Amended History

1. Approved as per AC-4 /202 , Resolution No.5. ; Dated / /202 .

Resolution No. 5.18 of Academic Council (AC-46/2023): Resolved to approve alignment of the MD Pharmacology Curriculum as per Revised PG Competency Based Medical Education (CBME) guidelines **[ANNEXURE-22].**

MD Pharmacology Revised CBME Curriculum

MGM University of Health Sciences, Navi Mumbai

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 (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

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 analgesics, 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:

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

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

4. 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

13. Autacoids and related pharmacological agents (analgesics) and drugs

used 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

33. National programmes for infectious and vector borne diseases including the

regimes.

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 ofdrugs, 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, anti-arrhythmic 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 ethical approval
- 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 and
- poisons 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

Clinical Posting

a) Allied Posting/Clinical Posting Rotation Plan

S. No	Department	Duration
1	Medicine	2 weeks
2	Anesthesia	2 weeks
3	Dermatology	2 weeks
4	Microbiology/ Infection control unit or dept	2 weeks
5	Biochemistry	2 weeks
6	Hospital Pharmacy	2 weeks

7	Clinical trial unit/Research unit/ Pharmaceutical industry	4-8 weeks
	Total Duration	**16-20 weeks**

b. Posting under "District Residency Programme" (DRP):

- All postgraduate students pursuing MD in Pharmacology in all Medical 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 rd or 4th or 5th 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".

MD Pharmacology Examination Pattern

Summative (University Exam) Assessment Pattern

Theory examination: 400 Marks

There shall be four theory papers (as per PG Regulations) of 100 Marks each

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

Practical examination: 400 Marks

S.No	Practical Head	Marks
1	**Long Exercise**	**150 Marks**
A	Protocol Designing including Informed Consent Document	75 Marks
B	Perform experiments or simulated experiments (Bioassay)	75 Marks
2	**Short Exercise**	**50 Marks**
A	Interpretation of results of a previous tracing/ Demonstration of effects of drugs/interpretation of results in human (Graphs)	25 Marks
B	Demonstration of effects of drugs/interpretation of results in small, animals (Minor Exp procedures)	25 Marks
3	**OSPE Stations (observed/unobserved stations)**	**100 Marks**
A	Various drug delivery systems	**10 OSPE Stations** **(10x 10 M= 100 Marks**
B	Calculating pharmacokinetic parameters	
C	Pharmaceutical calculations	
D	Critical appraisal of a published paper	
E	Abstract writing of a published paper	
F	Evaluation of drug promotional literature	
G	Adverse Drug Reaction (ADR) reporting and causality assessment	
H	Analysis of rational and irrational formulations	
I	Selecting a P-drug and writing rational prescriptions	
J	Analytical instruments – use and interpretation	
K	Identifying ethics related dilemmas / mistakes in clinical trial documents	
4.	**Assessment of teaching/presentation skills**	**100 Marks**
A	Microteaching	15 Marks
B	Dissertation Presentation	15 Marks
C	Grand Viva	70 Marks
	Grand Total Marks	**400 Marks**

Formative (Year Ending Exam) Assessment

(1st Year Ending Exam)

Theory examination: Total Marks-100

One Theory Paper of 100 marks

Portion for theory examination

- General Pharmacology
- Autonomic Nervous System
- Cardiovascular system and Diuretics
- Blood and Haematinics
- Hypolipidemic agents
- Biostatistics

Practical examination- Total Marks-100

S.No	Practical Head (1st Year Ending Exam)	Marks
1	**Long Exercise**	**50 Marks**
A	Informed Consent Document	25 Marks
B	Critical Appraisal of Published Literature	25 Marks
2	**Short Exercise**	**10 Marks**
A	Interpretation of results of a previous tracing/ Demonstration of effects of drugs/interpretation of results in human (Graphs)	10 Marks
3	**OSPE Stations (observed/unobserved stations)**	**20 Marks**
A	Various drug delivery systems	**4 OSPE Stations** **(4 x 5 M= 20 Marks**
B	Calculating pharmacokinetic parameters	
C	CNS Screening Instruments	
D	Abstract writing of a published paper	
E	Evaluation of drug promotional literature	
F	Adverse Drug Reaction (ADR) reporting and causality assessment	
G	Analysis of rational and irrational formulations	

