MGM INSTITUTE OF HEALTH SCIENCES

(Deemed to be University u/s 3 of UGC Act, 1956)
Grade 'A' Accredited by NAAC

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COMPETENCY BASED MEDICAL EDUCATION

(CBME)

(with effect from 2020-2021 Batches)

Curriculum for Doctor of Medicine Pharmacology

Approved as per AC-41/2021, Dated 27/08/2021

Amended History

1. Approved as per AC - 41/2021, [Resolution No.4.23]; Dated 27/08/2021.

MD Pharmacology

Curriculum (CBME)

Program Overview

Duration of the Course

The period of certified study and training for the Post-Graduate MD PHARMACOLOGY shall be Three Academic years.

Attendance

All students joining the postgraduate training program shall work as full time residents during the period of training, attending not less than 80% (eighty percent) of the training during each calendar year, and will be given full time responsibility, assignments and participation in all facets of the educational process.

The period of training for obtaining the degrees shall be three completed years including the period of examination.

SUBJECT SPECIFIC LEARNING OBJECTIVES

At the end of the MD training programme in Pharmacology, the student should acquire competencies in the following areas:

1. Acquisition ofknowledge

The student should be able to explain clearly concepts and principles of Pharmacology and therapeutics. The student should also be able to explain the drug development processes. S/he should be able to explain Drugs and Cosmetics Act, in addition to clinical trial procedures.

2. Teaching andtraining

The student should be able to effectively teach undergraduate students in medicine (MBBS) and allied health science courses (Dentistry and Nursing) so they become competent healthcare professionals and able to contribute to training of postgraduate trainees.

3. Research

The student should be able to carry out a research project (both basic and clinical) from planning to publication and be able to pursue academic interests and continue life-long learning to become more experienced in all the above areas and to eventually be able to guide postgraduates in their thesis work.

SUBJECT SPECIFIC COMPETENCIES

The student during the training program should acquire the following competencies:

A. Cognitivedomain

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 humanbody.
2. Explain pharmacodynamics and pharmacokinetics of drugs.
3. Describe mechanisms of drug-drug interactions and their clinicalimportance.
4. Apply and integrate knowledge of pathophysiology of diseases and its modulation bydrugs.
5. Acquire knowledge on pharmacogenetics andpharmacogenomics
6. Acquire knowledge on principles ofpharmacoeconomics
7. Acquire knowledge on pharmacoepidemiology, including drug utilizationstudies.
8. Aquire knowledge and understanding of principles of Good clinical practice (GCP) and Good laboratory practice (GLP) guidelines
9. Acquire knowledge on essentialmedicines
10. Acquire knowledge onpharmacovigilance
11. Acquire knowledge and apply the principle of biostatistics in the evaluation and interpretation of drug safety and efficacystudies
12. Describe how to evaluate, analyse and monitor preclinical and clinical data in drug discovery
13. Able to integrate principles of immunology inbiochemistry.
14. Demonstrate knowledge of basics of research methodology, develop a research protocol, conduct the study, record experimental observations, analyse data using currently available statistical software, interpret results and disseminate these results and to have the potential ability to pursue further specializations and eventually be competent to guidestudents.
15. Describe the principles of teaching - learning technology towards application and take interactive classroom lectures, modules for problem based learning (PBL), case discussions, small group discussions, seminars, Journal club and research presentations
16. Demonstrate knowledge about computer assisted learning (CAL) softwares and ability to use them efficiently to promote learning of pharmacology.
17. Demonstrate knowledge of principles ofInstrumentation.
18. Demonstrate knowledge about recent advances and trends in research in the field of pharmacology and clinical pharmacology.
19. Acquire knowledge on generic drugs and genericprescription.
20. Acquire knowledge on rational use of drugs and prescriptionauditing
21. Aquire knowledge about antimicrobial stewardship programs and strategies for containment of antibioticresistance
22. Acquire knowledge on animal toxicitystudies
23. Acquire knowledge on commonpoisoning
24. Acquire knowledge on the legal and ethical issues involved in drug development and research.

