GUIDELINES FOR COMPETENCY BASED POSTGRADUATE TRAINING PROGRAMME FOR MD IN PHARMACOLOGY

Preamble

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.

The applied nature of the discipline, the move towards integrated course structures, the widening of discipline boundaries and increasing number of students seeking post graduation degree raise issues concerning maintaining and improving competency as along with maintenance of academic standards. These issues also necessitate integration with other biomedical and clinical disciplines. A pragmatic approach to postgraduate pharmacology teaching in India is an important step towards addressing the aforesaid challenges and facilitating a fresh curriculum design.

The purpose of this document is to provide teachers and learners illustrative guidelines to achieve defined outcomes through learning and assessment. This document was prepared by various subject-content specialists. The Reconciliation Board of the Academic Committee has attempted to render uniformity without compromise to purpose and content of the document. Compromise in purity of syntax has been made in order to preserve the purpose and content. This has necessitated retention of “domains of learning” under the heading “competencies”.

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. Aquire 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) softwares 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. Aquire 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 behavior 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, 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
    i) Isolated rabbit/rat/ guinea-pig intestine
    ii) Isolated rat uterus
6. Determination of EC50, ED50, pD2 and pA_2 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, Fibrionolytics, 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, adrenocorticid 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), pharmacoeconomics (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:
    - **A**nalgesics, antipyretics, anticonvulsants, anti-inflammatory drugs, antidepressants, antianxiety and antipsychotics, sedatives, muscle

relaxants, antihypertensives, hypocholesterolaemic agents, anti-arrhythmics, 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 pA_2 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 - pA_2 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 **o**f 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).

TEACHING AND LEARNING METHODS

Postgraduate teaching programme

Teaching methodology

Learning in a PG program is primarily self-directed and in Pharmacology consists of laboratory and academic work. The formal sessions are merely meant to supplement this

core effort. Acquisition of practical competencies thus becomes the cornerstone of postgraduate medical education in Pharmacology.

Formal teaching sessions

- In addition to laboratory work, at least 6-hr of formal teaching per week is necessary. The departments may select a mix of the following sessions:

Journal club	Once a week
Seminar	Once a week
Practical	Once a week
Group Discussions	Once a week
Case discussions	Once a month
Interdepartmental case or seminar	Once a month

  Note: These sessions may be organized as an institutional activity for all postgraduates.
- Attend accredited scientific meetings (CME, symposia, and conferences).
- A postgraduate student of a postgraduate degree course in broad specialities/super specialities would be required to present one poster presentation, to read one paper at a national/state conference and to present one research paper which should be published/accepted for publication/sent for publication during the period of his postgraduate studies so as to make him eligible to appear at the postgraduate degree examination.
- Additional sessions on basic sciences, biostatistics, research methodology, teaching methodology, hospital waste management, health economics, medical ethics and legal issues related to experimentation are suggested.
- There should be a training program on Research methodology for existing faculty to build capacity to guide research and for keeping abreast with rapidly evolving methods and techniques in related disciplines.
- The postgraduate students shall be required to participate in the teaching and training programme of undergraduate students and interns.
- **Log book:** During the training period, the post graduate student should maintain a Log Book giving details of experimentation done and skills acquired. The log book shall be used to aid the internal evaluation of the student. The Log books shall be checked and assessed periodically by the faculty members imparting the training.
- Department should encourage e-learning activities.

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

I Theory: (lectures, seminars, group discussion, journal club) (at least 6 hours a week, daily 2 hours for 3 days)

II **Rotation:**

Practical training in the following suggested areas: (8 hours a week, daily 4 hours for 2 days)

- **Experimental Pharmacology:**
  In vitro (including bioassays), *in vivo* (including common methods of drug evaluation) experiments, computer simulations and toxicity tests
- **Chemical Pharmacology:**
  Identification of drug/toxin by using chemical, biological and analytical tests.
  Quantitative estimation - Use of colorimeter, spectrophotometer and/or other advanced analytical equipments
- **Clinical Pharmacology:**
  I Evaluation of drugs in healthy volunteers as well as patients
  II Critical evaluation of drug literature, pharmacoeconomics, 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.

ASSESSMENT

FORMATIVE ASSESSMENT ie., assessment during the training

Formative assessment should be continual and should assess medical knowledge, patient care, procedural & academic skills, interpersonal skills, professionalism, self directed learning and ability to practice in the system.

General Principles

Internal Assessment should be frequent, cover all domains of learning and used to provide feedback to improve learning; it should also cover professionalism and communication skills. The Internal Assessment should be conducted in theory and practical/clinical examination.

