

THE TAMIL NADU Dr. M.G.R. MEDICAL UNIVERSITY

No. 69, ANNA SALAI, GUINDY, CHENNAI – 600 032.

M.D. / M.S.
POST GRADUATE DEGREE COURSES



SYLLABUS AND CURRICULUM

2021 - 2022

M.D. PHARMACOLOGY

THE TAMIL NADU Dr. M.G.R MEDICAL UNIVERSITY, CHENNAI

M.D. PHARMACOLOGY

1. GOAL :

The aims of MD course in Pharmacology are:

To train a medical graduate to be a Pharmacologist who is well versed with the basic principles of Pharmacology and is up to date with the recent advances.

Acquisition of skills related to teaching, research methodology and corporate world.

Knowledge of elementary statistics and its applications.

Overall development of skills and personality of the PG resident.

Broaden the scope of Pharmacology from bench to bed side.

2. OBJECTIVES:

A) Knowledge:

At the end of the MD course in Pharmacology, the student should be able to: Recognize the importance of Pharmacology as a key branch in health sciences.

B) Attitude:

Develop skills as a self-directed learner, recognize continuing educational needs; use appropriate learning resources and be able to critically analyze relevant published literature.

Function as a productive member of a team engaged in research, education and industry.

Play the assigned role in the implementation of national health programs effectively, including planning of drug procurement and distribution.

C) Skills:

Utilize the acquired knowledge in teaching, research and industry ; Plan and organize projects using managerial and leadership skills.

Understand and apply ethical principles involved in animals and human experiments.

Handle animals to conduct experiments e.g. screening of various drugs.

Perform qualitative and quantitative identification and estimation of drugs in different samples of body fluids. Design protocol for clinical trials. Incorporate Knowledge of information technology in medical sciences. Monitor adverse drug reactions and provide drug information service to the needy

3.COMPONENTS OF THE POSTGRADUATE CURRICULUM

Theoretical Knowledge:

Course Content :-

General Pharmacology :

History of Pharmacology, Pharmacokinetics, Pharmacodynamics, Adverse Drug Reactions, Drug Interactions, Pediatric Pharmacology, Geriatric Pharmacology, Drugs in Pregnancy and Lactation. Dosage calculation in special situations, Factors modifying drug action, Pharmacokinetics, Drug delivery systems and Fixed dose combinations, Gene therapy, Sources of drugs. Principles of Toxicology, Principles of prescription writing.

Basic concepts of immunology needed to understand the immuno- modulatory action of drugs

Systemic Pharmacology, Chemotherapy and Therapeutics:

Pharmacology of drugs acting on autonomic, peripheral and central nervous systems; cardiovascular, endocrine, respiratory, renal, gastrointestinal and haemopoietic systems and treatment of diseases affecting these systems; Pharmacology of anti-microbial and anti-parasitic drugs and treatment of infective diseases; cancer chemotherapy, immunopharmacology and ocular Pharmacology. Dermatological pharmacology, Vitamins, Heavy metals and antagonists, Miscellaneous.

Experimental Pharmacology, Bioassay:

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.

Experimental methodologies involved in the discovery of drugs (in vivo, in vitro ex vivo). Animal handling and animal care. Methods of anaesthetizing animals and methods of euthanasia. Restraining and blood collection methods. Drug screening methods involved in the evaluation of anti-ulcer, antidepressant, anti-anginal, anti-hypertensive, anti-arrhythmic, anti-cataract, anti-platelet, anticancer, anti-inflammatory, anti-diarrheal, anti-epileptic, analgesic, anti-thyroid, antipyretic, anti-glaucoma, anti-hyperlipidemic, anti-asthmatic drugs and cough suppressants. Drug screening methods used in screening anti-fungal, antihelmintic, antibacterial and antiviral agents. Drug screening methods for heart failure, posterior pituitary, adrenal, steroid (gluco & mineralo), testicular, parathyroid, ovarian, thyroid hormones, Methods involved in testing teratogenicity, carcinogenicity and organ toxicities in animals. Bio-assay and dose response relationship.

