



MAHATMA GANDHI UNIVERSITY
of
MEDICAL SCIENCES & TECHNOLOGY
JAIPUR

Syllabus

MD – PHARMACOLOGY

(3 Years Post Graduate Degree Course)

Notice

1. Amendment made by the Medical Council of India in Rules/Regulations of Post Graduate Medical Courses shall automatically apply to the Rules/Regulations of the Mahatma Gandhi University of Medical Sciences & Technology (MGUMST), Jaipur.
2. The University reserves the right to make changes in the syllabus/books/guidelines, fees-structure or any other information at any time without prior notice. The decision of the University shall be binding on all.
3. The Jurisdiction of all court cases shall be Jaipur Bench of Hon'ble Rajasthan High Court only.

RULES & REGULATIONS
MD PHARMACOLOGY (9060)
(3 Years Post Graduate degree course)

TITLE OF THE COURSE:

It shall be called Doctor of Medicine.

ELIGIBILITY FOR ADMISSION:

No candidate of any category (including NRI quota) shall be eligible for admission to MD/MS courses, if he or she has not qualified NEET PG (MD/MS) conducted by National Board of Examinations or any other Authority appointed by the Government of India for the purpose.

(1) General Seats

- (a) Every student, selected for admission to postgraduate medical course shall possess recognized MBBS degree or equivalent qualification and should have obtained permanent Registration with the Medical Council of India, or any of the State Medical Councils or should obtain the same within one month from the date of his/her admission, failing which the admission of the candidate shall be cancelled;
- (b) Completed satisfactorily one year's rotatory internship or would be completing the same before the date announced by the University for that specific year as per MCI rules after passing 3rd professional MBBS Part II Examination satisfactorily.
- (c) In the case of a foreign national, the Medical Council of India may, on payment of the prescribed fee for registration, grant temporary registration for the duration of the postgraduate training restricted to the medical college/institution to which he/she is admitted for the time being exclusively for postgraduate studies; however temporary registration to such foreign national shall be subject to the condition that such person is duly registered as medical practitioner in his/her own country from which he has obtained his basic medical qualification and that his degree is recognized by the corresponding Medical Council or concerned authority.

(2) NRI Seats

- (a) Students from other countries should possess passport, visa and exchange permits valid for the period of their course of study in this Institution and should also observe the regulations of both central and state governments regarding residential permits and obtain no-objection certificate from the same.
- (b) The candidate should have a provisional "Student Visa". If he comes on any other visa and is selected for admission, he will have to first obtain a student visa from his country and then only he will be allowed to join the course. Therefore it is imperative to obtain provisional student visa before coming for Counseling.
- (c) This clause is applicable to NRI/Foreign Students only.

CRITERIA FOR SELECTION FOR ADMISSION:

(1) NRI Quota

15% of the total seats are earmarked for Foreign National / PIO / OCI/ NRI / Ward of NRI/NRI sponsored candidates who would be admitted on the basis of merit obtained in NEET PG or any other criteria laid down by Central Government/MCI.

(2) Remaining Seats (Other than NRI Quota Seats)

- (a) Admissions to the remaining 85% of the seats shall be made on the basis of the merit obtained at the NEET conducted by the National Board of Examinations or any other Authority appointed by the Government of India for the purpose.
- (b) The admission policy may be changed according to the law prevailing at the time of admission.

COUNSELING/INTERVIEW:

- (1) Candidates in order of merit will be called for Counseling/Interview and for verification of original documents and identity by personal appearance.
- (2) Counseling will be performed and the placement will be done on merit-cum-choice basis by the Admission Board appointed by the Government of Rajasthan.

RESERVATION:

Reservation shall be applicable as per policy of the State Government in terms of scheduled caste, scheduled tribe, back ward class, special back ward class, women and handicapped persons.

ELIGIBILITY AND ENROLMENT:

Every candidate who is admitted to MD/MS course in Mahatma Gandhi Medical College & Hospital shall be required to get himself/herself enrolled and registered with the Mahatma Gandhi University of Medical Sciences & Technology after paying the prescribed eligibility and enrolment fees.

