REGULATIONS AND CURRICULUM GOVERNING

MD PHARMACOLOGY PROGRAM

(2024-25)

Name of the Constituent Unit/Centre: Yenepoya Medical College



YENEPOYA

Deemed to be University

Deralakatte, Mangalore, Karnataka.

NOTIFICATION FROM THE UNIVERSITY

YENEPOYA
(DEEMED TO BE UNIVERSITY)
Recognized under Sec 3(A) of the UGC Act 1956
Accredited by NAAC with 'A' Grade

NOTIFICATION – 34-ACM/2019 dtd. 20.02.2019

Sub:- Implementation of Competency Based Medical Education PG Curriculum

Ref. : Resolution of the Academic Council at its 34th Meeting held on 08.02.2019 vide Agenda 33

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The Academic Council at its 34th Meeting held on 08.02.2019 and subsequently the 45th meetings of Board of Management held on 09.02.2019 have accepted the proposal for implementation of Competency Based Medical Education (CBME) for the PG Curricula of the following programs as per the MCI Norms.

1. MD in Pathology
2. MD in General Medicine
3. MD in Anaesthesiology
4. MD in Paediatrics
5. MD in Respiratory Medicine
6. MD in Radio-diagnosis
7. MD in Anatomy
8. MD in Physiology
9. MD in Biochemistry
10. MD in Microbiology
11. MD in Pharmacology
12. MD in Forensic Medicine
13. MD in Psychiatry
14. MD in Dermatology
15. MD in Community Medicine
16. MS in General Surgery
17. MS in OBG
18. MS in Otorhinolaryngology
19. MS in Ophthalmology
20. MS in Orthopaedics

This revised curriculum shall come into effect from the academic year 2019-2020 onwards.

REGISTRAR

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YENEPOYA
Deemed to be University

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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

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 & neuroeffect or 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

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

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

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Formative assessment plan for MD Pharmacology post graduates

FA plan	Activity	Every Term (6 months)
Theory	Written tests	2
	Seminar	5
	Journal club	5
	Inter departmental seminar	1
	Symposium	1
	Case discussion	5
Practical	OSPE	2
	Practical examination	1
	ADR case presentation	5
Viva voce	Theory Viva	1
	Thesis presentation (last term)	1
	Pedagogy	2

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MD Pharmacology Marks pattern

Theory Examination	Paper 1: (Basic sciences as applied to Pharmacology)	**1**00
	Paper II: (Systemic Pharmacology)	**1**00
	Paper III: (Clinical Pharmacology, Experimentation, Research, Biostatistics and Education)	**1**00
	Paper IV: (Recent advances in the Pharmacology)	**1**00
	Total marks for Theory	**400**
	Passing minimum for theory	200/400 (40% minimum in each paper)
Practical Examination	**Long exercises (40x3)**	**120**
	Short exercises a. Experimental Pharmacology **(60)** (15 x 2 +10 x 3) b. Clinical Pharmacology **(60)** (20 x 3)	**120**
	OSPE (Non interactive-24) + (Interactive – 16) (4x6) + (4x4)	**40**
	Thesis presentation	**20**
	Grand viva	**100**
	Total marks for Practical	**400**
	Passing minimum for practical including viva voce	**200/400**

*The candidate shall secure not less than 50% marks in each head of passing which shall include

1) Theory –aggregate 50% (In addition, in each theory paper a candidate has to secure minimum of 40%)
2) Practical and Viva voce- aggregate 50%

3) If any candidate fails even under one head, he/she has to re-appear for both Theory and Practical and Viva voce examination.

4) Five per cent of mark of total marks of Practical and Viva voce marks (20 marks) will be of dissertation/thesis and it will be part of practical examination marks.

External examiner outside the state will evaluate dissertation/thesis and take viva voce on it and marks will be given on quality of dissertation/thesis and performance on its viva voce.

5) No grace mark is permitted in post-graduate examination either for theory or for practical.

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).

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ANNEXURES

Blue print for MD Pharmacology theory question papers

Paper 1 (Basic sciences as applied to Pharmacology)

SI. No.	Section/Topics	Weightage	Marks allotted	No. of Questions
1.	Basic principles of Pharmacology including molecular pharmacology, Drug development , Historical journey and contribution of scientists	20%	20	2
2.	Principles of Pharmacokinectics	20%	20	2
3.	Therapeutic Drug Monitoring & Pharmacodynamics	20%	20	2
4.	Drug dosage & Pharmacotherapeutics: Essential Medicines in rational therapeutics Principles of rational prescribing. Prescription analysis Antimicrobial resistance, antibiogram, Antimicrobial stewardship program and strategies for containment of antimicrobial resistance.	20%	20	2
5.	Pharmacogenomics, Pharmacoepedemiology including Drug utilization studies & Pharmacoeconomics Pharmacovigilance, Drug- drug interactions	20%	20	2

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Paper II (Systemic Pharmacology)

SI. No.	Section/Topics	Weightage	Marks allotted	No. of Questions
1.	Drugs acting on Autonomic Nervous System, Peripheral Nervous System, Central Nervous System	20%	20	2
2.	Drugs acting on Cardiovascular system, Renovascular system, Hematological system, Autacoids	20%	20	2
3.	Drugs acting on Endocrine system Gastrointestinal system, Respiratory system	20%	20	2
4.	Antimicrobial Drugs & Cancer chemotherapy	30%	30	3
5.	Drugs acting on Immunological system, vaccines, anti sera & Immunoglobulins. Drugs used for dermatological and ocular disorders. Vitamins & dietary supplements. Environmental toxicology, poisonings, chelating agents	10%	10	1