25. Acquire knowledge in Biostatistics including use of statistical softwares:
    - Estimation Sample size for a clinicaltrial
    - Scales of measurement, data display, measures of central tendency (mean, median,mode)
        - Dispersion of data (variance, standarddeviation)
        - Selection of tests (of significance) and theirapplicability
        - Correlation and regressionanalysis
        - Basics of systematic reviews andmeta-analysis

B. Affectivedomain

1. Effectively explain to patients, the effects and side effects of drugs, including the need for medicationadherence.
2. Communicate effectively with pharmacological reasoning with students, peers, staff and faculty, and other members of the health care team on rational use of drugs and improving spontaneous reporting of adverse events.
3. Demonstrate respect in interactions with peers, and other healthcareprofessionals.
4. Demonstrate ethical behavior and integrity in one'swork.
5. Demonstrate ability to generate awareness about the use of generic drugs inpatients.
6. Acquire skills for self-directed learning to keep up with developments in the field and to continuously build to improve on skills, expertise and perpetual professionaldevelopment.
7. Storage of medicine and optimal use of devise
8. Educate regarding drugs causing addiction, use of OTCproducts

C. Psychomotordomain

1. Able to predict efficacy and adverse effects associated with use of drugs, along with causality assessment.
2. Demonstrate skills for prescriptionwriting
3. Perform major *in vivo* and *in vitro* animalexperiments.
4. Observe and understand basic principles of working of important advanced techniques, like High Performance Liquid Chromatography(HPLC).
5. Demonstrate standard operating procedures of various methods and techniques used in clinical trials andresearch.
6. Determine levels of common poisons inblood
7. Demonstrate presentation skills at academic meetings, publications and writing research projects for fundingagencies.
8. Be able to analyze and evaluate a researchpaper
9. Perform a and interpret critical apprasial of given prescription (prescriptionaudit)
10. Perform critical evaluation of promotional literature and interaction with pharmaceutical representative

By the end of the course, the trainee should have acquired practical skills in the following:

1. *In vivo* and *ex vivo* experiments, like organ bath, analgesiometer, physiography/ polygraph, convulsiometer, plethysmograph, learning and memory, models for affectivedisorders.
2. Administration of drugs by various routes (subcutaneous, intravenous, intraperitoneal) in experimentalanimals
3. Collection of blood samples and oral gavage in experimentalanimals
4. Preparation and administration of a drug solution in appropriate strength andvolume
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-pigintestine

ii) Isolated ratuterus

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 rabbiteye
8. Perform *in vivo* experiments to study effect of antiepileptic drugs using animal models of epilepsy
9. Perform *in vivo* experiments to study effect of analgesics using animal models ofanalgesia
10. Perform *in vivo* experiments to study effects of drugs on learning, memoryand motorcoordination
11. Estimate toxic drug levels using chemical and biological tests (alkaloids, glycosides, steroids, barbiturates, salicylates) by commonly usedmethods)
11. Able to perform critical appraisal of promotional liturature and published scientificpaper
12. Prescriptionaudit
13. Clinicalpharmacology
    i) Prepare protocol for a clinicaltrial
    ii) Prepare Informed consent form and participant information sheet for research involving humanparticipants
    iii) Report Serious Adverse Effect(SAE)
    iv) Evaluate promotional drugliterature
    v) Prepare "Drug Information Sheet" (WHOcriteria)
    vi) Interpret bioavailability parameters with the help of given pharmacokineticsdata
    vii) Perform causality assessment and report ADR as per Pharmacovigilance Programme of India (PvPI)

Animal Experiments: All animal experiments must be compliant with Govt. of India regulations, notified from time to time. Amphibian/Dog/Cat experiments should be conducted by computer assisted simulation models/ facilities. Other experiments should be performed as permissible by CPCSEA guidelines

Syllabus

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

1. Basic and molecularpharmacology
2. Drug receptors andPharmacodynamics
3. Pharmacokinetics (Absorption, Distribution, Metabolism andExcretion)
4. Biotransformation
5. Pharmacogenomics andPharmacogenetics
6. AutonomicPharmacology
7. Drugs acting on Smoothmuscles
8. Clinicalpharmacology
9. Drug development andRegulations
10. Clinical Pharmacokinetics
11. Drugs acting on Synaptic and Neuroeffector Junctionalsites
12. Drugs acting on Central Nervous System (Sedative, Hypnotics, Antiepileptics,

General Anesthetics, Local Anesthetics, Skeletal Muscle Relaxants, Antipsychotic, Antidepressants, Drugs used in Parkinson's disease and other neurodegenerative disorders, opioid agonists and antagonists, Drugs ofabuse)