The candidate shall have to submit an application to the MGUMST for the enrolment/eligibility along with the following original documents with the prescribed fees (upto November 30 of the year of admission without late fees and upto December 31 of the year of admission with late fees) –

- (a) MBBS pass Marks sheet/Degree certificate issued by the University (Ist MBBS to Final MBBS)
- (b) Certificate regarding the recognition of medical college by the Medical Council of India.
- (c) Completion of the Rotatory Internship certificate from a recognized college.
- (d) Migration certificate issued by the concerned University.
- (e) Date of Birth Certificate
- (f) Certificate regarding registration with Rajasthan Medical Council / Medical Council of India / Other State Medical Council.

REGISTRATION

Every candidate who is admitted to MD/MS course in Mahatma Gandhi Medical College & Hospital shall be required to get himself/herself registered with the Mahatma Gandhi University of Medical Sciences & Technology after paying the prescribed registration fees.

The candidate shall have to submit an application to the MGUMST for registration with the prescribed fees (upto November 30 of the year of admission without late fees upto December 31 of the year of admission with late fees).

DURATION OF COURSE:

The course shall be of 3 years duration from the date of commencement of academic session.

PERIOD OF TRAINING:

The period of training for obtaining Post graduate degrees (MD/MS) shall be three completed years including the period of examination.

MIGRATION:

No application for migration to other Medical Colleges will be entertained from the students already admitted to the MD/MS course at this Institute.

METHODS OF TRAINING FOR MD/MS:

Method of training for MD/MS courses shall be as laid down by the Medical Council of India.

ONLINE COURSE IN RESEARCH METHODS

- i. All postgraduate students shall complete an online course in Research Methods to be conducted by an Institute(s) that may be designated by the Medical Council of India by way of public notice, including on its website and by Circular to all Medical Colleges. The students shall have to register on the portal of the designated institution or any other institute as indicated in the public notice.
- ii. The students have to complete the course by the end of their 2nd semester.
- iii. The online certificate generated on successful completion of the course and examination thereafter, will be taken as proof of completion of this course
- iv. The successful completion of the online research methods course with proof of its completion shall be essential before the candidate is allowed to appear for the final examination of the respective postgraduate course.
- v. This requirement will be applicable for all postgraduate students admitted from the academic year 2019-20 onwards

ATTENDANCE, PROGRESS AND CONDUCT:

(1) Attendance:

- (a) 80% attendance in each course is compulsory. Any one failing to achieve this, shall not be allowed to appear in the University examination.
- (b) A candidate pursuing MD/MS course shall reside in the campus and work in the respective department of the institution for the full period as a full time student. No candidate is permitted to run a clinic/work in clinic/laboratory/ nursing home while studying postgraduate course. No candidate shall join any other course of study or appear for any other examination conducted by this university or any other university in India or abroad during the period of registration. Each year shall be taken as a unit for the purpose of calculating attendance.
- (c) Every candidate shall attend symposia, seminars, conferences, journal review meetings, grand rounds, CPC, CCR, case presentation, clinics and lectures during each year as prescribed by the department and not absent himself / herself from work without valid reasons. Candidates should not be absent continuously as the course is a full time one.

(2) Monitoring Progress of Studies- Work diary/Log Book:

- (a) Every candidate shall maintain a work diary in which his/her participation in the entire training program conducted by the department such as reviews, seminars, etc. has to be chronologically entered.
- (b) The work scrutinized and certified by the Head of the Department and Head of the Institution is to be presented in the University practical/clinical examination.

(3) Periodic tests:

There shall be periodic tests as prescribed by the Medical Council of India and/ or the Board of Management of the University, tests shall include written papers, practical/clinical and viva voce.

(4) Records:

Records and marks obtained in tests will be maintained by the Head of the Department and will be made available to the University when called for.