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Paper III (Clinical Pharmacology, Experimentation, Research, Biostatistics and Education)

SI. No.	Section/Topics	Weightage	Marks allotted	No. of Questions
1.	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	20%	20	2
2.	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	20%	20	2

	• Emergency use authorization for drugs eg., vaccine development • Pharmacometrics - methods of drug evaluation.			
3.	<u>General screening and evaluation of</u> Analgesics, antipyretics, anticonvulsants, anti-inflammatory drugs,antidepressants, Antianxiety, antipsychotics, sedatives, muscle relaxants, antihypertensives, hypocholesterolemic agents, anti-arrhythmic drugs, diuretics, adrenergic blocking drugs, local anaesthetics, antifertility agents, antidiabetics, drugs used in peptic ulcerdiseases ,drugs affecting learning and memory in animals <u>Biochemical Pharmacology</u> • 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).	20%	20	2
4.	<u>Experimentation:</u> • 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	30%	30	3

	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.			
5	<u>Education</u> • 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	10%	10	1

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Paper IV (Recent advances in the Pharmacology)

Sl.No.	Section/Topics	Weightage	Marks allotted	No. of Questions
1.	History and drug update Important scientific contributions by scientists, FDA approved newer drugs, Banned drugs, Essential drug List Newer Developments inPharmacology and newer and special drug delivery systems including Clinical pharmacology Stem Celltherapy,MonoclonalAntibodies, Genetherapy, JAKSTAT Kinasereceptors, Inhalationalinsulindelivery etc	20%	20	2
2.	Respiratory system, Blood Cardiovascular system including diuretics Recent advances inTreatment of respiratory disorders, cardiovascular, renal & blooddisorders	20%	20	2
3.	Central Nervous system and peripheral nervous system Recentadvancesin treatmentof Central nervous disorders and peripheral nervous system (Skeletal muscle relaxants and Local anesthetics)	20%	20	2
4.	Gastrointestinal system, autocoids and endocrine Recent advances in treatment of gastrointestinal	20%	20	2

	disorders,hormonal disorders			
5.	Antimicrobials & Cancerchemotherapy, Miscellaneous Recent advances in Treatment of microbial infections and cancer chemotherapy Recent advances in Treatmentof eye, skin disorders, rheumatoid arthritis, gout, migraine.	20%	20	2

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Model Question papers for MD Pharmacology

Paper 1 (Basic sciences as applied to Pharmacology)

SHORT ESSAYS: **Duration: 3 hrs**
(10×10=100 marks)

1. Drug delivery systems
2. Describe the preclinical phase of drug development
3. Microsomal enzyme induction
4. Factors modifying drug action
5. Essential Medicines in rational therapeutics
6. Discuss the strategies for containment of antimicrobial resistance
7. Principles of Pharmacogenomics and its clinical significance
8. G protein coupled receptors (GPCRs)
9. Therapeutic drug monitoring
10. Drug-drug interactions and their clinical importance.

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Paper 2 (Systemic Pharmacology)

SHORT ESSAYS: **Duration: 3 hrs**

(10×10=100 marks)

1. Explain the hemodynamic alterations in cardiac failure. Classify the drugs used in congestive cardiac failure with a special reference to vasodilators.
2. Non-inhalational anesthetic agents
3. What are the different types of pre-synaptic receptors and explain their role in the regulation of Neurotransmitter release in the Central and Peripheral Nervous systems.
4. Discuss the role of Hematopoietic growth factors and their analogs in therapeutics
5. Prophylaxis of HIV infection
6. Discuss the role of antibiotics in cancer chemotherapy
7. Hormone Replacement Therapy (HRT)
8. Pharmacotherapy for Inflammatory Bowel Disease (IBD)
9. Describe the role of immunosuppressants in organ transplantation
10. Discuss pharmacology of newer broad spectrum antimicrobial agents and add a note on principles for the selection of antimicrobial agents

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Paper 3 (Clinical Pharmacology, Experimentation, Research, Biostatistics and Education)

SHORT ESSAYS: **Duration: 3 hrs**
(10×10=100 marks)

1. Good Clinical Practices
2. Student t test
3. Discuss the screening methods for evaluation of analgesic drugs
4. Principles and application of ELISA
5. Physiological Salt Solution
6. Institutional Ethics Committee
7. Antibiotic Stewardship Programme
8. Salient features of Undergraduate Medical Education Curriculum in India.
9. Rat as an experimental animal
10. Alternatives to animal experiment

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Paper 4 (Recent advances in the Pharmacology)

SHORT ESSAYS: **Duration: 3 hrs**
(10×10=100 marks)

1. Role of biologics in therapy
2. Newer drug delivery systems in bronchial Asthma management
3. Colony stimulating factors and their role in therapy
4. Recent changes in the Management of TB as per National TB Programme
5. Recent advances in the treatment of Alzheimer's disease
6. HIV – newer drugs
7. Explain drug repositioning
8. Role of AI in drug discovery
9. Recent advances in antiepileptic therapy
10. Recent advances in the management of Hypertension

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										