4.	**Assessment of teaching/presentation skills**	**20 Marks**
A	Grand Viva	20 Marks
	Grand Total Marks	**100 Marks**

(2nd Year Ending Exam)

Theory examination: Total Marks-200

Two Theory Paper of 100 marks each

Portion for theory examination

Paper I

- Central Nervous System
- Endocrine including Uterus
- Autocoids,
- Respiratory system

Paper II

- Chemotherapy
- Gastro-intestinal system
- Miscellaneous topics (Ocular Pharmacology, Immunomodulators, Dermato-pharmacology, Vaccines and Sera, Vitamins, Chelating agents ets)
- Experimental Pharmacology

Practical examination: 200 Marks

S.No	Practical Head (2nd Year Ending Exam)	Marks
1	**Long Exercise**	**100 Marks**
A	Protocol Designing including Informed Consent Document	50 Marks
B	Perform experiments or simulated experiments (Bioassay)	50 Marks
2	**Short Exercise**	**20 Marks**

B	Demonstration of effects of drugs/interpretation of results in small, animals (Minor Exp procedures)	20 Marks
3	**OSPE Stations (observed/unobserved stations)**	**30 Marks**
A	Various drug delivery systems	**6 OSPE Stations (6 x 5 M= 30 Marks**
B	Calculating pharmacokinetic parameters	
C	CNS Screening Instruments	
D	Critical appraisal of a published paper	
E	Abstract writing of a published paper	
F	Evaluation of drug promotional literature	
G	Adverse Drug Reaction (ADR) reporting and causality assessment	
H	Analysis of rational and irrational formulations	
4.	**Assessment of teaching/presentation skills**	**50 Marks**
A	Grand Viva	50 Marks
	Grand Total Marks	**200 Marks**

Prelim Exam

Theory examination

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

Practical examination: 400 Marks

S.No	Practical Head (Prelim Exam)	Marks
1	**Long Exercise**	**150 Marks**
A	Protocol Designing including Informed Consent Document	75 Marks
B	Perform experiments or simulated experiments (Bioassay)	75 Marks
2	**Short Exercise**	**50 Marks**
A	Interpretation of results of a previous tracing/ Demonstration of effects of drugs/interpretation of results in human (Graphs)	25 Marks

B	Demonstration of effects of drugs/interpretation of results in small, animals (Minor Exp procedures)	25 Marks
3	**OSPE Stations (observed/unobserved stations)**	**100 Marks**
A	Various drug delivery systems	**10 OSPE Stations** **(10 x 10 M= 100 Marks**
B	Calculating pharmacokinetic parameters	
C	CNS Screening Instruments	
D	Critical appraisal of a published paper	
E	Abstract writing of a published paper	
F	Evaluation of drug promotional literature	
G	Adverse Drug Reaction (ADR) reporting and causality assessment	
H	Analysis of rational and irrational formulations	
I	Selecting a P-drug and writing rational prescriptions	
J	Analytical instruments – use and interpretation	
K	Identifying ethics related dilemmas / mistakes in clinical trial documents	
4.	**Assessment of teaching/presentation skills**	**100 Marks**
A	Microteaching	15 Marks
B	Dissertation Presentation	15 Marks
C	Grand Viva	70 Marks
	Grand Total Marks	**400 Marks**

Recommended Readings

Books:

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

2. Katzung BG. Basic & Clinical Pharmacology, 14th edition, McGraw Hill Education, 2018.

3. Papadakis MA, Mcphee SJ. Current Medical Diagnosis & Treatment. 60th edition New York. McGraw Hill Education.2021.

4. Ritter M, Flower R, Henderson G, Loke YK, MacEwan D, Rang HP. Pharmacology. Elsevier, 9th edition, 2020.

5. Tripathi KD. Essentials of Medical Pharmacology, 8th edition. Jaypee Brothers Medical Publishers Private Ltd: New Delhi 2019.

6. M. N. Ghosh. Fundamentals of Experimental Pharmacology. 7 th Edition. Hilton & Company, 2019.

7. Badyal D. Practical Manual of Pharmacology. Jaypee Brothers Medical Publishers; 3rd edition 2020.

8. Vogel HJ. Drug Discovery and Evaluation: Pharmacological Assays Springer; 3rd edition, 2007.

9. