

# Syllabus

## MD - PHARMACOLOGY (MD13)

(3 Years Post Graduate Degree Course)

Edition- 2022-23

### Notice

- 1. Amendment made by the NMC 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 (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 Management 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 NMC, 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 NMC rules after passing 3rd professional MBBS Part II Examination satisfactorily.

### CRITERIA FOR SELECTION FOR ADMISSION:

- 1. Out of total seats available for admission to the postgraduate courses 50% seats shall be ear marked for All India Quota and 50% shall be state Quota seats.
- 2. Out of total seats available for admission to the postgraduate courses 15% shall be management Quota seats. Theses seats shall be part of All India Quota seats.
- 3. Remaining 35% seats shall be of All India Quota nature.
- 4. Preference shall be given to state domicile candidates on all categories of seats.
- 5. Reservation shall be applicable on all category of seats as per the state government policy.

Admissions to the Postgraduate MD/MS Courses 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.

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 after application of roster by the Admission Board.

#### (3) **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 person with disability & EWS

### **ELIGIBILITY AND ENROLMENT:**

MD Pharmacology

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 through Principal of College for the enrolment/eligibility along with the following original documents and the prescribed fees within the prescribed period without late fees. Then after, students will have to pay applicable late fees as per prevailing University Rules –

- (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 / NMC/ 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 application to the MGUMST through Principal of College for registration with the prescribed fees within the prescribed period without late fees. Then after, students will have to pay applicable late fees as per prevailing University Rules.

#### **DURATION OF COURSE:**

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

### **PERIOD OF TRAINING:**

(1) 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 NMC.

### **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 NMC 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 the subject is compulsory. Any one failing to achieve this, shall notbe 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 NMC 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 Departmentand 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 recognitionby 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 reasonor 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 NMC 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.
  - 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 National Medical Commission .

### 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:
        - (1) **Paper I:** Basic sciences as applied to Pharmacology
        - (2) **Paper II:** Systemic Pharmacology
        - (3) Paper III: Clinical Pharmacology, Experimentation, Research,

Biostatistics and Education

- (4) **Paper IV:** Recent advances in the 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 fourpapers for degree examination to be cleared as "passed" at the said Degree examination.

(b) 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 thePractical including clinical and viva voce examinations.
- (5) 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 MDIN 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 10 assessment strategies. This document was prepared by various subject and education experts of the national Medical Commission. The subject Expert Group has attempted to render uniformity without compromising the purpose and content of the document. Compromise in purity of syntax has been made in order to preserve the purpose and content. This has necessitated retention of "domains of learning" under the heading "competencies".

### SUBJECT SPECIFIC LEARNING OBJECTIVES (GOALS)

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

### 1. Acquisition of knowledge

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

### 2. Acquisition of Skills

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

### 3. Teaching and training

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

### 4. Research

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

in their thesis, research work and all other academic activities.

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

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

### SUBJECT SPECIFIC COMPETENCIES

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

### A. Predominant in Cognitive domain

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

#### **General Pharmacology:**

- 1. Demonstrate an understanding of the basic principles of Pharmacology including molecular pharmacology.
- 2. Demonstrate an awareness of the historical journey and contributions of scientists in the drug development process.
- 3. Describe the process of new drug development including preclinical and clinical phases.
- 4. Describe principles of pharmacokinetics of drugs and apply these to prescribe medicines for individualization of pharmacological therapy, including use of medicines in special categories (Pediatrics, Geriatrics, Pregnancy and Pathological states).
- 5. Explain the principles of pharmacodynamics and apply these in different therapeutic situations.
- 6. Describe mechanisms of drug-drug interactions and their clinical importance.
- 7. Describe the principles of pharmacogenomics and its clinical significance.
- 8. Describe pharmacological principles underlying the effects of drugs used in diagnosis, prevention and treatment of common systemic diseases in man.

