BHARATI VIDYAPEETH
(DEEMED TO BE UNIVERSITY), PUNE

Faculty of Medical Sciences
MD - Pharmacology
New Syllabus

Bharati Vidyapeeth Deemed to be University, Pune

Faculty of Medical Sciences

Curriculum for MD in Pharmacology

As per Guidelines of

National Medical Commission

NATIONAL MEDICAL COMMISSION
Postgraduate Medical Education Board

D 11011/1/22/AC/Guidelines/PG 08 **Date: 01-08-2022**

GUIDELINES FOR COMPETENCY BASED POSTGRADUATE TRAINING PROGRAMME FOR MD IN PHARMACOLOGY

GUIDELINES FOR COMPETENCY BASED POSTGRADUATE TRAINING PROGRAMME FOR MD IN PHARMACOLOGY

Preamble

The purpose of the postgraduate (PG) education is to create specialists who would provide high quality education, health care and advance the cause of science through research and training.

Pharmacology consists of both experimental and clinical sciences. The experimental component is essential in understanding the drug action in diseases as well as for the research in drug discovery and development. Clinical application of pharmacology concepts is essential for rational prescribing practices, rational therapeutics, clinical trials, rational use of drugs including antimicrobials, pharmacovigilance and pharmacology consults.

The job prospects for a medical pharmacologist have evolved over time along with a congruent rise in the demand for trained pharmacologists in India, both in academics as well in other areas such as pharmacovigilance centres, regulatory bodies, national research institutes, pharmaceutical industry and as scientific writers or science managers. Hence, a PG student in Pharmacology should be competent to meet the growing challenges in job requirements at all levels in various fields and organizations.

Considering the emerging trends in pharmacology & therapeutics, clinical applications of the subject, its role in national programs, evolving integrated course schedules while broadening the subject scope and number of students seeking to join the PG degree in pharmacology, there is huge demand to standardize and update PG curricular components including competencies, teaching learning methods and assessment methods in the MD pharmacology course in India. This requires integration of pharmacology with other sciences including basic, para-clinical and clinical disciplines.

A pragmatic approach to postgraduate pharmacology teaching in India is a key step towards addressing the aforesaid challenges and facilitating a fresh curriculum design. The purpose of this document is to provide teachers and learners comprehensive guidelines to achieve the defined competencies through various teaching-learning and assessment strategies. This document was prepared by various subject and education experts of the national Medical Commission. The subject Expert Group has attempted to render uniformity without compromising the 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 (GOALS)

At the end of the MD training programme in Pharmacology, the student should meet the following goals:

1. **Acquisition of knowledge**

The student should be able to clearly explain concepts and principles of pharmacology and therapeutics, drug development processes, the drugs and cosmetics act, rational use of drugs, antimicrobial resistance, pharmacovigilance, pharmacy, health economics, clinical trial processes and relevant national programs.

2. **Acquisition of Skills**

The student should be able to develop and apply skills in pharmacology-based services (e.g. rational prescribing), in self-directed learning for evolving educational needs and scientific information, in conduct of research and in managerial assignments in the department/institution.

3. **Teaching and training**

The student should be able to effectively teach and assess undergraduate medical students (MBBS) and allied health science courses (Dentistry, Nursing, Physiotherapy) so that they become competent healthcare professionals and are able to contribute to training of undergraduates (UG) and postgraduates.

4. **Research**

The student should be able to conduct a research project (in both basic and clinical pharmacology) from the planning to the publication stage and be able to pursue academic interests and continue life-long learning to become a more experienced teacher & mentor in all the above areas and to eventually be able to guide postgraduates in their thesis, research work and all other academic activities.

5. **Professionalism, Ethics and Communication skills**

The student should be able to learn and apply principles of professionalism, ethics and effective communication in conduct of research, pharmacology-based services, educational activities and day to day work.

SUBJECT SPECIFIC COMPETENCIES

The competencies will have a judicious mix of all domains of learning and usually are predominant in one domain. The postgraduate student during the training program should acquire the following competencies to achieve the defined five goals:

A. Predominant in Cognitive domain

The MD Pharmacology student after training in the course should be able to:

General Pharmacology:

1. Demonstrate an understanding of the basic principles of Pharmacology including molecular pharmacology.
2. Demonstrate an awareness of the historical journey and contributions of scientists in the drug development process.
3. Describe the process of new drug development including preclinical and clinical phases.
4. Describe principles of pharmacokinetics of drugs and apply these to prescribe medicines for individualization of pharmacological therapy, including use of medicines in special categories (Pediatrics, Geriatrics, Pregnancy and Pathological states).