THESIS:

- (1) Every candidate pursuing MD/MS degree course is required to carry out work on research project under the guidance of a recognized post graduate teacher. Then such a work shall be submitted in the form of a Thesis.
- (2) The Thesis is aimed to train a postgraduate student in research methods & techniques.
- (3) It includes identification of a problem, formulation of a hypothesis, designing of a study, getting acquainted with recent advances, review of literature, collection of data, critical analysis, comparison of results and drawing conclusions.
- (4) Every candidate shall submit to the Registrar of the University in the prescribed format a Plan of Thesis containing particulars of proposed Thesis work within six months of the date of commencement of the course on or before the dates notified by the University.
- (5) The Plan of Thesis shall be sent through proper channel.
- (6) Thesis topic and plan shall be approved by the Institutional Ethics Committee before sending the same to the University for registration.
- (7) Synopsis will be reviewed and the Thesis topic will be registered by the University.
- (8) No change in the thesis topic or guide shall be made without prior notice and permission from the University.
- (9) The Guide, Head of the Department and head of the institution shall certify the thesis. Three printed copies and one soft copy of the thesis thus prepared shall be submitted by the candidate to the Principal. While retaining the soft copy in his office, the Principal shall send the three printed copies of the thesis to the Registrar six months before MD/MS University Examinations. Examiners appointed by the University shall evaluate the thesis. Approval of Thesis at least by two examiners is an essential pre-condition for a candidate to appear in the University Examination.
- (10) Guide: The academic qualification and teaching experience required for recognition by this University as a guide for thesis work is as laid down by Medical Council of India/Mahatma Gandhi University of Medical Sciences & Technology, Jaipur.
- (11) Co-guide: A co-guide may be included provided the work requires substantial contribution from a sister department or from another institution recognized for teaching/training by Mahatma Gandhi University of Medical Sciences & Technology, Jaipur/Medical Council of India. The co-guide shall be a recognized postgraduate teacher.
- (12) Change of guide: In the event of a registered guide leaving the college for any reason or in the event of death of guide, guide may be changed with prior permission from the University.

ELIGIBILITY TO APPEAR FOR UNIVERSITY EXAMINATION:

The following requirements shall be fulfilled by every candidate to become eligible to appear for the final examination:

- (1) Attendance: Every candidate shall have fulfilled the requirement of 80% attendance prescribed by the University during each academic year of the postgraduate course. (as per MCI rules)

- (2) Progress and Conduct: Every candidate shall have participated in seminars, journal review meetings, symposia, conferences, case presentations, clinics and didactic lectures during each year as designed by the department.
- (3) Work diary and Logbook: Every candidate shall maintain a work diary for recording his/her participation in the training program conducted in the department. The work diary and logbook shall be verified and certified by the Department Head and Head of the Institution.
- (4) Every student would be required to present one poster presentation, to read one paper at a National/State Conference and to have one research paper which should be published/accepted for publication/ sent for publication to an indexed journal during the period of his/her post graduate studies so as to make him/her eligible to appear at the Post Graduate Degree Examination.
- (5) Every student would be required to appear in and qualify the Pre-University Post graduate degree Mock examination. Post graduate students who fail to appear in or do not qualify the Pre-University Post graduate degree Mock examination shall not be permitted to appear in the final examination of the University.

The certification of satisfactory progress by the Head of the Department/ Institution shall be based on (1), (2), (3), (4) and (5) criteria mentioned above.

ASSESSMENT:

- (1) The progress of work of the candidates shall be assessed periodically by the respective guides and report submitted to the Head of the Institution through the Head of the Department at the end of every six months. The assessment report may also be conveyed in writing to the candidate who may also be advised of his/her shortcomings, if any.
- (2) In case the report indicate that a candidate is incapable of continuing to do the work of the desired standard and complete it within the prescribed period, the Head of the Institution may recommend cancellation of his/her registration at any time to the University.
- (3) Formative Assessment:
 - (a) General Principles
 - i. The assessment is valid, objective, constructive and reliable.
 - ii. It covers cognitive, psychomotor and affective domains.
 - iii. Formative, continuing and summative (final) assessment is also conducted.
 - iv. Thesis is also assessed separately.
 - (b) Internal Assessment
 - i. The internal assessment is continuous as well as periodical. The former is based on the feedback from the senior residents and the consultants concerned. Assessment is held periodically.
 - ii. Internal assessment will not count towards pass/fail at the end of the program, but will provide feedback to the candidate.
 - iii. The performance of the Postgraduate student during the training period should be monitored throughout the course and duly recorded in the log books as evidence of the ability and daily work of the student.
 - iv. Marks should be allotted out of 100 as under
 - 1) Personal Attributes - 20 marks
 - a. Behavior and Emotional Stability: Dependable, disciplined, dedicated, stable in emergency situations, shows positive approach.
 - b. Motivation and Initiative: Takes on responsibility, innovative, enterprising, does not shirk duties or leave any work pending.