Clinical Pharmacology and Biostatistics:

Principles of therapeutics, Individualisation of drug therapy, Drug regulatory systems, Placebo, Drug development, Drugs and cosmetics Act, Clinical trial procedures Pharmacoeconomics, Pharmacoepidemiology, Pharmacometrics

Therapeutic drug monitoring, Ethics of clinical trial, Ethical committee, Drug utilization studies, Essential drug concept and rational drug use. Patient compliance. GCP (Good Clinical Practice) Guidelines, Pharmacovigilance, Bioavailability studies (Writing protocol, Preparing consent forms, Checklist for bioavailability studies, Collection, Separation of samples, and Regulatory aspects)

Evaluation of promotional drug literature

Preparation of Drug Information Sheet (WHO criteria)

Bioethics :

1. Respect human life and the dignity of every individual.
2. Refrain from supporting or committing crimes against humanity and condemn all such acts.
3. Treat the sick and injured with competence and compassion and without prejudice and apply the knowledge and skills when needed.
4. Protect the privacy and confidentiality of those for whom we care and breach that confidence only when keeping it would seriously threaten their health and safety or that of others.
5. Work freely with colleagues to discover, develop, and promote advances in medicine and public health that ameliorate sufferings and contribute to human well being.
6. Educate the public about present and future threats to the health of humanity.
7. Advocate for social, economic, educational and political changes that ameliorate suffering and contribute to human well being.
8. Teach and mentor those who follow us, for they are the future of our caring profession.

- PRACTICAL AND CLINICAL SKILLS

Practical Training:-

Experimental Method Discussion:

1. Screening and Evaluation of Drug Activities including Animal Models for Study of following Actions:

- | | |
|----------------------------------|---|
| 1) Analgesic. | 15) Antihistaminics, Antiallergic. |
| 2) Antiinflammatory. | 16) Antisecretory & drugs for peptic ulcer. |
| 3) Antipyretic; pyrogen testing. | 17) Antiemetic. |
| 4) Anticonvulsant. | 18) Hypoglycaemic. |
| 5) Antianxiety. | 19) Antifertility. |
| 6) Antipsychotic. | 20) Anticancer. |
| 7) Antidepressant. | 21) Diuretic. |
| 8) Antiparkinsonian. | 22) Antimalarial. |
| 9) Sedative, hypnotics. | 23) Antitubercular. |
| 10) Antihypertensive. | 24) Antidiabetic. |
| 11) Antianginal. | 25) Antiatherosclerotic. |
| 12) Antiarrhythmic. | 26) Bronchodilator & anti-asthmatic drugs. |
| 13) Skeletal muscle relaxant. | |
| 14) Local anaesthetic. | |

B. Bioassay of :

- | | |
|--------------------------------|--------------------|
| 1) Acetylcholine. | 5) Insulin. |
| 2) Adrenaline / noradrenaline. | 6) Antibiotics. |
| 3) Histamine. | 7) Digoxin. |
| 4) 5- Hydroxytryptamine. | 8) Glucocorticoids |

- Quantitative study of agonists and antagonists on isolated tissues.
- Measurement of blood pressure in conscious and anaesthetized animals.

EXPERIMENTAL PHARMACOLOGY EXERCISES:-

- Frog's rectus abdominis muscle : dose response curve (DRC) and cumulative DRC of acetylcholine; potentiation of ACh by physostigmine and antagonism by tubocurarine / pancuronium.
- Study of drug action on perfused frog's heart.
- Dose-response curve of histamine on isolated guinea pig ileum, Cumulative dose response curve of histamine in isolated guinea pig tracheal chain.
- Bioassay of histamine on guinea pig ileum by matching assay, 3 point assay and 4 point (Latin square design) assay.
- Bioassay of ACh on frog's rectus abdominis muscle.
- Determination of EC₅₀ and pD₂ values of histamine and ACh on guinea pig ileum and frog rectus abdominis muscles.
- Bio-assay on estrogen primed rat uterus.
- Demonstration of muscarinic and nicotinic actions of ACh and carbachol on the B.P. and respiration.
- Study of local anaesthetics by rabbit cornea guinea pig intradermal wheal, frog lumbar plexus.
- Study of analgesic activity of drugs using rat tail-hotwire method, hot plate method, acetic acid induced writhing.
- Study of analgesic activity of drugs against carrageenan induced rat paw oedema.
- Antagonism of histamine aerosol induced bronchospasm by anti-histaminics.
- Effect of psychopharmacological drugs on conditioned avoidance response (Cook's pole climbing).

- Effect of psychopharmacological agents on foot shock induced aggression in rats.
- Effect of psychopharmacological agents on elevated plus maze.
- Effect of drugs on spontaneous motor activity of mice, photoactometer.
- Study of anorectic activity of amphetamine in mice.
- Potentiation of barbiturate sleeping time.
- Study of miotics and mydriatics on rabbit's eye.

Minor Procedures:

- Rat tail vein injection.
- Administration of drugs to rats by gastric cannula.
- Collection of blood from rat tail.
- Collection of blood by Cardiac puncture in rat.
- Injection of drugs through marginal ear vein of rabbits.
- Intraperitoneal and subcutaneous injection to rats and mice.