5. Explain the principles of pharmacodynamics and apply these in different therapeutic situations.
6. Describe mechanisms of drug-drug interactions and their clinical importance.
7. Describe the principles of pharmacogenomics and its clinical significance.
8. Describe pharmacological principles underlying the effects of drugs used in diagnosis, prevention and treatment of common systemic diseases in man.
9. Demonstrate an understanding of the factors that modify drug action.
10. Define Therapeutic Drug Monitoring (TDM), describe the methods of TDM and importance in therapeutic decision making.
11. Describe the principles and importance of Pharmacoeconomics in healthcare delivery. Describe the methods in pharmacoeconomic studies and the economic considerations in the use of medicines in individuals and in the community.
12. Describe the principles, methods and importance of pharmacoepidemiology, including drug utilization studies.
13. Define pharmacovigilance. Describe the importance of pharmacovigilance in ensuring patient safety and the various methods/procedures in pharmacovigilance.
14. Describe the role of Essential Medicines in rational therapeutics. Describe principles for selecting Essential Medicines for a defined healthcare delivery system.
15. Demonstrate an understanding of principles of rational prescribing.
16. Demonstrate an understanding of prescription analysis and be able to conduct prescription analysis in a healthcare facility.
17. Demonstrate an understanding of antimicrobial resistance, antibiogram, antimicrobial stewardship program and strategies for containment of antimicrobial resistance.

Systemic Pharmacology:

1. Apply and integrate knowledge of pathophysiology of diseases and pharmacological principles underlying the effects of drugs, for the purpose of diagnosis, prevention and treatment of common systemic diseases in man including disorders of:
    a. Synaptic & neuroeffector junctional sites of the autonomic nervous system
    b. Neuromuscular junction

c. Central nervous system
d. Cardiovascular system
e. Endocrine system
f. Gastrointestinal system
g. Respiratory system
h. Renovascular system
i. Hematological system
j. Immunological system
k. Autacoids

(Note: The above is only an indicative list).

2. Describe the mechanism of action, pharmacological effects and therapeutic status of drugs used for prevention and management of microbial and parasitic infections/infestations and neoplastic disorders.
3. Describe the pathophysiological basis and management of common poisonings.
4. Demonstrate an awareness about the recent advances in pharmacology and therapeutics.
5. Demonstrate an understanding of the special considerations in pharmacokinetics, mechanism of action, pharmacological effects and therapeutic status of drugs used for dermatological and ocular disorders.

Research:

1. Demonstrate an understanding of the importance and ethical considerations of biomedical research in animals and man.
2. Describe the principles and methods of biomedical research in animals and man.
3. Describe the current principles of Good Clinical Practice (GCP) and Good Laboratory Practice (GLP) guidelines, as applicable.
4. Demonstrate an understanding of the different tools and methods for literature search.
5. Describe and apply the principles of biostatistics in the evaluation and interpretation of efficacy and safety studies of drugs in man. Apply and interpret the various statistical tools in biomedical research.
6. Demonstrate an understanding of the principles of Good Publication practices as applicable to publication of research studies.

7. Describe different methods of drug assays - biological, chemical, immune-assay including knowledge of analytical techniques like HPLC, TLC etc. and their applications in therapeutics.
8. Describe the methods for screening/evaluation of **a**nalgesics, antipyretics, anticonvulsants, anti-inflammatory drugs, antidepressants, antianxiety and antipsychotics, sedatives, muscle relaxants, antihypertensives, hypocholesterolemic agents, antiarrhythmic drugs, diuretics, adrenergic blocking drugs, drugs affecting learning and memory in animals and man. *(Note: This is only an indicative list).*
9. Describe the regulatory and ethical issues involved in drug development and research.

