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Department of Pharmacology

MD (Pharmacology) Curriculum, AIIMS, Nagpur

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MD (Pharmacology) Curriculum, AIIMS, Nagpur

1. Goal

Pharmacology encompasses all aspects of knowledge about drugs, for effective and safe use of drugs in patient care.

The ultimate goal of teaching pharmacology to postgraduate student is to develop expertise in the field of pharmacology and to expand the scope of pharmacology from bench to bedside.

2. Programme Outcome

At the end ofthe MD (Pharmacology) training, the postgraduatestudent shall be able to achieve following **learning objectives** related to general pharmacology, experimental /clinical pharmacology, research, teaching and communication skill.

2.1 General Pharmacology

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. Describe mechanisms of drug-drug interactions and their clinical importance.
3. Apply and integrate knowledge of pathophysiology of diseases and its modulation by drugs.
4. Explain pharmacogenetics and pharmacogenomics, pharmaco economics, Pharmacoepidemiology and its applied aspect.
5. Acquire knowledge and understanding of principles of Good clinical practice (GCP) and Good laboratory practice (GLP)guidelines
6. Explain and implement rational use of medicine, essential medicine and use of generic medicines.
7. Demonstrate skills for prescription writing.

2.2 Experimental/Clinical Pharmacology

8. Clinical pharmacology practicals (7-10 experiments on human volunteers)
9. Pharmacokinetic problems
10. Perform major *in vivo* and *in vitro* animal experiments including toxicity studies.

11. Describe how to evaluate, analyze and monitor preclinical and clinical data in drug discovery
12. Describe strategies for containment of antibiotic resistanceincludingantimicrobial stewardship programs
13. Monitor and report adverse drug reactions under Pharmacovigilance programme of India (PvPI) and provide drug information services to the needy.
14. Provide therapeutic drug monitoring services through estimation of drug concentration in plasma using advanced techniques, like High Performance Liquid Chromatography (HPLC)/LCMS/MS
15. Acquire knowledge on the legal and ethical issues involved in drug development and research.

2.3 Biostatistics

16. Acquire knowledge and apply the principle of biostatistics in the evaluation and interpretation of drug safety and efficacy studies
17. Able to perform biostatistical analysis of data obtained from preclinical and clinical studies using statistical softwares

2.4 Research

18. Write a research protocol, conduct the study, record experimental observations, analyze data using currently available statistical software and interpret results.
19. Demonstrate presentation skills at academic meetings, publications and writing research projects for funding agencies.
20. Write protocols to conduct experimental studies in animals and clinical trials in human beings.
21. Plan and conduct research works, applying the principles of research methodology including biomedical statistics.
22. Write and publish research papers in peer reviewed journals;
23. Critically review and comment on published research papers/ Promotional drug literature

2.5 Teaching/ Communication skill

24. 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
25. Demonstrate knowledge about computer assisted learning (CAL) softwares and ability to use them efficiently to promote learning of pharmacology.

26. 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.
27. Communicate effectively with pharmacological reasoning with patients, students, peers, staff and faculty, and other members of the health care team on rational use of drugs and improving spontaneous reporting of adverseevents.

3. Syllabus

The **course contents** should cover the following broad topics:

3.1 Theory

a. General Pharmacology and allied topics

1. Principles of drug action, agonist, antagonist, partial agonist, inverse agonist, spare receptors and types of antagonism.
2. Molecular mechanisms of drug action including drug receptor interactions, transducer mechanisms, second messenger systems in transmembrane signaling, G – protein coupled receptors, tyrosine kinase linked receptors, ion channel linked receptors, nuclear receptors, P-glycoprotein.
3. Pharmacokinetic principles: Factors governing transport of drugs across biological membranes; basis of selective distribution of drugs in the body; biotransformation and elimination of drugs; drug elimination kinetics and its clinical importance; bioavailability and bioequivalence
4. Drug interactions, fixed dose combinations and combined use of drugs.
5. Adverse effects of drugs including drug toxicity, hypersensitivity, idiosyncrasy, tolerance, dependence, teratogenicity, mutagenecity and carcinogenicity.
6. Dose-response relationships, variation in drug response and factors governing it.
7. Physiological processes and biochemical mechanisms relevant to the understanding of drug action.
8. Ethnopharmacology.
9. Essential drugs, P drug concept and list, rational prescribing.
10. Structure – activity relationships in drug action.
11. Molecular biology in Pharmacology: pharmacogenomics, proteomics, epigenetics, gene expression, PCR, antisense oligonucleotides, molecular targets of drug actions etc.