- 9. Demonstrate an understanding of the factors that modify drug action.
- 10. Define Therapeutic Drug Monitoring (TDM), describe the methods of TDM and importance in therapeutic decision making.
- 11. Describe the principles and importance of Pharmacoeconomics in healthcare delivery. Describe the methods in pharmacoeconomic studies and the economic considerations in the use of medicines in individuals and in the community.
- 12. Describe the principles, methods and importance of pharmacoepidemiology, including drug utilization studies.
- 13. Define pharmacovigilance. Describe the importance of pharmacovigilance in ensuring patient safety and the various methods/procedures in pharmacovigilance.
- 14. Describe the role of Essential Medicines in rational therapeutics. Describe principles for selecting Essential Medicines for a defined healthcare delivery system.
- 15. Demonstrate an understanding of principles of rational prescribing.
- 16. Demonstrate an understanding of prescription analysis and be able to conduct prescription analysis in a healthcare facility.
- 17. Demonstrate an understanding of antimicrobial resistance, antibiogram, antimicrobial stewardship program and strategies for containment of antimicrobial resistance.

### Systemic Pharmacology:

- 1. Apply and integrate knowledge of pathophysiology of diseases and pharmacological principles underlying the effects of drugs, for the purpose of diagnosis, prevention and treatment of common systemic diseases in man including disorders of:
  - a. Synaptic & neuroeffector junctional sites of the autonomic nervous system
  - b. Neuromuscular junction
  - c. Central nervous system
  - d. Cardiovascular system
  - e. Endocrine system
  - f. Gastrointestinal system
  - g. Respiratory system
  - h. Renovascular system
  - i. Hematological system
  - j. Immunological system

### k. Autacoids

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

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

### **Research:**

- 1. Demonstrate an understanding of the importance and ethical considerations of biomedical research in animals and man.
- 2. Describe the principles and methods of biomedical research in animals and man.
- 3. Describe the current principles of Good Clinical Practice (GCP) and Good Laboratory Practice (GLP) guidelines, as applicable.
- 4. Demonstrate an understanding of the different tools and methods for literature search.
- 5. Describe and apply the principles of biostatistics in the evaluation and interpretation of efficacy and safety studies of drugs in man. Apply and interpret the various statistical tools in biomedical research.
- 6. Demonstrate an understanding of the principles of Good Publication practices as applicable to publication of research studies.
- 7. Describe different methods of drug assays biological, chemical, immune-assay including knowledge of analytical techniques like HPLC, TLC etc. and their applications in therapeutics.
- 8. Describe the methods for screening/evaluation of **a**nalgesics, antipyretics, anticonvulsants, anti-inflammatory drugs, antidepressants, antianxiety and antipsychotics, sedatives, muscle relaxants, antihypertensives, hypocholesterolemic agents, antiarrhythmic drugs, diuretics, adrenergic blocking

drugs, drugs affecting learning and memory in animals and man. (*Note: This is only an indicative list*).

9. Describe the regulatory and ethical issues involved in drug development and research.

### **Teaching and Assessment:**

- 1. Demonstrate an awareness about the salient features of Undergraduate Medical Education Curriculum in India.
- 2. Demonstrate an awareness about Postgraduate Medical Education Curriculum and Guidelines in India.
- 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 ofclinical trials.
  - Prepare Informed Consent Form and Participant Information Sheet forclinical trials/research.
  - Administer Informed Consent Form
  - Evaluate promotional drug literature
  - Prepare "Package insert"
  - Calculate and interpret pharmacokinetic parameters of a drug from agiven data
  - Demonstrate skills to prepare material for teaching-learning and assessment.

- 10. Test and predict efficacy of drugs following appropriate guidelines and
- **ii.** The students after training in the MD (Pharmacology) course should be able to *do/perform following procedures under supervision*:

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 beable to:
- 17. Collect blood samples and oral gavage from experimental animals.
- 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
- 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
- Autacoids and related pharmacological agents (analgesics) and drugsused 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
- National programmes for infectious and vector borne diseases including theregimes.
- 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, antiarrhythmic drugs, diuretics, adrenergic blocking drugs, local anaesthetics, antifertility agents,

antidiabetics, drugs used in peptic ulcer diseases and drugs affecting learningand 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 ethicalapproval
  - 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 andpoisons 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 indepth 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 teachinglearning 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)
	Department of Medical Education (DOME)	i 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 3<sup>rd</sup> or 4<sup>th</sup> or 5<sup>th</sup> 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 workdone and intervene, if necessary,
- c) provide feedback and assess the progress of learning with experiencegained periodically.