Bio-Chemical Pharmacology Exercises :

- Identification of unknown compounds by using chemical tests.
- Estimation of drug levels using colorimetry, spectrophotometry, fluorimetry, flame photometry, high performance liquid chromatography (HPLC), enzyme linked immunoassay

Molarity calculations and preparations of reagents

Clinical Pharmacology Exercises:

- I Evaluation of drugs in healthy volunteers as well as patients
- II Critical evaluation of drug literature, pharmaco economics, pharmacovigilance and pharmacoepidemiology.
- III Thesis on a suitable problem
- IV Training in undergraduate teaching
- V Computer training

4. WRITING THESIS/ RESEARCH ARTICLES

Registration of title of thesis to be done within six months of joining the course.

Topic Change will be permitted only once with proper justification before the end of first year.

Attendance in research methodology workshop is mandatory before initiation of dissertation work. The candidate may be required to present the dissertation work during the final year examination.

5. TRAINING IN RESEARCH METHODOLOGY, MEDICAL ETHICS, BIO ETHICS AND MEDICOLEGAL ASPECTS:

Students should compulsorily attend the research Methodology workshop conducted by the University within first six months of the M.D course.

Students are encouraged to attend workshops/CME's on Bioethics conducted by the University and other reputed Institutions.

Medical ethics, moral and legal issues are part and parcel of our curriculum and syllabus

6. SCHEME OF TRAINING :-

I Year:

<u>Duration</u>	<u>Department</u>	<u>Department</u>
	<u>(Forenoon: 10-1 p.m.)</u>	<u>(Afternoon: 2-4.30 p.m.)</u>
	Pharmacology.	Pharmacology.

Getting acquainted with the Department.

Attending all the classes.

Introduction to Dissertation including statistical classes. Visits to

Pharmaceutical Industries and Toxicology centres.

12th month Selection & Planning of Dissertation.
Submitting the topic to the University.

II & III Year

II & III yr. In the Department of Pharmacology

wherein:

- ← The Practical Training as specified by the M.C.I. will be given, depending upon the availability of animals & other facilities.
- ← The student will acquire skills-
- ← To conduct practical classes for the U.Gs.
- ← To take lectures for the U.Gs.
- ← To plan an undergraduate teaching programme & to set questions including MCQs.
- ← The student will participate & contribute to other academic activities of the Department like Journal clubs, Seminars and CME programmes. Students will be, in addition, encouraged to attend conferences, workshops and present papers in scientific sessions.

* During IInd year, the Students are encouraged to undergo special postings for learning new advanced techniques / procedure / skills in institutions of higher repute where the requisite facilities are available without affecting the duties of the parent department.

7. TEACHING LEARNING METHODS

The following teaching learning methods are recommended.

Lectures

Symposia

Seminars

Journal clubs

Problem based learning

Telemedicine (where available)

Computer assisted learning (CAL)

8. Evaluation of the candidates in both theory and practical aspects will help the candidate in improvement of his/her knowledge, skills and attitude.

9. COMPETENCY ASSESSMENT:

1. OVERALL:

a) Communication / commitment / Contribution / Compassion towards patient and Innovation	- 5 marks
b) Implementation of newly learnt techniques/Skills	

- 2.** Number of cases presented in Clinical Meetings/
Journal Clubs/Seminars – 5 marks
- 3.** Number of papers presented in conferences/Publications /Research
Projects. - 5 marks
- 4.** No. of Medals / Certificates won in the conference /
Quiz competitions and other academic meetings with details. - 5 marks
- 20 marks

PG NON – CLINICAL COURSE

VIVA including Competency Assessment	- 60 Marks (40 + 20)
Pedagogy	- 40 marks

ASSESSMENT SCHEDULE IS AS FOLLOWS

Year of study	Period				Total Max.20 marks
I year	Upto Dec	10 marks	Upto June	10 marks	20 Marks
II year	Upto Dec	10 marks	Upto June	10 marks	20 Marks
III year	Upto Oct	10 marks	Upto Feb	10 marks	20 Marks
	AVERAGE				20 Marks

Note:

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)

10. DISSERTATION AND UNIVERSITY JOURNAL OF MEDICAL SCIENCES

As per the 49th SAB Resolution under Point No. 2 and in the 52nd SAB it was reiterated regarding the topic for dissertation

The topic for the dissertation should be registered and sent to the University after Ethics Committee approval before 31st of December of the first Post Graduate Year. Only one change of topic with proper justification from the Head of the Department is permitted before 31st March of the first Post Graduate Year. The change of dissertation title will not be permitted after 31st March of the First Post Graduate Year. This modification in regulation will be scrupulously followed from the academic year 2015-16 admission onwards.