- c. Honesty and Integrity: Truthful, admits mistakes, does not cook up information, has ethical conduct, exhibits good moral values, loyal to the institution.
- 2) Clinical Work - 20 marks
 - a Availability: Punctual, available continuously on duty, responds promptly on calls and takes proper permission for leave.
 - b Diligence: Dedicated, hardworking, does not shirk duties, leaves no work pending, does not sit idle, competent in clinical case work up and management.
 - c Academic Ability: Intelligent, shows sound knowledge and skills, participates adequately in academic activities and performs well in oral presentation and departmental tests.
 - d Clinical Performance: Proficient in clinical presentations and case discussion during rounds and OPD work up. Preparing Documents of the case history/examination and progress notes in the file (daily notes, round discussion, investigations and management) Skill of performing bed side procedures and handling emergencies.
 - 3) Academic Activities - 20 marks
Performance during presentation at Journal club/ Seminar/Case discussion/Stat meeting and other academic sessions. Proficiency in skills as mentioned in job responsibilities.
 - 4) End of term theory examination - 20 marks
End of term theory examination conducted at end of 1st, 2nd year and after 2 years 9 months.
 - 5) End of term practical examination - 20 marks
 - a. End of term practical/oral examinations after 2 years 9 months.
 - b. Marks for personal attributes and clinical work should be given annually by all the consultants under whom the resident was posted during the year. Average of the three years should be put as the final marks out of 20.
 - c. Marks for academic activity should be given by the all consultants who have attended the session presented by the resident.
 - d. The Internal assessment should be presented to the Board of examiners for due consideration at the time of Final Examinations.
 - e. Yearly (end of 1st, 2nd & 3rd year) theory and practical examination will be conducted by internal examiners and each candidate will enter details of theory paper, cases allotted (2 long & 2 short) and viva.
 - f. Log book to be brought at the time of final practical examination.

APPOINTMENT OF EXAMINERS:

Appointment of paper setters, thesis evaluators, answer books evaluators and practical & viva voce examiners shall be made as per regulations of the Medical Council of India.

SCHEME OF EXAMINATION:

Scheme of examination in respect of all the subjects of MD/MS shall be as under :

- (1) The examination for MD/MS shall be held at the end of three Academic Years.
- (2) Examinations shall be organized on the basis of marking system.
- (3) The period of training for obtaining MD/MS degrees shall be three completed years including the period of examination.

- (4) The University shall conduct not more than two examinations in a year for any subject with an interval of not less than 4 months and not more than 6 months between the two examinations.
- (5) The examinations shall consist of:
- (a) Thesis :
- i. Thesis shall be submitted at least six months before the main Theory examinations.
 - ii. 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/Practical.
 - iii. In departments where besides the two earmarked practical/clinical examiners no one else is a qualified P.G. teacher, in that case the Thesis shall be sent to the third external examiner who shall actually be in place of the internal examiner.
 - iv. Only on the acceptance of the thesis by any two examiners, the candidate shall be eligible to appear for the final examination.
 - v. A candidate whose thesis has been once approved by the examiners will not be required to submit the Thesis afresh, even if he/she fails in theory and/or practical of the examination of the same branch.
 - vi. In case the Thesis submitted by a candidate is rejected, he/she should be required to submit a fresh Thesis.
- (b) Theory papers:
- i. There shall be four theory papers, as below:
Paper I: General Pharmacology
Paper II: Clinical Pharmacology
Paper III: Systemic Pharmacology
Paper IV: Recent Advances in Pharmacology
 - ii. Each theory paper examination shall be of three hours duration.
 - iii. Each theory paper shall carry maximum 100 marks.
 - iv. The question papers shall be set by the External Examiners.
 - v. There will be a set pattern of question papers.
Every question paper shall contain three questions. All the questions shall be compulsory, having no choice.
Question No. 1 shall be of long answer type carrying 20 marks.
Question No. 2 shall have two parts of 15 marks each. Each part will be required to be answered in detail.
Question No. 3 shall be of five short notes carrying 10 marks each.
 - vi. The answer books of theory paper examination shall be evaluated by two External and two internal examiners. Out of the four paper setters, the two paper setters will be given answer books pertaining to their papers and the answer books of the remaining two papers will be evaluated by two Internal Examiners. It will be decided by the President as to which paper is to be assigned to which Internal Examiner for evaluation.
 - vii. A candidate will be required to pass theory and practical examinations separately in terms of the governing provisions pertaining to the scheme of examination in the post graduate regulations. The examinee should obtain minimum 40% marks in each theory paper and not less than 50% marks cumulatively in all the four papers for degree examination to be cleared as “passed” at the said Degree examination.
- (c) Clinical/ Practical & Oral examinations:

- i. Clinical/Practical and Oral Examination of 400 marks will be conducted by at least four examiners, out of which two (50%) shall be External Examiners.
 - ii. A candidate will be required to secure at least 50% (viz. 200/400) marks in the Practical including clinical and viva voce examinations.
- (6) If a candidate fails in one or more theory paper(s) or practical, he/she shall have to reappear in the whole examination i.e. in all theory papers as well as practical.

GRACE MARKS

No grace marks will be provided in MD/MS examinations.

REVALUATION / SCRUTINY:

No Revaluation shall be permitted in the MD/MS examinations. However, the student can apply for scrutiny of the answer books as per University Rules.

GUIDELINES FOR COMPETENCY BASED POSTGRADUATE TRAINING PROGRAMME FOR MD IN PHARMACOLOGY (9060)

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 pharmacoconomics
7. Acquire knowledge on pharmacoepidemiology, including drug utilization studies.
8. Acquire knowledge and understanding of principles of Good clinical practice (GCP) and Good laboratory practice (GLP) guidelines
9. Acquire knowledge on essential medicines
10. Acquire knowledge on pharmacovigilance
11. Acquire knowledge and apply the principle of biostatistics in the evaluation and interpretation of drug safety and efficacy studies
12. Describe how to evaluate, analyse and monitor preclinical and clinical data in drug discovery
13. Able to integrate principles of immunology in biochemistry.
14. Demonstrate knowledge of basics of research methodology, develop a research protocol, conduct the study, record experimental observations, analyse data using currently available statistical software, interpret results and disseminate these results and to have the potential ability to pursue further specializations and eventually be competent to guide students.
15. Describe the principles of teaching - learning technology towards application and take interactive classroom lectures, modules for problem based learning (PBL), case discussions, small group discussions, seminars, Journal club and research presentations
16. Demonstrate knowledge about computer assisted learning (CAL) 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. Acquire knowledge about antimicrobial stewardship programs and strategies for containment of antibiotic resistance
22. Acquire knowledge on animal toxicity studies
23. Acquire knowledge on common poisoning
24. Acquire knowledge on the legal and ethical issues involved in drug development and research.

25. Acquire knowledge in Biostatistics including use of statistical softwares :
- Estimation Sample size for a clinical trial
 - Scales of measurement, data display, measures of central tendency (mean, median, mode) • Dispersion of data (variance, standard deviation)
 - Selection of tests (of significance) and their applicability
 - Correlation and regression analysis
 - Basics of systematic reviews and meta-analysis