Teaching and Assessment:

1. Demonstrate an awareness about the salient features of Undergraduate Medical Education Curriculum in India.
2. Demonstrate an awareness about Postgraduate Medical Education Curriculum and Guidelines in India.
3. Describe the principles of teaching-learning technology and apply these to conduct classroom lectures, self-directed learning (SDL) sessions, Case-Based Learning (CBL), case discussions, integrated teaching, small group discussions, seminars, journal club and research presentations.
4. Describe the principles of assessment of learning and be able to use the different methods for assessment of undergraduate students in pharmacology.
5. Demonstrate knowledge about the utility of computer assisted learning and be able to use them efficiently to promote learning of pharmacology.

Note: *The list mentioned above is indicative. A postgraduate student is expected to be knowledgeable about all aspects of the subject and be updated about the contemporary advances and research in the subject.*

B. Predominant in Affective Domain

The students after training in the MD (Pharmacology) course should be able to:

1. Effectively explain to patients, the effects, appropriate use and adverse effects of drugs, including drug interactions and the need for medication adherence.
2. Communicate effectively with students, peers, staff, faculty and other members of the health care team about rational use of medicines and improving spontaneous reporting of adverse drug reactions, with pharmacological reasoning
3. Demonstrate respect in interactions with peers, patients and other healthcare professionals.
4. Demonstrate professionalism, ethical behavior and integrity in one's work.
5. Demonstrate ability to generate awareness about the use of generic drugs in various conditions.
6. Acquire skills for self-directed learning to keep up with advances in the subject and to improve the skills and expertise towards continuous professional development.

C. Predominant in Psychomotor Domain

a. Mandatory

i. The students after training in the MD (Pharmacology) course should be able to *perform the following procedures independently* or as a part of a team and/or interpret the results:

1. Predict, report, monitor and participate in the management and causality assessment of adverse drug reactions associated with use of drugs, as per national program.
2. Demonstrate skills for writing rational prescriptions and prescription analysis.
3. Demonstrate proper use of equipment following the SOPs e.g. organ bath, analgesiometer, physiograph, convulsiometer, plethysmograph, equipment for testing/measuring learning and memory, affective disorders, muscle relaxants, blood pressure, ECG, respiration and pain.
4. Prepare drug solutions of appropriate strength and volume.
5. Determine EC_{50}, ED_{50}, pD2 and pA_2 values of drugs.
6. Demonstrate presentation skills in a classroom setting as well as in academic meetings at local and national levels.
7. Provide critical appraisal of a research paper.

8. Perform experiments to demonstrate and interpret the dose response curve and effect of agonists (in the presence or absence of an antagonist) on simulations.
9. Perform the following:
    - Design protocol for evaluation of a given drug for various phases of clinical trials.
    - Prepare Informed Consent Form and Participant Information Sheet for clinical trials/research.
    - Administer Informed Consent Form
    - Evaluate promotional drug literature
    - Prepare "Package insert"
    - Calculate and interpret pharmacokinetic parameters of a drug from a given data
    - Demonstrate skills to prepare material for teaching-learning and assessment.

ii. The students after training in the MD (Pharmacology) course should be able to ***do/perform following procedures under supervision***:

10. Test and predict efficacy of drugs following appropriate guidelines and regulations e.g. drugs affecting memory and psychomotor functions (e.g. critical flicker fusion tests in human volunteers), pain, cardiovascular functions, respiratory functions etc.
11. Observe and understand basic principles of working of important contemporary drug analytical techniques, interpret the observations about the drug levels and their therapeutic applications.
12. Demonstrate skills for contributing to antibiotic stewardship program of the institute to manage antimicrobial resistance.
13. Demonstrate Standard Operating Procedures (SOPs) for various methods and techniques used in pharmacology including SOPs in clinical trials and research.
14. Administer drugs by various routes (subcutaneous, intravenous, intraperitoneal) in simulations and hybrid models.
15. Demonstrate acquisition of writing skills for scientific publications and research projects for funding agencies and approval by Ethics Committee.
16. Demonstrate scientific writing skills.

b. Desirable: The students after training in the MD (Pharmacology) course should be able to:

17. Collect blood samples and oral gavage from experimental animals.
18. Administer drugs by various routes (subcutaneous, intravenous, intraperitoneal) in experimental animals.
19. Perform *in vivo* and *in vitro* animal experiments or simulated experiments, interpret the observations and relate these to potential clinical applications of the experimental drug:

    e.g. - effect of mydriatics and miotics on rabbit eye,

    - effect of anti-epileptic drugs using appropriate animal models of epilepsy,
    - effect of analgesics using appropriate animal models of analgesia, and
    - effect of drugs on learning, memory and motor coordination and effect of local anesthetics.