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

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

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

### L. Other aspects

- The postgraduate trainees must participate in the teaching and training program of undergraduate students and interns attending the department.
- Trainees shall attend accredited scientific meetings (CME, symposia, and

conferences) at least once a year.

- Department shall encourage e-learning activities.
- The postgraduate trainees must undergo compulsory training in Basic Cardiac Life Support (BCLS) and Advanced Cardiac Life Support (ACLS).
- The postgraduate trainees must undergo training in information technology and use of computers.
- The postgraduate trainees should preferably undergo training in Good Clinical Practice (GCP)

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

### ASSESSMENT

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

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

### **General Principles**

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

### Quarterly assessment during the MD training should be based on:

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

- Interdepartmental case or seminar : once a month
- **Note:** These sessions may be organized and recorded as an institutional activity for all postgraduates.
  - Attendance at Scientific meetings, CME programmes (at least 02 each)

### Important instructions:

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

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

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

### Essential pre-requisites for appearing for examination include:

- 1. **Log book** of work done during the training period including rotation postings, departmental presentations, and internal assessment reports should be submitted.
- 2. At least two presentations at national level conference. One research paper should be published / accepted in an indexed journal. (It is suggested that the local or University Review committee assess the work sent for publication).

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

The postgraduate examination shall be in three parts:

1. Thesis

Thesis shall be submitted at least six months before the Theory and Clinical / Practical examination. The thesis shall be examined by a minimum of three examiners; one internal and two external examiners, who shall not be the examiners

for Theory and Clinical examination. A post graduate student in broad specialty MD Pharmacology 27

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 3<sup>rd</sup> 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 examinationPractical examination

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

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

### **Practical Examination Exercises:**

### a) long exercises:

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

### b) short exercises:

- Interpretation of results of a previous tracing Table exercise
- Demonstration of effects of drugs/interpretation of results in human
- Demonstration of effects of drugs/interpretation of results in small,animals - optional (as per Regulations notified)
  The exercises should be observed and assessed.
- c) **OSPE exercises:** Objective Structured Practical Examination (OSPE)

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

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

### d) Assessment of teaching/presentation skills

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

### **Recommended Readings**

### **Books:**

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

2. Katzung BG. Basic & Clinical Pharmacology, 15th edition, McGraw Hill MD Pharmacology 29 Education, 2018.

- 3. Papadakis MA, Mcphee SJ. Current Medical Diagnosis & Treatment. 62<sup>nd</sup> edition New York. McGraw Hill Education.2023.
- 4. Ritter M, Flower R, Henderson G, Loke YK, MacEwan D, Rang HP. Pharmacology. Elsevier, 9<sup>th</sup> edition, 2019.
- Tripathi KD. Essentials of Medical Pharmacology, 8<sup>th</sup> edition. Jaypee Brothers Medical Publishers Private Ltd: New Delhi 2021.
- M. N. Ghosh. Fundamentals of Experimental Pharmacology. 7<sup>th</sup> Edition. Hilton & Company, 2019.
- Badyal D. Practical Manual of Pharmacology. Jaypee Brothers Medical Publishers; 3<sup>rd</sup> edition 2021.
- Vogel HJ. Drug Discovery and Evaluation: Pharmacological Assays Springer; 3<sup>rd</sup> edition, 2008.
- Sharma S, Velpandian T. Illustrated Reviews Pharmacology. Wolter Kluver, South Asian Edition, 2019.
- Medhi B, Prakash A. Practical Manual of Experimental & Clinical Pharmacology. Jaypee Brothers Medical Publishers, 2<sup>nd</sup> edition, 2017.
- 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, 10<sup>th</sup> edition, 2012.
- 12. Medhi B, Prakash A. Advanced pharmacology. Academa Publishers, 2<sup>nd</sup> edition, 2019.