b. Systemic Pharmacology

- Autonomic nervous system
- Central nervous system
- Autacoids
- Drugs affecting kidney function and Cardiovascular system
- Drugs affecting gastrointestinal and respiratory system
- Drugs affecting uterine motility
- Chemotherapy of parasite infections
- Chemotherapy of microbial diseases
- Antineoplastic agents
- Immunomodulators
- Drugs acting on blood and blood forming organs
- Hormones
- Miscellaneous

c. Experimental Pharmacology

1. Principles governing animal experimentation and their limitations in drug evaluations.
2. General screening and evaluation of :

   Analgesic, anticonvulsant, antipyretic, antipsychotic, antidepressant, hypnotic, antiparkinsonian, antiinflammatory, skeletal muscle relaxant, local anaesthetic, antihistaminic, hypoglycemic, antifertility, antitussive, antiulcerogenic, antitumour, diuretic, antiemetics.antihypertensive, antianginal, antiarrhythmic, cardiotonic drugs.
3. General principles of bioassay of drugs, methods of bioassay.
4. Toxicity studies including acute, sub acute and chronic toxicity studies including special toxicity studies (teratogenicity, carcinogenicity and mutagenicity)
5. Basics of cell cultures techniques and in vitro cell culture based on drug toxicity testing.
6. Evaluation of addicting liability of drugs, methods of studying intestinal absorption of drugs, methods of studying biotransformation and excretion of drugs.
7. Basic principles and applications of simple analytical methods
8. 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).

d. Biostatistics

Estimation Sample size for a clinical trial

Elements of data collection and presentation of data

Measures of central tendency and dispersion

Non-parametric tests

Parametric test

Correlation and regression

Meta-analysis

e. Clinical Pharmacology

1. The scope of clinical pharmacology and its relevance to optimum use of drugs.
2. Preclinical data needed by regulatory authorities before undertaking clinical trial of a new drug.
3. Clinical trials: GCP, protocol designing, placebos, phases of clinical trial – their purpose and methodology.
4. Ethical aspects of clinical trials and studies of drugs in human beings.
5. Drug regulations: Drug regulatory requirements for clinical trials in India, drugs and cosmetic act, drug price control order
6. Pharmacovigilance.
7. Therapeutic drug monitoring: Dosage strategies, influence of hepatic, renal, cardiovascular, hormonal, gastrointestinal diseases and ageing on pharmacokinetics of drugs.
8. Drug utilization studies, pharmacoeconomics, rational prescribing and concept of essential drugs.
9. Recent advances in the understanding of drug action and their future therapeutic relevance.

3.2 Practicals

1. *In vivo* and *ex vivo* experiments in experimental animals using various instruments like organ bath, analgesiometer, physiography/ polygraph, convulsiometer, plethysmograph, learning and memoryetc as per CPCSEA guidelines. At present, no animal house and committee, hence practicals will be done using CAL
2. Administration of drugs by various routes (subcutaneous, intravenous, intraperitoneal) in experimental animals OR using maniquins
3. Collection of blood samles and oral gavage in experimental animals if available
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 ileum/chicken ileum

ii) Isolated rat uterus

6. Determination of EC50, ED50, pD2 and pA_2 values of drugs
7. Perform *in vivo* experiments to study effect of mydiatrics and miotics on rabbit eye
8. Perform *in vivo* experiments to study effect of antiepileptic drugs usinganimal 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. Proficiency in using computer aided learning (CAL) programme for demonstration of effects of drugs on animals.
12. Demonstration of effect of various drugs on blood pressure in anaesthetized animal and demonstration of various phenomenon like vasomotor reversal of Dale, Tachyphylaxis, Potentiation, Nicotinic action of acetyl choline using CAL.
13. Estimation of drugs in plasma using HPLC/LCMS
14. Clinical pharmacology