    These are examples, but the list is not limited to this only.
20. Perform experiments to demonstrate and interpret the dose response curve and effect of agonists (in the presence or absence of an antagonist) on various biological tissues.

Animal Experiments: All animal experiments must be compliant with the Regulations of Government of India, notified from time to time. Amphibian/Dog/Cat experiments should be conducted by computer assisted simulation models/facilities. Other experiments can be performed, but as permissible by existing 'Committee for the Purpose of Control and Supervision of Experiments on Animals (CPCSEA)' guidelines and other Government regulations.

SYLLABUS

The course contents should cover the following broad topics:

1. History of Pharmacology and medicine
2. Basic and molecular pharmacology
3. Drug receptors and Pharmacodynamics
4. Pharmacokinetics (Absorption, Distribution, Biotransformation, Excretion & kinetic parameters)

5. Therapeutic Drug Monitoring
6. Drugs acting on synaptic and neuroeffector junctional sites
7. Autonomic pharmacology
8. Drugs acting on central nervous system
9. Drugs modifying renal functions
10. Drugs acting on cardiovascular system and hemostatic mechanisms
11. Reproductive Pharmacology
12. Agents affecting calcium homeostasis
13. Autacoids and related pharmacological agents (analgesics) and drugs used in Rheumatoid arthritis and Gout
14. Drugs acting on Gastrointestinal system
15. Pharmacology of drugs affecting the respiratory system
16. Chemotherapy- General principles and various antimicrobials
17. Chemotherapy of neoplastic disease
18. Drugs used in Autoimmune disorder and Graft versus Host Disease
19. Dermatological pharmacology
20. Ocular pharmacology
21. Use of drugs in special population
22. Immunomodulators - immunosuppressants and immunostimulants
23. Pharmacology of drugs used in endocrine disorders
24. Drug delivery systems
25. Heavy metal poisoning
26. Non-metallic toxicants - air pollutants, pesticides etc.
27. Research methodology and biostatistics
28. Pharmacogenomics, pharmacovigilance, pharmacoeconomics and pharmacoepidemiology
29. Over the counter drugs, essential medicines, P-drug, commonly used Over-The-Counter (OTC) drugs, generic drugs, drugs banned in India
30. Principles of rational use of drugs and rational prescribing
31. Dietary supplements and herbal medicines
32. Pathophysiological basis and management of common poisonings
33. National programmes for infectious and vector borne diseases including the regimes.
34. Professionalism & ethics

35. Clinical pharmacology

- Functioning of the Drugs and Therapeutics Committee.
- Hospital formulary development.
- Drug information services.
- Medication error detection and mitigation advice.
- Antimicrobial resistance and antibiotic stewardship.
- Prescription auditing
- Drug counseling - explain to patients, the effects and adverse effects of drugs, including the need for medication adherence
- Emergency drugs used in crash cart/ resuscitation

36. Drug development research and Regulations

- Principles of Good Clinical Practice (GCP) and Good Laboratory Practice (GLP) guidelines, and Good publication practices
- Recent regulatory guidelines for drugs/research and clinical trials
- Drug development and research and ethical issues involved in it
- Research protocol development, research study conduct, experimental observations, analysis of data using currently available statistical software
- Emergency use authorization for drugs eg., vaccine development

37. Pharmacometrics - methods of drug evaluation.

38. General screening and evaluation of:

- analgesics, antipyretics, anticonvulsants, anti-inflammatory drugs, antidepressants, antianxiety and antipsychotics, sedatives, muscle relaxants, antihypertensives, hypocholesterolemic agents, anti-arrhythmic drugs, diuretics, adrenergic blocking drugs, local anaesthetics, antifertility agents, antidiabetics, drugs used in peptic ulcer diseases and drugs affecting learning and memory in animals and man.

39. Experimentation

- Bioassay methods
- Animal experiments: Ethical considerations, ethical approval, applicable Regulatory Guidelines, 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, Ethics Committee and ethical approval
- Regulatory Guidelines and alternatives to animal experimentation.

40. 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).