As per Medical Council of India Post Graduate Medical Education Regulations 2000 (amended upto 10th August 2016) clause 13.9 A Postgraduate student of a Postgraduate degree Course in broad specialties/Super Specialties 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.

As per MCI Clause 14 (4)(a), thesis shall be submitted atleast 6 Months before the Theory and Clinical/Practical Examination.

A candidate shall be allowed to appear for the Theory and Practical/Clinical Examination only after the acceptance of the Thesis by the Examiners.

The periodical evaluation of dissertation/log book should be done by the guide / HOD once in every six months. The HOD should ensure about the submission of dissertation within the stipulated time.

Regarding submission of articles to the University Journal of Medical Sciences for all the PG Degree/Diploma courses, it is mandatory that the students have to submit at-least one research paper. Case Reports are not considered as Research Paper

11. THEORY EXAMINATIONS

Theory examination will comprise 4 papers.

<u>PATTERN OF EXAMINATION:</u>			
FOUR PAPERS – 100 Marks each		3 Hours duration each	
<u>Theory</u>	<u>Title</u>	<u>Duration</u>	<u>Marks</u>
Paper –I	GENERAL PHARMACOLOGY (General Pharmacology, Experimental Pharmacology and Bioassay)	3 hrs.	100
Paper - II	CLINICAL PHARMACOLOGY (Clinical Pharmacology and Pharmacotherapeutics including recent advances)	3 hrs.	100
Paper - III	SYSTEMIC PHARMACOLOGY (Systemic Pharmacology)	3 hrs.	100
Paper -IV	RECENT ADVANCES IN PHARMACOLOGY (Recent Advances including Applied Pharmacology and Laws governing Drug Regulations)	3 hrs.	100
		Total	400

Distribution of Marks:**

Structured Essay Questions - 2 x 15 Marks = 30 Marks

Notes - 10 x 5 Marks = 50 Marks

Reasoning out - 4 x 5 Marks = 20 Marks

100 Marks

12. SCHEME OF PRACTICAL EXAMINATION:

A.	LONG EXPERIMENT	MARKS
1.	PROTOCOL DESIGNING	25
2.	CRITICAL APPRAISAL OF A PUBLISHED PAPER	25
3.	DEMONSTRATING EFFECTS OF DRUGS/INTERPRETATION OF RESULTS IN ANESTHETIZED ANIMAL/COMPUTER ASSISTED LEARNING	20
4.	CALCULATING PHARMACOKINETIC PARAMETERS/STATISTICAL EXERCISE/ASSESSMENT OF PRE CLINICAL TOXICITY DATA	20
5.	EVALUATION OF DRUG LITERATURE/ANALYSIS OF RATIONAL AND IRRATIONAL FORMULATIONS	20
6.	ADR REPORTING AND CAUSALITY ASSESSMENT	20
B.	SHORT EXPERIMENT	MARKS
a.	ISOLATED TISSUE EXPERIMENT (BIOASSAY OF DRUGS)/INTERPRETATION OF RESULTS OF A PREVIOUS TRACING (BIOASSAY CHART)	20
b.	IN VIVO EXPERIMENT (TOXICOLOGY)	30
C.	SPOTTING EXERCISES(Various drug delivery systems, inhalers, insulin syringe, drip chamber, various tablets etc)	20
	TOTAL	200

S.No	ORAL/VIVA VOCE EXAMINATION	MARKS
1.	MICROTEACHING(TEACHING EXERCISE- PEDAGOGY)	30
2.	DISCUSSION ON DISSERTATION	10
3.	VIVA	60
	TOTAL	100

AGGREGATE(CLINICAL+ VIVA) TOTAL (A+B)	300 MARKS
MINIMUM REQUIRED FOR PASS(50%)	150 MARKS
DISSERTATION	APPROVED / NOT APPROVED

13. LOG BOOK

A detailed log book should be maintained for the entire duration of the course. It should contain the following details.

1. Experiments performed
2. Journal clubs
3. Seminars
4. Important cases discussed / presented

The post graduate students shall maintain a record(log)book of the work carried out by them and the training program undergone during the period of training.

Periodic review of Log book and Dissertation have to be done in the Department by guide/HOD once in every 6 months.