13. Drugs modifying renalfunction
14. Drugs acting on cardiovascular system and haemostatic mechanisms (Antihypertensives, Antianginal, Antiarrhythmics, Drugs used in heart failure, Drugs used in Dyslipidemias, Fibrionolytics, Anticoagulants,Antiplatelets
15. ReproductivePharmacology
16. Agents effecting calcification and boneturnover
17. Autacoids and related pharmacological agents (NSAIDs) and drugs used in Rheumatoid arthritis andGout
18. Gastrointestinaldrugs
19. Pharmacology of drugs affecting the respiratory system (drugs used in Bronchial Asthma and COPD)
20. Antimicrobial, antiparasitics, disinfectants,antiseptics
21. Chemotherapy of neoplasticdisease
22. Antiviraldrugs
23. Drugs used in Autoimmune disorder and Graft versus HostDisease)
24. Dermatologicalpharmacology
25. Ocularpharmacology
26. Use of drugs inpregnancy
27. Perinatal and PediatricPharmacology
28. GeriatricPharmacology
29. Immunomodulators - immunosuppressants andimmunostimulants
30. Pharmacology of drugs used in endocrine disorders (drugs used in diabetes mellitus, hypothalamic and pituitary hormones, thyroid and antithyroid drugs, adrenocorticid hormones and their antagonists, gonadal hormones and theirinhibitors)
31. Drug deliverysystems
32. Heavy metalpoisoning
33. Non-metallic toxicants - air pollutants, pesticidesetc.
34. Research methodology andbiostatistics
35. Literaturesearch.
36. Pharmacogenomics, Pharmacovigilance (ADR reporting), pharmaco-economics (cost- effectiveness study) and pharmacoepidemiology
37. Over the counterdrugs
38. Dietary supplements and herbalmedicines
39. Pharmacometrics - methods of drug evaluation.
40. General screening and evaluationof:
    - **A**nalgesics, antipyretics, anticonvulsants, anti-inflammatorydrugs,
    - antidepressants, antianxiety and antipsychotics, sedatives, muscle relaxants, antihypertensives, hypocholesterolaemic agents,antiarrhythmics,
    - diuretics, adrenergic blockingdrugs
    - Drugs used in peptic ulcer diseases/Prokinetic agents/antiemetics
    - Antitussives, /anti-asthmaagents

- LocalAnaesthetics
- Oxytocics, antifertilityagents
- Antidiabetics
- Behavioral pharmacology models and evaluation of drugs affecting learning and memory
- ClinicalPharmacology

41. Bioassays

- Bioassay methods
- Animal experiments: Ethical considerations, ethical approval, applicable regulatory Guidelines (CPCSEA), humane animal research (principles of 3Rs) and alternatives to animal experimentation. General and statisticalconsideration
- Anesthetics used in laboratoryanimals
- Principles of EC50, ED50, pD2 and pA_2 values ofdrugs
- 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 - pA_2values
- Immunoassays: Concept, types of bioassays and theirapplication/s
- Animal experiments: Ethical consideration, ethicalapproval
- Regulatory Guidelines (CPCSEA) and alternatives to animal experimentation

42. BiochemicalPharmacology

- Basic principles and applications **o**f simple analyticalmethods
- Principles of quantitative estimation of drugs, endogenous compounds and poisons using Colorimetry, Spectrophotometry, flame photometry, High Performance Liquid Chromatography (HPLC) and enzyme-linked immunosorbent assay(ELISA).

TEACHING AND LEARNING METHODS

Postgraduate teaching programme

Teaching methodology

Learning in a PG program is primarily self-directed and in Pharmacology consists of laboratory and academic work. The formal sessions are merely meant to supplement this core effort. Acquisition of practical competencies thus becomes the cornerstone of postgraduate medical education in Pharmacology.

Formal teaching sessions

- In addition to laboratory work, at least 6-hr of formal teaching per week is necessary. The departments may select a mix of the following sessions:

Journalclub	Once aweek
Seminar	Once aweek
Practical	Once aweek
GroupDiscussions	Once aweek
Casediscussions	Once amonth
Interdepartmental caseorseminar	Once amonth

ALLIED POSTING

SN	Department /Unit	Duration
1	**General Medicine**	2 Months
2	**Pediatrics**	15 days
3	**Dermatology**	15 days
4	**Psychiatry**	15 days
5	**Central research/ Biochemistry Lab**	15 days
	Duration	4 Months
6	**Industrial Training (Optional)**	2 Months

- **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.

Formative and Summative Assessment Pattern

1. Thesis

Every post graduate student shall carry out work on an assigned research project under the guidance of a recognised Post Graduate Teacher, the result of which shall be written up and submitted in the form of a Thesis. Work for writing the Thesis is aimed at contributing to the development of a spirit of enquiry, besides exposing the post graduate student to the techniques of research, critical analysis, acquaintance with the latest advances in medical science and the manner of identifying and consulting availableliterature.