41. Education

- Salient features of Undergraduate Medical Education Curriculum in India.
- Postgraduate Medical Education Curriculum and Guidelines in India.
- Principles of teaching - learning methods and technology
- Principles of assessment of learners

TEACHING AND LEARNING METHODS

General principles

Acquisition of competencies being the keystone of doctoral medical education, such training should be skills oriented. Learning in the program, essentially autonomous and self-directed, and emanating from academic and clinical work, shall also include assisted learning. The formal sessions are meant to supplement this core effort.

All students joining the postgraduate courses shall work as full-time (junior) residents during the period of training, attending not less than 80% of the training activity during the calendar year, and participating in all assignments and facets of the educational process. They shall maintain a log book for recording the training they have undergone, and details of the procedures done during laboratory and clinical postings in real time.

Teaching-Learning methods

This should include a judicious mix of demonstrations, symposia, journal clubs, clinical meetings, seminars, small group discussions, bed-side teaching, case-based learning, simulation-based teaching, self-directed learning, integrated learning, interdepartmental meetings and any other collaborative activity with the allied departments. Methods with exposure to the applied aspects of the subject relevant to basic/clinical sciences should also be used.

The suggested examples of teaching-learning methods are given below but are not limited to these. The frequency of various below mentioned teaching-learning methods can vary based on the subject's requirements, competencies, work load and overall working schedule of the department.

A. Lectures: Didactic lectures should be used sparingly. A minimum of 10 lectures per year in the concerned PG department is suggested. Topics to be selected as per subject requirements. All postgraduate trainees will be required to attend these lectures. Lectures can cover topics such as:

1. Subject related important topics
2. Recent advances
3. Research methodology and biostatistics
4. Salient features of Undergraduate/postgraduate medical curriculum
5. Teaching and assessment methodology
6. Toxicity studies
7. Screening for pharmacological activity of drugs
8. Technical and ethical issues in clinical research and practice
9. Good laboratory practice
10. Good manufacturing practice
11. Health economics

No 3, 4, 5 can be done in the course of research/biostatistics and medical education workshops in the institute.

B. Journal club: Minimum of once in 1-2 weeks is suggested.

Topics will include presentation and critical appraisal of original research papers published in peer reviewed indexed journals. The presenter(s) shall be assessed by faculty and grades recorded in the logbook.

C. Student Seminar: Minimum of once every 1-2 weeks is suggested.

Important topics should be selected as per subject requirements and allotted for in-depth study by a postgraduate student. A teacher should be allocated for each seminar as faculty moderator to help the student prepare the topic well. It should aim at comprehensive evidence-based review of the topic. The student should be graded by the faculty and peers.

D. Student Symposium: Minimum once every 3 months.

A broad topic of significance should be selected, and each part shall be dealt by one postgraduate student. A teacher moderator should be allocated for each symposium and moderator should track the growth of students during moderation. It should aim at complete evidence-based review of the topic. All participating postgraduates should be graded by the faculty and peers.

E. Laboratory work / Bedside clinics: Minimum - once every 1-2 weeks.

Laboratory work/clinics/bedside teaching should be coordinated and guided by faculty from the department. Various methods like DOAP (Demonstrate, Observe, Assist, Perform), simulations in skill lab, and case-based discussions etc. are to be used. Faculty from the department should participate in moderating the teaching-learning sessions during clinical rounds.

F. Interdepartmental colloquium

Faculty and students must attend monthly meetings between the Department of Pharmacology and another department or departments on topics of current/common interest or clinical cases.

G. a. Rotational clinical / community / institutional postings

Depending on local institutional policy and the subject specialty needs, postgraduate trainees may be posted in relevant departments/ units/ institutions. The aim would be to acquire more in-depth knowledge as applicable to the concerned specialty. Postings would be rotated between various units/departments.

The postings schedule with duration is given below:

- Medicine -2 weeks
- Anesthesia -2 weeks
- Dermatology -1 week
- Medical oncology -2 weeks (if available)
- Microbiology/ Infection control unit or dept -2 weeks
- Biochemistry -2 weeks
- Hospital Pharmacy -1 week (if available)
- Clinical trial unit/Research unit/ Pharmaceutical industry -2-8 weeks (as per availability)
- Medical Education Unit (MEU) or Department of Medical Education (DOME) -1 week (optional)

G b. Posting under "District Residency Programme" (DRP):

All postgraduate students pursuing MD in Pharmacology in all Medical Colleges/Institutions shall undergo a compulsory rotation of three months in District Hospitals/District Health System as a part of the course curriculum, as per the Postgraduate Medical Education (Amendment) Regulations (2020). Such rotation shall take place in the 3rd or 4th or 5th semester of the Postgraduate programme and the rotation shall be termed as "District Residency Programme" and the PG medical student undergoing training shall be termed as "District Resident".