B. Affective domain

1. Effectively explain to patients, the effects and side effects of drugs, including the need for medication adherence.
2. Communicate effectively with pharmacological reasoning with students, peers, staff and faculty, and other members of the health care team on rational use of drugs and improving spontaneous reporting of adverse events.
3. Demonstrate respect in interactions with peers, and other healthcare professionals.
4. Demonstrate ethical 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 pA2 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. Drugs acting on Smooth muscles
7. Drug Interactions of Adverse drug Reactions.
8. Clinical pharmacology
9. Drug development and Regulations, Toxicity studies
10. Clinical Pharmacokinetics, Rational basis of therapeutics
11. Autonomic Pharmacology
12. Drugs acting on Synaptic and Neuroeffector Junctional sites
13. 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)
14. Drugs modifying renal function
15. Drugs acting on cardiovascular system and haemostatic mechanisms (Antihypertensives, Antianginal, Antiarrhythmics, Drugs used in heart failure, Drugs used in Dyslipidemias, Fibrinolytics, Anticoagulants, Antiplatelets, Hematopoietic system)
16. Reproductive Pharmacology
17. Agents effecting calcification and bone turnover

18. Autacoids and related pharmacological agents (NSAIDs) and drugs used in Rheumatoid arthritis and Gout
19. Gastrointestinal drugs
20. Pharmacology of drugs affecting the respiratory system (drugs used in Bronchial Asthma and COPD)
21. Antimicrobial, antiparasitics, disinfectants, antiseptics
22. Chemotherapy of neoplastic disease
23. Antiviral drugs
24. Drugs used in Autoimmune disorder and Graft versus Host Disease)
25. Dermatological pharmacology
26. Ocular pharmacology
27. Use of drugs in pregnancy
28. Perinatal and Pediatric Pharmacology
29. Geriatric Pharmacology
30. Immunomodulators - immunosuppressants and immunostimulants
31. Pharmacology of drugs used in endocrine disorders (drugs used in diabetes mellitus, hypothalamic and pituitary hormones, thyroid and antithyroid drugs, adrenocorticoid hormones and their antagonists, gonadal hormones and their inhibitors)
32. Drug delivery systems
33. Heavy metal poisoning, vitamins, vaccines and sera.
34. Non-metallic toxicants - air pollutants, pesticides etc.
35. Research methodology and biostatistics
36. Literature search.
37. Pharmacogenomics, Pharmacovigilance (ADR reporting), pharmacoconomics (cost-effectiveness study) and pharmacoepidemiology
38. Over the counter drugs
39. Dietary supplements and herbal medicines
40. Pharmacometrics - methods of drug evaluation.
41. General screening and evaluation of:
 - Analgesics, antipyretics, anticonvulsants, anti-inflammatory drugs, antidepressants, antianxiety and antipsychotics, sedatives-hypnotics, 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, Antiparkinsonian, Anticancer drugs
 Behavioral pharmacology models and evaluation of drugs affecting learning and memory
42. Bioassays
 - Bioassay methods
 - Animal experiments: Ethical considerations, ethical approval, applicable regulatory Guidelines (CPCSEA), humane animal research (principles of 3Rs) and alternatives to animal experimentation. General and statistical considerations
 - Anesthetics used in laboratory animals
 - Principles of EC50, ED50, pD2 and pA2 values of drugs
 - Describe methods of bioassay for estimation of : Acetylcholine, skeletal neuromuscular junction blockers, adrenaline, noradrenaline, histamine, 5 HT, hormones, insulin, vasopressin/oxytocin, estrogen, progestins, ACTH

- Competitive antagonism - pA2 values
 - Immunoassays: Concept, types of bioassays and their application/s
 - Animal experiments: Ethical consideration, ethical approval
 - Regulatory Guidelines (CPCSEA) and alternatives to animal experimentation
43. 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).

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, pharmacoconomics, pharmacovigilance and pharmacoepidemiology.
 - III Thesis on a suitable problem
 - IV Training in undergraduate teaching
 - V Computer training

During the training programme, patient safety is of paramount importance; therefore, s kills 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.

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. 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
5. Rang and Dale's Pharmacology by H.P. Rang
6. Koda Kimble and Youngs Applied Therapeutics by Brian K Alldredge and Robin L Corelli
7. Practical Manual of Experimental and Clinical Pharmacology by Bikash Medhi and Ajay Prakash
8. Fundamentals of experimental Pharmacology by M.N. Ghosh
9. Postgraduate topics in Pharmacology by Rituperna Maiti
10. Drug screening methods by S K Gupta
11. Methods in Biostatistics by B K Mahajan

Journals

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

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.