- Draft a protocol for different phases of clinicaltrials
- Draft an IND and NDA application
- Prepare Informed consent form and participant information sheetfor research involving human participants
- Writing a research proposal involving humans for ethics committee approval.
- Evaluate promotional drug literature
- Prepare "Drug Information Sheet" (WHOcriteria)
- Interpret bioavailability parameters with the help ofgivenpharmacokineticsdata
- Report Serious Adverse Effect(SAE)
- Perform causality assessment and report ADR as per pharmacovigilance Programme of India(PvPI)
- Posting in ethics committee to know the functioning of Ethics committee and roles & responsibilities of each member.
- Visit to clinical trial sites to know the functioning of clinical trials
- Estimation of drug concentration in serum under Therapeutic drug monitoring (TDM) and its clinical correlation
- Preparation of Essential Drug List (EDL)

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

- **Learning experience**: Lectures, group discussions, symposia, practicaldemonstrations, dissertation, posting at various labs (clinical dept, IEC, Pharmacovigilance unit, TDM unit, Drug store)
- **Journal club: T**o familiarize with research methodologies and analysis of results.
- **Seminars: T**o update newer developments in pharmacology, emerging trends intherapeutics, novel mechanisms of drug action, novel use of an old drug etc.
- **Group discussion**
- **Clinical case discussion/PBL**
- **Departmental and Institutional posting**

Sr No	**Place of posting**	**Year**	**Duration**	**Objectives**
Departmental posting				
1	Ethic committee	1st	4 months	Get acquainted with functioning of EC and SAE analysis
2	Pharmacovigilance	1st	4 months	To know PvPI and ADR reporting
3	Therapeutic drug monitoring	1st	4 months	To learn estimation of plasma drug concentration
4	Clinical trial site visit	2nd	1 month	To know CRF, Informed consent process and other details.
Institutional Posting				
1	Medicine	2nd	15 days	Prescription analysis for rational use of medicine and clinical case discussion
2	Surgery	2nd	15 days	Perioperative drug management
3	Microbiology	2nd	7 days	Antibiotic stewardship programme
4	Pharma industry/CRO internship	2nd	2 months	1.To know about various aspects of conducting clinical trials. 2.To get familiarize with its functioning, new drug development

				process,pharmacovigilance, drug marketing etc
5	Hospital drug store	1st	2 months	To know ABC/VED clasiification and management of drug store.

- **Practical exercises:** At least once a week, under the supervision of a faculty todevelop practical skills to conduct similar experiments in the future. The student must maintain a record of conducted practicals.
- **Thesis**:
- Each PG student will carry out a research work under the supervision of aPGguidefrom the Pharmacology department. PG guide will be allotted within 2 months of joining of PG students. Selection of thesis topic, review of topic in department and its approval by IEC should be completed within first 6 months. Data collection of thesis should be started from 2nd term. The dissertation will be reviewed by all faculty members of the department before submission to the institute.Acceptance of thesis by panel of examiners will be a prerequisite for the candidate to appear in the final examination.
- Attend accredited scientific meetings (CME, symposia, andconferences).
- A postgraduate student would be required to present one poster presentation, one oral presentation of research paper at a national/state conference. He/Sheshould publish/accept for publication/sent for publication one research paper during the period of his postgraduate tenure.
- Additional sessions on basic sciences, biostatistics, research methodology, teaching methodology,health economics, medical ethics and legal issues related to experimentation are suggested.
- It is mandatory for the postgraduate student to attend workshop/training program on Research methodology/ Biostatistics.
- The postgraduate students shall be required to participate in the teaching and training programmeof undergraduate students andinterns.
- **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.