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 shall be allowed to appear for the Theory and Practical/Clinical examination only after the acceptance of the Thesis by theexaminers.

2. Theory and Practical examination:

The examinations shall be organized on the basis of 'Marking system' to evaluate and to certify post graduate student's level of knowledge, skill and competence at the end of the training. 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 shall be held at the end of 3rd academic year.

Theory

There shall be four theory papers:

Paper I: General Pharmacology

Paper II: Clinical Pharmacology

Paper III: Systemic Pharmacology

Paper IV: Recent Advances in Pharmacology

Formative and Summative Exam Pattern

1st Year Ending Exam	**Portion**
• Theory (One Paper) of 100mks	• Paper – I Systemic Pharmacology • Portion for Theory Examination • General Pharmacology, ANS, CVS • BAQs:(10 out of 11)X 10 Mks each=100 Mks • **Total: 100Mks**
• Practical- 100 Marks	• Clinical Pharmacology 25 Marks • (Critical Appraisal of Published Literature /Informed Consent Document/Drug Promotional literature) • Interpretation of drug results in anesthetized animal (Experimental Graphs) 25 Marks • Experimental Pharmacology 25 Marks • (Minor procedures) • Viva 25 Marks • **Total: 100Mks**
2nd Year Ending exam	**Portion**
• Theory (Two papers) 100 Mks each	**Portion for Theory Examination** • **Paper I-** Autocoids , Respiratory system, CNS • **Paper II-** Blood , Lipid dysfunction, Endocrine including Uterus, GIT • BAQs:(10 out of 11) X 10 Mks each=100 Mks • **Total: 200 Mks**
• Practical- 200 Marks	• Clinical Pharmacology Exercise 30 Marks • (Critical Appraisal of Published Literature/Drug Promotional Literature/ Informed Consent Document) • Spotting Exercise# 10 Marks • FDC/ADR Reporting Forms 10 Marks • Bioassay 50 Marks

	• Minor Exp procedures 25 Marks • Graphs 25 Marks • Viva 50 Marks **Total: 200 Mks** **Spotting Exercise#** • Various drug delivery systems, inhalers, insulin syringe, drip chamber, various tablets, Drug Screening Instruments
Prelim exam(3rd Year Ending Exam)and University Exam Pattern	
• Theory (Four papers) 100 Mks each	• **Paper I:** General Pharmacology • **Paper II:** Clinical Pharmacology • **Paper III:** Systemic Pharmacology • **Paper IV:** Recent Advances in Pharmacology • BAQs:(10 out of 11)X 10 Mks each=100 Mks • **Total: 400Mks**
• Practical-- 400 Marks	• **Long Exercise 200 Marks** • Protocol Designing including • Informed Consent Document 100 Marks • Critical Appraisal of Published Literature or Drug Promotional Literature 50 Marks • ADR Reporting & Causality Assessment 15 Marks • FDC/Clinical PK Exercises 10 Marks • Interpretation of drug results in anesthetized animal (Experimental Graphs) 25 Marks • **Short Exercise 100 Marks** • Bioassay 70 Marks • Minor Exp. Procedure 20 Marks • Spotting Exercise# 10 Marks • Viva 100 Marks • Microteaching 15 Marks • Thesis PPt 15 Marks • Grand Viva 70 Marks • **Total: 400Mks** **Clinical Pharmacology Exercise* (Any One)** • Calculating pharmacokinetic parameters • Analysis of rational and irrational formulations **Spotting Exercise#** • Various drug delivery systems, inhalers, insulin syringe, drip chamber, various tablets, Drug Screening Instruments etc.

Recommended Reading Material Books (latest edition)

1. Goodman & Gilman's The Pharmacological Basis of Therapeutics, ed. Laurence Brunton, Bruce A. Chabner, BjornKnollman.
2. Essentials of Medical Pharmacology, by KDTripathi
3. Basic and Clinical Pharmacology, by Bertram G. Katzung and Anthony J. Trevor
4. Drug Discovery and Evaluation: Pharmacological Assays Editors: Vogel,Hans
5. Clinical Pharmacology by Laurence, Bennett andBrown
6. Rang and Dale's Pharmacology by H.P.Rang
7. Koda Kimble and Youngs Applied Therapeutics by Brian K Alldredge and Robin L Corelli

Journals

1. 03-05 international Journals and 02 national (all indexed) journals

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