14. VIVA (including Competency Assessment) – 60 Marks (40 + 20)

An unstructured viva will be carried out by the examiners. VIVA including Competency Assessment for PG Non – Clinical courses

15. PEDAGOGY - 40 marks

(8 minutes Presentation and 2 Minutes Q & Ans)

- | | |
|--|------|
| • Demeanour | - 10 |
| • Audio visual Aids usage, voice modulation and Attitude | - 10 |
| • Subject Content | - 10 |
| • Q & Ans /Interaction | - 10 |

Total	40 Marks
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16. OSPE

- Interpretation of clinical pharmacology charts
- Interpretation of pharmacokinetic charts
- Interpretation of pharmacodynamic charts
- Prescription audit
- Causality analysis
- Calculation of bio availability , Therapeutic Drug Monitoring, Steady State Concentration
- Ethics-exercise based on ethical decision making
- Exercise based on evidence based medicine (meta analysis)
- Dosage calculation in paediatrics and geriatrics
- Dosage calculation in compromised renal and liver function
- Computer assisted learning
- Instrument demonstration ex. Rotarod , photoactometer, etc.

17. PANDEMIC MODULE

- New drug development – challenges and solutions (focus on antiviral drug discovery)
- Evaluation of off- label use of drugs
- Pharmacovigilance activities of drugs used in pandemics
- Ethical aspects of clinical trials in pandemics

18. Books recommended

- Goodman & Gilman's The Pharmacological basis of therapeutics. Ed. Hardman JG, Limbird LE (13th edn/ latest edition) McGraw Hill press New York (2005/ latest).
- Essentials of Medical Pharmacology – Tripathi KD 8th Editions Jaypee Brothers.
- Pharmacology & Pharmacotherapeutics – Satoskar.RS., BhandarkarSD, Popular Prakashan.
- Basic & Clinical Pharmacology – Bertram G Katzung, Tata McGraw Hill education Pvt. Ltd.
- Fundamentals of experimental pharmacology. Ed. Ghosh MN. (3rd edition/latest) Scientific book agency, Calcutta (2005 / latest).
- Drug discovery and evaluation – Pharmacological assays. Ed. Vogel HG &Vogel WH. Springer – New York (2002 / latest).
- Harrison's Principles of Internal Medicine. (16th edition/latest) McGraw Hill pressNew York volume I & II (2005 / latest).
- Principles of Clinical Pharmacology.Ed.Arthur J.Atkinson,JR.Academic Press(2001).
- Oxford Textbook of Clinical Pharmacology and Drug Therapy. (3rd edition/latest). Smith G & Aronson JK. (2002 / latest)
- Pharmacotherapy – A pathophysiological approach. (6th edition / latest)DiPiro JT. McGraw Hill press New York (2005 / latest).
- Applied therapeutics - The Clinical Use of Drugs. (8th edition / latest) KimbleMA. Lippincott Williams & Wilkins.
- Clinical Pharmacokinetics Concepts & Applications. (3rd edition / latest)Rowland M & Tozer TN(1996 / latest).
- Avery's Drug Treatment. (4th edition / latest) Eds. Speight TM & Holford NHG. Adis International Ltd (1997 / latest)
- Design and analysis of clinical trials – concepts & methodologies. Chow SC &Liu JP. (2nd edition / latest) Wiley.
- Methods in Biostatistics – B.K.Mahajan, Jaypee brothers
- Hand Book of Experimental Pharmacology – Kulkarni S.K., Vallabh Publication Prakasham.
- Rang and Dale's Pharmacology – Rang HP, Dale M, Ritter JM, Churchill Livingstone, Elsevier.

- Clinical Pharmacology-Laurence DR, Bennet PN, Brown MJ, Elsevier.

** Note : The editions are as applicable and the latest editions shall be the part of the syllabi

18. Journals to be referred

1. Indian Journal of Pharmacology
2. Indian Journal of Physiology & Pharmacology
3. Trends in Pharmacological Sciences
4. Annual Review of Pharmacology and Toxicology
5. Pharmacological Reviews
6. Drugs
7. Indian Drugs
8. Clinical Pharmacology and Therapeutics
9. British Journal of Pharmacology
10. British Journal of Clinical Pharmacology
11. Journal of Pharmacology and Experimental Therapeutics
12. European Journal of Clinical Pharmacology
13. New England Journal of Medicine
14. Lancet

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ANNEXURE 1
Postgraduate Students Appraisal Form
Department of Pharmacology

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.	Laboratory or Skill based learning				
3.	Self directed learning and teaching				
4.	Departmentaland 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 is suggested. Individual feedback to postgraduate student is strongly recommended.

SIGNATURE OF ASSESSEE

SIGNATURE OF HOD