Every posting should have its defined learning objectives. It is recommended that the departments draw up objectives and guidelines for every posting offered in conjunction with the collaborating department/s or unit/s. This will ensure that students acquire expected competencies and are not considered as an additional helping hand for the department / unit in which they are posted. The PG student must be tagged along with those of other relevant departments for bedside case discussion/basic science exercises as needed, under the guidance of an assigned faculty.

Opportunities to present and discuss infectious disease cases through bedside discussion and ward/grand rounds with specialists / clinicians in different

hospital settings must be scheduled to address antimicrobial resistance issues and strategies to deal with it.

H. Teaching research skills

Writing a thesis should be used for inculcating research knowledge and skills. All postgraduate students shall conduct a research project of sufficient depth to be presented to the University as a postgraduate thesis under the supervision of an eligible faculty member of the department as guide and one or more co-guides who may be from the same or other departments.

In addition to the thesis project, every postgraduate trainee shall participate in at least one additional research project that may be started or already ongoing in the department. It is preferable that this project will be in an area different from the thesis work. For instance, if a clinical research project is taken up as thesis work, the additional project may deal with community/field/laboratory work. Diversity of knowledge and skills can thereby be reinforced.

I. Training in teaching skills

Medical Education Unit (MEU)/ Department of Medical education (DOME) should train PG students in education methodologies and assessment techniques. The PG students shall conduct UG classes in various courses and a faculty shall observe and provide feedback on teaching skills to the student.

J. Log book

During the training period, the postgraduate student should maintain a Log Book indicating the duration of the postings/work done in Wards, OPDs, Casualty and other areas of posting. This should indicate the procedures assisted and performed and the teaching sessions attended. The log book entries must be done in real time. The log book is thus a record of various activities by the student like: (1) Overall participation & performance, (2) attendance, (3) participation in sessions, (4) record of completion of pre-determined activities, and (5) acquisition of selected competencies.

The purpose of the Log Book is to:

a) help maintain a record of the work done during training,
b) enable Faculty/Consultants to have direct information about the work done and intervene, if necessary,

c) provide feedback and assess the progress of learning with experience gained periodically.

The Log Book should be used in the internal assessment of the student, should be checked and assessed periodically by the faculty members imparting the training. The PG students will be required to produce completed log book in original at the time of final practical examination. It should be signed by the Head of the Department. A proficiency certificate from the Head of Department regarding the clinical competence and skillful performance of procedures by the student will be submitted by the PG student at the time of the examination.

The PG students shall be trained to reflect and record their reflections in log book particularly of the critical incidents. Components of good teaching practices must be assessed in all academic activity conducted by the PG student and at least two sessions dedicated for assessment of teaching skills must be conducted every year of the PG program. The teaching faculty are referred to the MCI Logbook Guidelines uploaded on the Website.

K. Course in Research Methodology: All postgraduate students shall complete an online course in Research Methodology within six months of the commencement of the batch and generate the online certificate on successful completion of the course.

L. Other aspects

- The postgraduate trainees must participate in the teaching and training program of undergraduate students and interns attending the department.
- Trainees shall attend accredited scientific meetings (CME, symposia, and conferences) at least once a year.
- Department shall encourage e-learning activities.
- The postgraduate trainees must undergo compulsory training in Basic Cardiac Life Support (BCLS) and Advanced Cardiac Life Support (ACLS).
- The postgraduate trainees must undergo training in information technology and use of computers.

- The postgraduate trainees should preferably undergo training in Good Clinical Practice (GCP)

During the training program, patient safety is of paramount importance; therefore, relevant clinical skills are to be learnt initially on the models, later to be performed under supervision followed by independent performance. For this purpose, provision of skills laboratories in medical colleges is mandatory.

ASSESSMENT

FORMATIVE ASSESSMENT, i. e., assessment to improve learning

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

The Internal Assessment should be conducted in theory and practical/clinical examination, 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 include quarterly assessment.

