

SYLLABUS OF PHARMACOLOGY FOR POSTGRADUATE MEDICAL STUDENTS

GOAL

The future prospects for a medical pharmacologist may be in academics, pharmaceutical industry/clinical research organization, research institution and in regulatory bodies, 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.

OBJECTIVES

Keeping in view the possible functions of a medical post-graduate in Pharmacology, the postgraduate student in pharmacology should acquire the following capabilities under the described domains.

(i) Knowledge:

1. Possess a sound knowledge of the subject in the following areas:
 - i) Basic principles of pharmacology (including molecular pharmacology); understanding of basic sciences relevant to Pharmacology
 - ii) Process of new drug development
 - iii) Clinical pharmacology (including clinical pharmacokinetics, individualization of drug therapy, drug use in special categories, adverse drug reactions and drug-drug interactions)
 - iv) Systemic pharmacology
 - v) Principles of essential drugs and rational use of medicines
 - vi) Pharmacoeconomics
 - vii) Pharmacoepidemiology
 - viii) Pharmacovigilance
 - ix) Pharmacogenomics
 - x) Research methodology (animal as well as clinical)
 - xi) Biostatistics
 - xii) Commonly used laboratory techniques, analytical methods and instrumentation
 - xiii) Major national health problems and programmes
 - xiv) Drug regulations in India and abroad and National Drug Policy
 - xv) Teaching technology
 - xvi) Methods of communication and medical writing.

(ii) Skills:

The student should acquire the skills that are commensurate with the expected knowledge as outlined above. Some of the desirable skills are:

- (i) Performing commonly employed experiments and clinical techniques in Pharmacology and drug research
- (ii) Plan and conduct toxicity studies and clinical trials
- (iii) Formulate and undertake research projects independently including statistical analyses
- (iv) Perform a number of service activities e.g. therapeutic drug monitoring, pharmacovigilance, pharmacoeconomics and pharmacoepidemiology

- (v) Perform various teaching and training activities for undergraduate and post-graduate medical students and others with a sound understanding of the modern tools of teaching technology.
- (vi) Be conversant with the adequate communication skills of both the written and verbal nature (e.g. publishing scientific papers, training doctors, paramedics, patients and public regarding relevant aspects of pharmacotherapy).
- (vii) Be proficient in use of computers in various aspects of their day to day work.
- (viii) Be able to analyze and evaluate a research paper
- (ix) Be able to formulate and conduct problem based teaching/learning exercises
- (x) Be capable of various managerial skills e.g Drug store management in a hospital; organization of workshops/training programmes etc.
- (xi) Be aware of the legal and ethical issues involved in drug development and research.
- (xii) Be able to constitute and conduct the proceedings of various committees e.g. IAEC, IEC, DTC etc.

This list is not exhaustive and can be expanded to include all those skills that may be deemed fit to meet the desired expectations from a medical/clinical pharmacologist.

Attitude:

The students should have developed an attitude to be objective, scientifically oriented and ethical towards drugs, drug use and drug research. They should also become a lifetime learner so as to be regularly updated about the advances in the field of Pharmacology.

COURSE CONTENTS

The post-graduate students in M.D (Pharmacology) shall undergo a 3 - year (6 terms of 6 months each) training that will comprise of the following:

1. Theory: (lectures, seminars, group discussion, journal review, etc.)
2. Practical training in the following suggested areas:

Experimental Pharmacology:

In vitro (including bioassays), in vivo (including common methods of drug evaluation) experiments and toxicity tests

Chemical Pharmacology:

Identification of drug/toxin by using chemical, biological and analytical tests.

Quantitative estimation- Use of colorimeter, spectrophotometer &/or other advanced analytical equipment

Clinical Pharmacology:

- Evaluation of drugs in healthy volunteers as well as patients
- Critical evaluation of drug literature, pharmacoeconomics, pharmacovigilance and pharmacoepidemiology etc.
 - Dissertation on a suitable problem
 - Training in undergraduate teaching
 - Computer training

A 6 month rotating posting will be allowed in the allied subjects, of which one month of casualty posting will be compulsory. A limited period (maximum 3 months) of internship during the course

may also be allowed in a pharmaceutical company/contract research organization or a state/national research laboratory/organization.

The syllabus will be based broadly on the following:

(A) KNOWLEDGE:

TEACHING –LEARNING ACTIVITIES

The P G students are to be encouraged to largely carry out self learning with the help of libraries and teachers. Preponderance of didactic teaching is to be avoided. They are expected to actively seek knowledge and skills on their own initiative. Sound knowledge of general and systemic pharmacology including therapeutics of graduate level is to be acquired by self-study and by participating in the teaching of graduate students.

1. P.G. Lectures, Seminars & Journal Club:

These are to be held once a week and are to include talks delivered by qualified faculty members of Pharmacology as well as allied disciplines. Topics of interest common to PGs of other basic and/or clinical disciplines (e.g. statistics, educational science, communication skills, information technology, biomedical ethics, human behavior) could be covered in programmes drawn out jointly with other departments. Suggested topics for multidisciplinary teaching (Appendix 1), PG lectures (Appendix 2) and PG seminars, experimental methods discussion. A timetable of these programmes should be drawn every 6 months. Each PG student should present at least 4-6 seminars every year and actively participate in seminars presented by other PGs.

2. Practical exercises:

The PG students will perform experimental pharmacology and chemical pharmacology exercises once a week under the supervision of a faculty member, who will also hold a group discussion on the exercise after it is completed. On other days, PGs should repeat the experiment until they acquire adequate skill and dexterity in the technique. The PGs should be encouraged to develop confidence in handling laboratory animals and instruments. The PGs will maintain a detailed record of the exercises performed by them and get it checked by a faculty member.

3. Thesis (Dissertation)

Each PG student will carry out research work under the supervision of a faculty member of the pharmacology department who is recognized as per M.C.I. guidelines. One or more co-guides may be appointed from the same or other departments when the work involves multidisciplinary participation. The purpose of this activity is to train the student in all aspects of scientific research and scientific communication, which includes identification of a problem/lacuna in knowledge, hypothesis formulation, literature search, study designing, learning the techniques and execution of the study, data collection, statistical analysis, drawing inferences and writing up the thesis/papers.

4. Teaching

The PG students are to participate in all aspects of graduate teaching, specially practicals, demonstrations and tutorials. In the first 6 months they should be attached to senior group teachers. Subsequently they should be given independent charge of a group. One or two graduate lecture classes should also be allocated to each PG student in the 2nd and 3rd year of course. A faculty member should attend these lectures and give constructive suggestions for improvement.

5. Intradepartmental postings

Every PG student should be posted by rotation to the different sections/laboratories of the Pharmacology department, viz. experimental pharmacology, pharmacy, chemical pharmacology and drug assay, clinical pharmacology including ADR monitoring and drug information service, toxicology.

A 2 weeks part time posting to the hospital pharmacy should be arranged so that the PG student could learn drug procurement, storage, record keeping, dispensing and quality control. A record of the observations made and lessons learnt should be maintained by the students.

6. Posting in allied disciplines

Every PG student should be posted for 2 weeks each to the physiology, biochemistry, microbiology and medicine departments on part time basis to learn the techniques and instrumentation being used in these departments. The schedule for these postings should be drawn every year in consultation with these departments.

7. Ward rounds

In consultation with major clinical departments, arrangement should be made that the PG students of pharmacology attend the ward rounds once a week to get an exposure to the trends in the use of drugs.

8. Conferences/Workshops

The PG students should be encouraged to attend national/regional pharmacology conferences. Attendance at a minimum one conference during the 3 year course is mandatory. Credits should be given for attending more conferences and making poster/oral presentations at these. At least one research paper should be Published/Communicated/Accepted.

Theory covering the following broad topics:

1. Basic & molecular pharmacology
2. Biochemical pharmacology
3. Clinical pharmacology
4. Clinical Pharmacokinetics
5. Drugs acting on Synaptic & Neuroeffector junctional sites
6. Drugs modifying renal function
7. Drugs acting on cardiovascular system and haemostatic mechanisms
8. Reproductive Pharmacology
9. Pharmacology of endocrines
10. Agents effecting calcification and bone turnover
11. Autacoids and related pharmacological agents
12. Gastrointestinal drugs
13. Pharmacology of drugs affecting the respiratory system
14. Chemotherapy of microbial and parasitic diseases
15. Chemotherapy of neoplastic disease
16. Dermatological pharmacology
17. Ocular pharmacology
18. Immunomodulators – immunosuppressants and immunostimulants

19. Pharmacology of drugs used in metabolic syndromes
20. Drug delivery systems
21. Heavy metals and heavy metal antagonists
22. Non-metallic toxicants – Air pollutants, pesticides etc.
23. Research methodology and biostatistics
24. Literature search.
25. Pharmacogenomics
26. Gene therapy
27. Stem cell research
28. Pharmacometrics-Methods of Evaluation

(B) EXPERIMENTAL SKILLS.

[1] Experimental Pharmacology

1. General:

- Study of some basic instruments used for isolated tissue experiments
- Study of some basic animal techniques:
- Techniques for injection of drugs and collection of blood samples, feeding of animals, etc.
- Techniques of Euthanasia
- Different laboratory animals and their application in experimental pharmacology, breeding data, housing and maintenance and animal feeds
- Preparation and administration of a drug solution in appropriate strength and volume.

2. In vitro Experiments:

- A) Dose Response curves of agonists on various biological tissues
- B) Effects of drugs on various biological tissues like:
 - Isolated Rabbit/Guinea-pig/Rat Intestine
 - Isolated rat uterus
 - Isolated Guinea pig tracheal chain (histamine and histamine antagonists on cumulative DRC)
 - Langendorff's heart preparation (Study of different drugs on isolated perfused rabbit heart).
- C) Bioassay (by using different methods):
 - Adrenaline on Rabbit/Guinea-pig/Rat intestine/duodenum
 - Histamine on Guinea-pig ileum / Tracheal chain
 - Acetylcholine on rat colon
 - Mepyramine on guinea pig ileum
 - 5-HT on rat fundus strip and estrogen primed rat uterus
- C) Demonstration of competitive antagonism using suitable in vitro methods
- E) Determination of EC₅₀, ED₅₀, pD₂ and pA₂ values of drugs

3. In vivo Experiments:

- Study of drugs using various psychopharmacological techniques
- Effect of mydiatics and miotics on rabbit eye

- Study of CNS stimulants and depressants using photoactometer
- Study of antiepileptic drugs by using animal models of epilepsy
- Study of analgesics using animal methods of analgesia
- Study of anti-inflammatory drugs using carageenin induced rat paw edema and other methods if possible
- Study of histamine aerosol induced bronchospasm and its antagonism by antihistamines
- Administration of drugs by various routes
- Collection of blood from animals

4. **Anaesthetized animal studies:**

- Anesthetics used in laboratory animals
- Recording of blood pressure and respiration of anesthetized animals and Identification of unknown drug based on responses
- Sacrificing anesthetized animals
- Demonstration of head drop with dTC and its reversal
- Study of local anesthetics by various animal techniques

[2] **Biochemical Pharmacology**

- Preparing standard operative practice for Bioavailability and bioequivalence studies
- Introduction to simple analytical methods-Basic principles and applications
- Quantitative estimation using Colorimetry and Spectrophotometry, flame photometry, HPLC and ELISA.
- Toxicological Studies using chemical and biological tests
- Identifying toxic drugs using chemical and biological tests (alkaloids, glycosides, steroids, barbiturates, salicylates)

[3] **Clinical Pharmacology**

- Preparation of protocol for human experiments/clinical trials
- Preparation of “Informed consent form” for human experiments
- Evaluation of promotional drug literature
- Preparation of “Drug Information Sheet” (WHO criteria)
- Interpretation of bioavailability parameters with the help of given pharmacokinetics data

[4] **Clinical Pharmacy**

- Dosage forms and calculations
- Evaluation of fixed dose combinations and Rational Drug Therapy
- Instructions for use of dosage forms
- Preparing instructions for patients regarding use of some drugs

[5] **Computer Skills:**

- Use of audio-visual aids
- Use of computers in biomedical research
- Computer assisted learning
- Computer based illustration and data presentation

[6] **Research Methodology:**

- Literature search and bibliography
- Data management and presentation
- GCP and GLP

- Formulation of research topic, study design, blinding procedures and protocol writing
- Ethical principles of animal & human experimentation. Publication ethics

[7] Biostatistics:

- Sampling techniques, randomization, sample size estimation
- 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
- Statistical software

EVALUATION

Dissertation:

- Assessment by 2 independent assessors
- Acceptance of dissertation is a precondition for appearing at Final Examination

Day to day evaluation will be based on:

- Regularity in attendance (minimum attendance 80% per term)
- Performance in Seminars, journal reviews etc.
- Performance in practical exercises
- Participation in conferences, workshops etc.
- Regular record keeping: The student will keep regular record of all activities in the form of a log book including attendance of lectures, seminars, conferences / workshops, records of paper presented and a practical journal

Final (summative) evaluation:

(A) Theory:

Total 4 papers Of 100 marks each. Each question paper to have 5 questions and each question to have 2 parts. Division of topics may be as follows:

Paper-1: General Pharmacological Principles & Allied Sciences 100 marks

Theories and mechanism of drug action, Pharmacokinetic principles and parameters, Factors modifying drug action, Pharmacogenetics, Chronopharmacology, Adverse effects of drugs, Drug dependence, Toxicology, Dose response relationships, Structure-activity relationships, Physiological and biochemical basis of drug action, Etiopathogenesis of diseases relevant to therapeutic use of drugs, basic microbiology, Immunology and molecular biology, History of pharmacology, sources of drug information and Use of information technology.

Paper-2 systemic Pharmacology, Chemotherapy and Therapeutics 100 marks

Pharmacology of drugs acting on autonomic, peripheral and central nervous systems; cardiovascular, endocrine, respiratory, renal, gastrointestinal and haemopoietic systems, treatment of diseases affecting these systems. Pharmacology of anti-microbial and anti-parasitic drugs and treatment of infective diseases; cancer chemotherapy, immunopharmacology, gene therapy and evidence based medicine.