### 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).

- 1. Basic and Clinical Pharmacology and Toxicology
- 2. British Journal of Clinical Pharmacology
- 3. Journal of Pharmacology & Pharmacotherapeutics
- 4. Journal of Basic and Clinical Physiology and Pharmacology
- 5. Journal of Physiology and Pharmacology
- 6. Indian Journal of Pharmacology
- 7. Indian Journal of Pharmacy and Pharmacology

### Annexure I

	Student app	rai	sal	for	m f	or N	<b>ID</b>	in P	har	mac	cology
	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										

	Desthelesst	1			1	r			
	Participation and								
	compliance with								
	the quality								
	improvement								
2.4	process at the								
	work environment								
	Ability to record								
	and document								
	work accurately								
2.5	and appropriate for								
	level of training								
	Professional				1				
3	attributes								
						-			
	Responsibility and								
3.1	accountability								
	Contribution to								
	growth of learning								
3.2	of the team								
0.2									
	Conduct that is								
	ethically								
	appropriate and								
	respectful at all								
3.3	times								
	Space for	-							
	additional								
4	comments								
5	Disposition								
	Has this								
	assessment								
	pattern been								
	discussed with the	Va-	No						
	trainee?	Yes							
	If not explain	1			1				
$\left  - \right $							 	 	
	Name and								
	Signature of the								
	assesse								
	assessor								
	Date								

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

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### 5. Dr. Avijit Hazare

Professor, Department of Pharmacology Institute of Postgraduate Medical Education & Research (IPGME&R), Kolkata 700020, West Bengal **MODEL PAPER** 

MD Examination Month, Year

### PHARMACOLOGY Paper I: Basic sciences as applied to 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:-

**MD13** 

- a) Clinical significance of clinical pharmacokinetics in geriatric & paediatric age group. Give answer with suitable examples.
- b) Define Pharmacovigilance, Haemovigilance & Materiovigilance. Describe briefly current status of Pharmacovigilance programme in India.

Q.3. Write	short	notes	on	-
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- a) Essential drug concept.
- b) New drug delivery system in cancer Chemotherapy.
- c) Rational & Irrational drug combinations.
- d) Dug Induced Teratogenicity.
- e) Pharmacoeconomics

Pharm.-I

 $5 \times 10 = 50$ 

 $2 \times 15 = 30$ 

### **MODEL PAPER**

Pharm.-II

MD Examination Month, Year **PHARMACOLOGY Paper II: 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. Write in brief pathophysiology and risk factors associated with following diseases drug therapy.	. Write 20
a) Diabetes	
b) Bronchial Asthma	
c) Myocardial Infarction	
d) Osteoporosis	
Q.2. Write in detail about:-	$2 \times 15 = 30$
a) Current clinical status of drugs modifying the Renin-Angiotensin System.	
b) The role of anti-microbials in treatment of psuedomonas infection.	
Q.3. Write short notes on	$5 \times 10 = 50$
a) Nitric Oxide modulation in therapeutics.	
b) Status of Immunomodulators in viral infections.	
a) Dharmanalogical basis of drug therapy in Dhaumatoid arthritic	

- c) Pharmacological basis of drug therapy in Rheumatoid arthritis.
- d) Treatment of extensively drug resistant tuberculosis (XDR TB)
- e) Non-endocrinal uses of Glucocorticoids.

**MD13** 

Clinical Pharmacology, Experimentation, Research, Biostatistics and Education 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 methods of evaluation of following activity of drugs. 20 a) Anti-inflammatory b) Anti-anxiety c) Anti-emetic  $2 \times 15 = 30$ Q.2. Write in detail about:a) The role of internet application in modern pharmacological research. b) Competency based medical education and its rationale. Q.3. Write short notes on a) ANOVA b) Principles of Good clinical practice

MD Examination Month, Year PHARMACOLOGY

# Paper III:

### $5 \times 10 = 50$

**MD13** 

- c) Meta-analysis
- d) Bioavailability studies
- e) Ethical considerations in animals experiments

**MODEL PAPER** 

Pharm.-III

### **MODEL PAPER**

Pharm.-IV

### MD Examination Month, Year **PHARMACOLOGY Paper - IV Recent advances in the 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 and its importance in cancer therapy. Write on newer targeted therapy of cancer. 20

Q.2. Write in detail about :	$2 \times 15 = 30$

- a) Recent advances for treatment of infertility.
- b) New approaches to treat obesity.

Q.3. Write short notes on -

**MD13** 

- 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

 $5 \times 10 = 50$ 

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