5. Assessment plan

5.1 Internal assessment

(A) Theory:

Schedule	Marks
At end of First year	100 (1 Paper)
At end of Second year	100 (1 Paper)
Pre-professional	400 (4 Papers of 100 marks each)
Total	**600**

(B) Practical:

Schedule	Marks
At end of First year	100
At end of Second year	100
Pre-professional	400 (Practical 300 + Viva 100)
Total	**600**

Candidate should secure a minimum of 50 %marks in theory and practical separately, in order to be eligible to appear for professional examination

Summative

A	Theory	4 Papers each of 100 Marks = 400 Marks
B	Practical	Practical 300 + Viva 100 = 400 Marks

Final Result

(A) Theory =400 marks (Minimum 40% marks in each paper and aggregate of 50 % in order to be declared pass)

(B) Practical = 400 Marks

Minimum 50% marks required in theory and practical separately in order to be declared successful at MD examination

Theoryexamination

Type of examination	No of Papers	Exam Pattern for each paper (80 marks)
At the end of 1st year	1	2 Long answer questions (LAQ) (2 *20= 40 marks) 6short answer questions (SAQ)(6 * 10= 60 marks)
At the end of 2nd year	1	
Pre-professional & Professional examination	4	2 Long answer questions (LAQ) (2 *20= 40 marks) 6short answer questions (SAQ)(6 * 10= 60 marks)

There shall be four theory papers for Pre-professional & Professional exam(100 marks each)

Paper	Course content
I	General pharmacology, Screening and evaluation of drugs (Animal and Clinical), biostatistics & Research methodology
II	Systemic pharmacology. (Drugs, affecting – autonomic nervous system, cardiovascular system, kidney, blood and blood forming organs, respiratory system, gastrointestinal tract, uterus, skin & mucous membrane, autacoids, ocular pharmacology, vitamins and chelating agents)
III	Systemic pharmacology (Drugs affecting- central nervous system, endocrinal system, chemotherapy of microbial diseases, chemotherapy of parasitic diseases, antineoplastic drugs, immunopharmacology, drug usage in children, in elderly, in organ failure, during pregnancy & lactation)
IV	Clinical Pharmacology & therapeutics including recent advances

3. Practical examination

Type of examination	Total marks 100
At the end of 1st year (1 day)	Que 1:Demonstrating effects of drugs/interpretation of results in anesthetized animal Or Demonstration of experimental technique and equipment handling (30) using CAL OR Clinical pharmacology practical Que 2:Short experiment (any two) 20 marks each Calculating pharmacokinetic parameters Criticalappraisalofapublishedpaper Microteaching Evaluation of promotional drug literature. Que 3: Viva (30 marks)
At the end of 2nd year (1 day)	Que 1: Bioassay on isolated tissue (guineapig ileum, chiken ileum etc)Or Interpretation of results of a previous tracing (30 marks) Que 2: Short experiment (any two) 20 marks each i. Protocoldesigning ii. ADR reporting and causalityassessment iii. Assessment of preclinical toxicitydata iv. Analysis of rational and irrationalformulations v. Statistical exercise Que 3: Viva (30 marks)
Pre-professional & Professional	**Que 1: Long Experiment (160 marks)** a. Experiment based on experimental Pharmacology (Bioassay on chicken ileum)Or Clinical Pharmacology (2 exercise) (130marks)

examination (400 marks) (For 2 days)	b. Demonstrating effects of drugs/interpretation of results in anesthetized animal OrDemonstration of experimental technique and equipment handling (30 marks) **Que 2: Short experiment (Any four exercises -140 marks)** i. Calculating pharmacokinetic parameters ii. Statistical exercise iii. Criticalappraisalofapublishedpaper iv. Microteaching v. Evaluation of promotional drug literature. vi. Protocoldesigning vii. ADR reporting and causalityassessment iii. Assessment of preclinical toxicitydata ix. Analysis of rational and irrationalformulations x. Clinical pharmacology xi. Any other exercise **Que 3: Viva voce (including Thesis) Examination (100 marks)**

General instructions:

1. Thesis shall be submitted at least six months before the Theory and Practical examination. A post graduate student shall be allowed to appear for the Theory and Practical examination only after the acceptance of the Thesis by the examiners.
2. Internship to pharmaceutical industry will be informed to head of the department & Director for permission well in advance.
3. Postgraduate student should attend undergraduate classes conducted by horizontal/vertical integration.
4. It is mandatory to score minimum 50% marks in theory & practical each in internal assessment examination to be eligible to appear for professional examination.
5. Obtaining a minimum of 50% marks in 'Theory' as well as 'Practical' separately shall be mandatory for passing Professional examination as a whole.
6. The examination for M.D.shall be held at the end of 3rd academic year.
7. **Timing of six monthly progress report submission to Academic Section:**

Report	**July Session**		**January session**	
	Period	**To be submitted**	**Period**	**To be submitted**
First	July to December	7th January	January to June	7th July
Second	January to June	7th July	July to December	7th January

Third	July to December	7th January	January to June	7th July
Fourth	January to June	7th July	July to December	7th January
Fifth	July to December	7th January	January to June	7th July
Sixth	January to June	10th June	July to December	10th December

Note: The first five reports will be taken into consideration to decide the eligibility of the student to appear for the Professional Examination.

8. Dissertation

Synopsis submission and approval:Process to be completed within six months of admission to MS/MD program:

Activity	July admission	January admission
Selection of topic in consultation with PG Guide	September / October	March / April
Approval by Department PG Committee		
Institute Scientific Committee approval	November / December	May / June
Institute Ethics Committee approval		
Final approval letter by Academics Section	31st December	30th June

Submission of Dissertation:
The Dissertation will be submitted to Academic Section at least six months prior to the scheduled examination, i.e. by 31st December for June examination and by 30th June for December examination.

Recommended books (latest edition)

1. Goodman &Gilman's The Pharmacological basis of Therapeutics, Laurence L Brunton, 13thed, 2017, McGraw Hill
2. Essentials of Medical Pharmacology,KD Tripathi,8thed,2018,JPBrothers Medical Publisher
3. Principles of Pharmacology, HL Sharma, KK Sharma,3rded,2017, Paras Medical Publisher.
4. Textbook of Pharmacology & Therapeutics, R S Satoskar, N NRege, R K Tripathi, S D Bhandarkar, 25thed, 2017, Elsevier.
5. Basic & Clinical Pharmacology, Bertram Katzung, 14thed, 2017, McGraw Hill.
6. Rang &Dale's Pharmacology, H P Rang, J M Ritter, R J Flower, G Henderson, 8thed(International ed), 2015, Churchill Livingstone.
7. Fundamentals of Clinical Trials, Lawrence M Friedman, Curt D Furberg, David L DeMets, David M Reboussin, Christopher b Granger, 5thed, 2015, Springer Nature

8. Lippincott Illustrated Reviews: Pharmacology, Karen Whalen, 6th ed, 2014, Wolters Kluwer India Pvt Ltd
9. Practical manual of Experimental & Clinical Pharmacology, BikashMedhi, Ajay Prakash, 2nd ed, 2017, Jaypee Brothers Medical Publisher
10. Fundamental of Experimental Pharmacology, M N Ghosh, 4th ed, 2008, S K Ghosh
11. Harrison's Principles of Internal Medicine. (16th edition/latest) McGraw Hill press New York volume I & II (2005 / latest)
12. Complete text book of medical pharmacology. S K Shrivastava, 2nd edition
13. Post graduate pharmacology.Sougata Sarkar, Paras medical publisher
14. Post graduate topics in pharmacology,RituparnaMaiti, Paras medical publisher

Journals to be referred

1. Annual Review of Pharmacology and Toxicology
2. British Journal of Pharmacology
3. British Journal of Clinical Pharmacology
4. Clinical Pharmacology and Therapeutics
5. Drugs
6. European Journal of Clinical Pharmacology
7. Fundamental and Clinical pharmacology
8. Indian Journal of Pharmacology
9. Indian Journal of Physiology & Pharmacology
10. Journal of Pharmacology and Experimental Therapeutics
11. Pharmacological Reviews
12. The new England journal of Medicine
13. Trends in Pharmacological Science