Paper-3 Experimental Pharmacology, Bioassay and Statistics 100 marks

Experimental methodologies involved in the discovery of drugs (in vivo, in vitro, ex vivo). Animal handling and animal care. Methods of anaesthetizing animals and methods of euthanasia. Restraining and blood collection methods. Drug screening methods.

Paper-4 Clinical Pharmacology Recent Advances **100 marks**

Development of new drugs, protocol designing, phases, methodology and ethics of clinical trials, clinical pharmacokinetics and pharmacodynamic studies, post marketing surveillance, therapeutic drug monitoring, pharmacovigilance, ADR monitoring, Drug information service, drug utilization studies, therapeutic audit, essential drug concept and rational prescribing, GLP and GMP. Recent advances in understanding of mechanism of drug action and treatment of diseases; new drugs and new uses of old drugs.

400 marks

(B) PRACTICAL: **Total - 500 marks**

a) Long Experiment: **(200 marks)**

Demonstrating effects of drugs/interpretation of results in anesthetized animal 150marks

Table exercise – Examples are given below: **50 marks**

- Calculating bio-availability parameters
- Statistical exercise
- Critical appraisal of a published paper
- Evaluation of drug literature.
- Protocol designing
- Designing a proforma for ADR monitoring
- Assessment of preclinical toxicity data
- Analysis of rational and irrational formulations

b) Short experiment **(200 marks)**

- Isolated tissue experiment (Bioassay of drugs) 150 marks
- In vivo experiment 50 marks

c) Grand Viva **(100 marks)**

- Microteaching 20 marks
- Discussion on dissertation 20 marks
- Principles of general and systemic pharmacology 40 marks
- Recent advances in pharmacology & drug therapy 20 marks

Internal Assessment **(100 marks)**

Number of examiners: a minimum of Six examiners: 3 external & 3 internal. Passing Standard: 50% independently in theory and practical examinations.

Appendix - 1

Multidisciplinary topics

1. Biostatistics: Sampling techniques, randomization, sample size estimation, scales of measurement, data display, measures of central tendency (mean, mode, median) dispersion of data (variance, standard deviation, standard error), bias, tests of significance, selection of tests and their applicability, correlation, regression analysis, statistical software.
2. Literature search: different methods (including computer database) with their advantages and limitations
3. Organization of data; data checking, data cleaning, transformation of data, raw and derived data
4. Formulation of research topic, study design, blinding procedures, protocol writing, placebos
5. Good laboratory practices (GLP) and good clinical practices (GCP)
6. Ethical principles of animal and human experimentation, ethical clearance procedures, consent forms and information sheets, publication ethics
7. Educational sciences: Teaching-learning concepts, teaching-learning methods, learning resource materials, audio visual aids, educational objectives and curriculum development, communication skills, evaluation methods (essay type and multiple-choice questions), item analysis etc.
8. Use of computer in biomedical research; computer assisted learning; computer based illustration and data presentation.
9. Care and breeding of laboratory animals
10. Human behavior
11. Scientific writing and publication skills

Appendix – 2

General screening and evaluation of:

- Analgesics, antipyretics, anticonvulsants, anti-inflammatory drugs, antidepressants, antianxiety & antipsychotics antiarrhythmics,
- Hypotensives/antihypertensives, hypocholesterolaemic agents, diuretics, adrenergic blocking drugs
- Gastric acid secretion/antiulcer drugs
- Antitussives, bronchodilators
- Local Anaesthetics
- Oxytocics, antifertility agents
- Hypoglycemics/antidiabetics
- Antileprosy,
- Anti-TB,
- Anti-Cancer
- Antihistaminics
- Antimalarials
- Anti-HIV
- Antihelminthics
- Antiparkinsonism
- Alzheimers disease
- Pyrogen testing
- Sedatives & hypnotics

Bioassay

- Bioassay methods
- General & statistical considerations
- Methods of bioassay for:
Acetylcholine, skeletal neuromuscular junction blockers, adrenaline, noradrenaline, histamine, 5HT, hormones, insulin, vasopressin/oxytocin, estrogen, progestins, ACTH
- Competitive antagonism- pA_2 values
- Radio immunoassay: Basic Concepts & applications, ELISA
- Animal experiments – Legal and Ethical considerations

Educational Science:

- Teaching learning concept
- Teaching learning methods including problem based learning (PBL)
- Learning resource materials
- Instructional aids
- Educational objectives and curriculum development
- Communication skills
- Evaluation methods (Essay type, SAQs, MCQs, item analysis etc)

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