Quarterly assessment during the MD training should be based on:

1. **Journal based / recent advances learning**
2. **Patient based /Laboratory or Skill based learning**
3. **Self directed learning and teaching**
4. **Departmental and interdepartmental learning activity**
5. **External and Outreach Activities / CMEs**

The student to be assessed periodically as per categories listed in postgraduate student appraisal form (Annexure I)

SUMMATIVE ASSESSMENT, ie., assessment at the end of training

The summative examination would be carried out as per the Rules given in POSTGRADUATE MEDICAL EDUCATION REGULATIONS, 2000.

The post graduate examination shall be in three parts**:**

1. **Thesis**

   Every post graduate student shall carry out work on an assigned research project under the guidance of a recognised Post Graduate Teacher, the result of which shall be written up and submitted in the form of a Thesis. Work for writing the Thesis is aimed at contributing to the development of a spirit of enquiry, besides exposing the post graduate student to the techniques of research, critical analysis, acquaintance with the latest advances in medical science and the manner of identifying and consulting available literature.

   Thesis shall be submitted at least six months before the Theory and Clinical / Practical examination. The thesis shall be examined by a minimum of three examiners; one internal and two external examiners, who shall not be the examiners for Theory and Clinical examination. A post graduate student shall be allowed to appear for the Theory and Practical/Clinical examination only after the acceptance of the Thesis by the examiners.

2. **Theory examination:**

   The examinations shall be organized on the basis of 'Grading'or 'Marking system' to evaluate and to certify post graduate student's level of knowledge, skill and competence at the end of the training. Obtaining a minimum of 50% marks in 'Theory' as well as 'Practical' separately shall be mandatory for passing examination as a whole. The examination for M.D./ MS shall be held at the end of 3rd academic year. An academic term shall mean six month's training period.

   There shall be four theory papers:

   Paper I: General Pharmacology

   Paper II: Clinical Pharmacology

   Paper III: Systemic Pharmacology

   Paper IV: Recent Advances in Pharmacology

3. **Practical/clinical and Oral/viva voce examination**

   Practical:

a) Long Experiment:

Demonstrating effects of drugs/interpretation of results in anesthetized animal Table exercise - Examples are given below:

- Calculating pharmacokinetic parameters
- Statistical exercise
- Critical appraisal of a published paper (abstract writing of a published paper)
- Evaluation of drug literature.
- Protocol designing
- ADR reporting and causality assessment
- Assessment of preclinical toxicity data
- Analysis of rational and irrational formulations

b) Short experiment

a. Isolated tissue experiment (Bioassay of drugs) (as per Govt regulations)

Or

interpretation of results of a previous tracing

b. *In vivo* experiment

c) Spotting exercises: Various drug delivery systems, inhalers, insulin syringe, drip chamber, various tablets, etc.

Oral/Viva voce Examination

Microteaching (teaching exercise)

Discussion on dissertation

Principles of general and systemic pharmacology

Recent advances in pharmacology & drug therapy

Recommended Reading Material

Books (latest edition)

1. Goodman & Gilman's The Pharmacological Basis of Therapeutics, ed. Laurence Brunton, Bruce A. Chabner, Bjorn Knollman.
2. Essentials of Medical Pharmacology, by KD Tripathi
3. Basic and Clinical Pharmacology, by Bertram G. Katzung and Anthony J. Trevor
4. Drug Discovery and Evaluation: Pharmacological Assays Editors: Vogel, Hans Clinical Pharmacology by Laurence, Bennett and Brown
6. Rang and Dale's Pharmacology by H.P. Rang
7. Koda Kimble and Youngs Applied Therapeutics by Brian K Alldredge and Robin L Corelli

Journals

03-05 international Journals and 02 national (all indexed) journals

Annexure 1

Postgraduate Students Appraisal Form

Pre / Para /Clinical Disciplines

Name of the Department/Unit :

Name of the PG Student :

Period of Training : FROM.....TO.....

Sr. No.	PARTICULARS	Not Satisfactory	Satisfactory	More Than Satisfactory	Remarks
		1 2 3	4 5 6	7 8 9	
1.	Journal based / recent advances learning				
2.	Patient based /Laboratory or Skill based learning				
3.	Self directed learning and teaching				
4.	Departmental and interdepartmental learning activity				
5.	External and Outreach Activities / CMEs				
6.	Thesis / Research work				
7.	Log Book Maintenance				

Publications **Yes/ No**

Remarks* _____
_____
_____
_____

***REMARKS: Any significant positive or negative attributes of a postgraduate student to be mentioned. For score less than 4 in any category, remediation must be suggested. Individual feedback to postgraduate student is strongly recommended.**

SIGNATURE OF ASSESSEE **SIGNATURE OF CONSULTANT** **SIGNATURE OF HOD**