Quarterly assessment during the MD training should be based on:

- Case presentation, case work up, case handling/management : once a week
- Laboratory performance : twice a week
- Journal club : once a week
- Seminar : once a fortnight
- Case discussions : once a fortnight/month
- Interdepartmental case or seminar : once a month

Note: These sessions may be organized and recorded as an institutional activity for all postgraduates.

- Attendance at Scientific meetings, CME programmes (at least 02 each)

Important instructions:

- The feedback should be given to students timely and frequently so that they get a chance to improve.
- All teachers of the Department should be involved in assessment.
- The records and Log book shall be checked and assessed periodically by the faculty members imparting the training.

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

SUMMATIVE ASSESSMENT, i.e., assessment at the end of training

Essential pre-requisites for appearing for examination include:

1. **Log book** of work done during the training period including rotation postings, departmental presentations, and internal assessment reports should be submitted.

2. At least **two presentations** at national level conference. One research paper should be published / accepted in an indexed journal**. (It is suggested that the local or University Review committee assess the work sent for publication).**

The summative examination would be carried out as per the Rules given in the latest POSTGRADUATE MEDICAL EDUCATION REGULATIONS. The theory examination shall be held in advance before the Clinical and Practical examination, so that the answer books can be assessed and evaluated before the commencement of the clinical/Practical and Oral examination**.**

The postgraduate examination shall be in three parts**:**

1. Thesis

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 in broad specialty 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, as given in the latest POSTGRADUATE MEDICAL EDUCATION REGULATIONS. 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./ M.S shall be held at the end of 3rd academic year.

There shall be four theory papers (as per PG Regulations).

Paper I: Basic sciences as applied to Pharmacology

Paper II: Systemic Pharmacology

Paper III: Clinical Pharmacology, Experimentation, Research, Biostatistics and Education

Paper IV: Recent advances in the Pharmacology

3. Practical/clinical and Oral/viva voce examination

Practical examination

Practical examination should be spread over **two** days and include various major components of the syllabus focusing mainly on the psychomotor domain.

Oral/Viva voce examination on defined areas should be conducted by each examiner separately. Oral examination shall be comprehensive enough to test the postgraduate student's overall knowledge of the subject focusing on psychomotor and affective domain.

Practical Examination Exercises:

a) long exercises:

- Protocol design for a given scenario
- Case audit for a given case
- Perform experiments or simulated experiments (as per PG Regulations) The exercises should be observed, response of student noted and assessed. The question related to these exercises can be asked

b) short exercises:

- Interpretation of results of a previous tracing - Table exercise

- Demonstration of effects of drugs/interpretation of results in human
- Demonstration of effects of drugs/interpretation of results in small, animals - optional (as per Regulations notified)

  The exercises should be observed and assessed.

c) OSPE exercises: Objective Structured Practical Examination (OSPE)

OSPE should have 10-15 stations. Stations should be mixture of observed (observer present) and unobserved stations (without an observer). Few examples are given below:

- Various drug delivery systems
- Calculating pharmacokinetic parameters
- Pharmaceutical calculations
- Statistical exercise
- Pharmacoeconomics
- Critical appraisal of a published paper
- Abstract writing of a published paper
- Evaluation of drug promotional literature.
- Adverse Drug Reaction (ADR) reporting and causality assessment
- Assessment of preclinical toxicity data
- Analysis of rational and irrational formulations
- Selecting a P-drug and writing rational prescriptions
- Analytical instruments - use and interpretation
- Identifying ethics related dilemmas / mistakes in clinical trial documents

d) Assessment of teaching/presentation skills

- e.g., presentation of a UG lecture, making Question paper, Learning Objectives
- Discussion on dissertation

Recommended Readings

Books:

1. Brunton LL, Hilal-Dandan R, Knollmann BC. Goodman and Gilman's The Pharmacological Basis of Therapeutics, 13th edition, Mc Graw Hill Education, 2018.

