one's work.
5. Demonstrate ability to generate awareness about the use of generic drugs in patients.
6. 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.

## **C. Psychomotor domain**

1. Able to predict efficacy and adverse effects associated with use of drugs, along with causality assessment.
2. Demonstrate skills for prescription writing.
3. Perform major in vivo and in vitro animal experiments.
4. Observe and understand basic principles of working of important advanced techniques, like High Performance Liquid Chromatography (HPLC).
5. Demonstrate standard operating procedures of various methods and techniques used in clinical trials and research.
6. Determine levels of common poisons in blood

7. Demonstrate presentation skills at academic meetings, publications and writing research projects for funding agencies.
8. 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, convulsimeter, 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
  - i). Isolated rabbit/rat/ guinea-pig intestine
  - ii). 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 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)

Animal Experiments: All animal experiments must be compliant with Govt. of India regulations, notified from time to time. Amphibian/Dog/Cat experiments should be conducted by computer assisted simulation models/ facilities. Other experiments should be performed as permissible by CPCSEA guidelines

## Syllabus

The course contents should cover the following broad topics:

1. Basic and molecular pharmacology
2. Drug receptors and Pharmacodynamics
3. Pharmacokinetics (Absorption, Distribution, Metabolism and Excretion)
4. Biotransformation
5. Pharmacogenomics and Pharmacogenetics
6. Autonomic Pharmacology
7. Drugs acting on Smooth muscles
8. Clinical pharmacology
9. Drug development and Regulations
10. Clinical Pharmacokinetics

11. Drugs acting on Synaptic and Neuroeffector Junctional sites
12. Drugs acting on 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)
13. Drugs modifying renal function
14. Drugs acting on cardiovascular system and haemostatic mechanisms (Antihypertensives, Antianginal, Antiarrhythmics, Drugs used in heart failure, Drugs used in Dyslipidemias, Fibrinolytics, Anticoagulants, Antiplatelets)
15. Reproductive Pharmacology
16. Agents effecting calcification and bone turnover
17. Autacoids and related pharmacological agents (NSAIDs) and drugs used in Rheumatoid arthritis and Gout
18. Gastrointestinal drugs
19. Pharmacology of drugs affecting the respiratory system (drugs used in Bronchial Asthma and COPD)
20. Antimicrobial, antiparasitics, disinfectants, antiseptics
21. Chemotherapy of neoplastic disease
22. Antiviral drugs
23. Drugs used in Autoimmune disorder and Graft versus Host Disease)
24. Dermatological pharmacology
25. Ocular pharmacology
26. Use of drugs in pregnancy
27. Perinatal and Pediatric Pharmacology
28. Geriatric Pharmacology
29. Immunomodulators - immunosuppressants and immunostimulants
30. 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)
31. Drug delivery systems
32. Heavy metal poisoning
33. Non-metallic toxicants - air pollutants, pesticides etc.
34. Research methodology and biostatistics
35. Literature search.
36. Pharmacogenomics, Pharmacovigilance (ADR reporting), pharmacoconomics (cost-effectiveness study) and pharmacoepidemiology
37. Over the counter drugs
38. Dietary supplements and herbal medicines
39. Pharmacometrics - methods of drug evaluation.
40. General screening and evaluation of:
  - ☐ Analgesics, antipyretics, anticonvulsants, anti-inflammatory drugs, antidepressants, anti-anxiety and antipsychotics, sedatives, muscle relaxants, antihypertensives, hypocholesterolaemic agents, antiarrhythmics, diuretics, adrenergic blocking drugs
  - ☐ Drugs used in peptic ulcer diseases/Prokinetic agents/antiemetics
  - ☐ Antitussives, /anti-asthma agents
  - ☐ Local Anaesthetics
  - ☐ Oxytocics, antifertility agents
  - ☐ Antidiabetics Behavioral pharmacology models and evaluation of drugs affecting learning and memory
41. Bioassays
  - ☐ Bioassay methods
  - ☐ Animal experiments: Ethical considerations, ethical approval, applicable regulatory Guidelines (CPCSEA), humane animal research (principles of 3Rs) and alternatives to animal experimentation. General and statistical considerations
  - ☐ Anesthetics used in laboratory animals
  - ☐ Principles of EC50, ED50, pD2 and pA2 values of drugs
  - ☐ Describe methods of bioassay for estimation of : Acetylcholine, skeletal neuromuscular junction blockers, adrenaline, noradrenaline, histamine, 5 HT, hormones, insulin, vasopressin/oxytocin, estrogen, progestins, ACTH
  - ☐ Competitive antagonism - pA2 values
  - ☐ Immunoassays: Concept, types of bioassays and their application/s
  - ☐ Animal

experiments: Ethical consideration, ethical approval ☒ Regulatory Guidelines (CPCSEA) and alternatives to animal experimentation

#### 42. Biochemical Pharmacology

☒ Basic principles and applications of simple analytical methods ☒ 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).

- i). Evaluation of drugs in healthy volunteers as well as patients
- ii). Critical evaluation of drug literature, pharmacoconomics, pharmacovigilance and pharmacoepidemiology.
- iii). Thesis on a suitable problem
- iv). Training in undergraduate teaching
- v). Computer training

During the training programme, patient safety is of paramount importance; therefore, skills are to be learnt initially on the models, later to be performed under supervision followed by performing independently; for this purpose, provision of skills laboratories in medical colleges is mandatory.