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MODEL PAPER

MD-9061

Pharma.-I

**MD Examination Month, Year
PHARMACOLOGY**

**Paper – I
GENERAL PHARMACOLOGY**

Time : Three Hours
Maximum Marks : 100

Attempt all questions
All the parts of one question should be answered at one place in sequential order.
Draw diagrams wherever necessary

- Q.1 Describe G-Protein in detail. Critically describe the role of G – Protein in signal transduction in various cells. 20
- Q.2 Write in detail about. 2x15=30
- a) Clinical significance of clinical pharmacokinetics in geriatric & paediatrics age group. Give answer with suitable examples.
 - b) What is teratogenicity ? Enumerate the drugs producing such effects & different stages at which such effects are produced. What precautions should be taken to prevent teratogenicity?
- Q.3 Short Notes on : 5x10=50
- a) Essential drug concept.
 - b) New drug delivery system in cancer chemotherapy.
 - c) Rationale & irrational drug combinations.
 - d) Drug schedule & new amendment in schedule “Y”.
 - e) Public policy consideration & criticism of pharmaceutical industry.

MD-9062

MODEL PAPER

Pharma.-II

**MD Examination Month, Year
PHARMACOLOGY**

**Paper – II
CLINICAL PHARMACOLOGY**

Time : Three Hours
Maximum Marks : 100

Attempt all questions
All the parts of one question should be answered at one place in sequential order.
Draw diagrams wherever necessary

- Q.1 Write in brief pathophysiology and risk factors associated with following diseases. Write drug therapy. 20
- a) Diabetes.
 - b) Bronchial Asthma.
 - c) Myocardial Infarction.
 - d) Osteoporosis.
- Q.2 Write in detail about : 2x15=30
- a) Define pharmacovigilance, haemovigilance & materiovigilance. Describe briefly current status pharmacovigilance programme in India.
 - b) Current clinical status of drug modifying the Renin-Angiotensin System.
- Q.3 Write short notes on : 5x10=50
- a) Pharmacoeconomics.
 - b) Status of immunomodulators in viral infections.
 - c) Nitric Oxide modulation in therapeutics.
 - d) Treatment of extensively drug resistant tuberculosis (XDR TB).
 - e) Pharmacological basis of drug therapy in Rheumatoid arthritis.

MD-9063

MODEL PAPER

Pharma.-III

**MD Examination Month, Year
PHARMACOLOGY**

**Paper – III
SYSTEMIC PHARMACOLOGY**

Time : Three Hours
Maximum Marks : 100

Attempt all questions
All the parts of one question should be answered at one place in sequential order.
Draw diagrams wherever necessary

- Q.1 Discuss methods of evaluation of following drugs 20
- a) Anti-inflammatory drugs.
 - b) Anti-anxiety drugs.
 - c) Anti-emetics.
- Q.2 Write in detail about: 2 x15=30
- a) Discuss the role of internet application in modern pharmacological research.
 - b) The role of anti-microbials in treatment of pseudomonas infection.
- Q.3 Write short notes on : 5x10 = 50
- a) Animal toxicity studies.
 - b) CPCSEA.
 - c) ANOVA.
 - d) Causality assessment of adverse drug reactions.
 - e) Drug repositioning.

MD-9063

MODEL PAPER

Pharma.-III

**MD Examination Month, Year
PHARMACOLOGY**

**Paper – IV
RECENT ADVANCES IN PHARMACOLOGY**

Time : Three Hours
Maximum Marks : 100

Attempt all questions
All the parts of one question should be answered at one place in sequential order.
Draw diagrams wherever necessary

- Q.1 Describe in detail about cell cycle Angiogenesis and metalloproteinase as target for new drug development. 20
- Q.2 Write in detail about : 2x15=30
- a) Recent advances for treatment of infertility.
 - b) New approaches to treat obesity.
- Q.3 Write short notes on : 5x10=50
- a) Antibiotic policy & antibiotic stewardship.
 - b) Nanotechnology in medicine .
 - c) Gene therapy & Gene doping.
 - d) Role of bedaquiline in treatment of tuberculosis.
 - e) Recent advances in anti-malarial drugs.