2. Katzung BG. Basic & Clinical Pharmacology, 14th edition, McGraw Hill Education, 2018.
3. Papadakis MA, Mcphee SJ. Current Medical Diagnosis & Treatment. 60th edition New York. McGraw Hill Education.2021.
4. Ritter M, Flower R, Henderson G, Loke YK, MacEwan D, Rang HP. Pharmacology. Elsevier, 9th edition, 2020.
5. Tripathi KD. Essentials of Medical Pharmacology, 8th edition. Jaypee Brothers Medical Publishers Private Ltd: New Delhi 2019.
6. M. N. Ghosh. Fundamentals of Experimental Pharmacology. 7th Edition. Hilton & Company, 2019.
7. Badyal D. Practical Manual of Pharmacology. Jaypee Brothers Medical Publishers; 3rd edition 2020.
8. Vogel HJ. Drug Discovery and Evaluation: Pharmacological Assays Springer; 3rd edition, 2007.
9. Sharma S, Velpandian T. Illustrated Reviews Pharmacology. Wolter Kluver, South Asian Edition, 2019.
10. Medhi B, Prakash A. Practical Manual of Experimental & Clinical Pharmacology. Jaypee Brothers Medical Publishers, 2nd edition, 2017.
11. Alldredge BK, Corelli RL, Ernst ME, Guglielmo Jr. BJ, Jacobson PA, Kradjan WA, Williams BA. Koda-Kimble and Young's Applied Therapeutics Lippincott Williams and Wilkins, 10th edition, 2012.
12. Cheston B Cunha, Burke A Cunha. Antibiotic essentials. Jaypee Brothers Medical Publishers 17th edition, 2021.

Websites:

1. National Guidelines on national programs e.g. https://cdsco.gov.in/opencms/opencms/en/Home
2. MOHFW Website https://www.mohfw.gov.in/
3. WHO Website https://www.who.int/

Journals:

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

Annexure I

Student appraisal form for MD in Pharmacology											
	Elements	**Less than Satisfactory**			**Satisfactory**			**More than satisfactory**			**Comments**
		1	2	3	4	5	6	7	8	9	
1	**Scholastic aptitude and learning**										
1.1	Has knowledge appropriate for level of training										
1.2	Participation and contribution to learning activity (e.g., Journal Club, Seminars, CME etc)										
1.3	Conduct of research and other scholarly activity assigned (e.g., Posters, publications etc)										
1.4	Documentation of acquisition of competence (e.g., Log book)										
1.5	Performance in work-based assessments										
1.6	Self-directed Learning										
2	**Work related to training**										
2.1	Practical skills that are appropriate for the level of training										
2.2	Respect for processes and procedures in the work space										
2.3	Ability to work with other members of the team										
2.4	Participation and compliance with the quality improvement process at the work environment										

2.5	Ability to record and document work accurately and appropriate for level of training										
3	**Professional attributes**										
3.1	Responsibility and accountability										
3.2	Contribution to growth of learning of the team										
3.3	Conduct that is ethically appropriate and respectful at all times										
4	**Space for additional comments**										
5	**Disposition**										
	Has this assessment pattern been discussed with the trainee?	Yes	No								
	If not explain										
	Name and Signature of the assesse										
	Name and Signature of the assessor Date										

Subject Expert Group members for preparation of REVISED Guidelines for competency based postgraduate training programme for MD in Pharmacology

1. **Dr Dinesh Kumar Badyal**,
   Convener, Expert Group
   Professor & Former Head, Department of Pharmacology,
   Christian Medical College, Ludhiana,
   Punjab 141008

2. **Dr. Chetna Desai**
   Professor & Head
   Department of Pharmacology,
   B.J. Medical College, Ahmedabad,
   Gujarat 380016

3. **Dr. A. Geetha,**
   Professor & Head
   Department of Pharmacology,
   Bangalore Medical College & Research Institute
   Bangalore - 560002,
   Karnataka

4. **Dr. Rakesh Kumar Dixit**
   Professor, Department of Pharmacology,
   King George Medical University, Lucknow, UP.

5. **Dr. Avijit Hazare**
   Professor, Department of Pharmacology
   Institute of Postgraduate Medical Education & Research (IPGME&R),
   Kolkata 700020,
   West Bengal

BHARATI VIDYAPEETH
(DEEMED TO BE UNIVERSITY), PUNE

Faculty of Medical Sciences
MD - Pharmacology
Old Syllabus

Bharati Vidyapeeth Deemed to be University,

Pune

Faculty of Medical Sciences

Curriculum for MD in Pharmacology

As per Guidelines of

Medical Council of India

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**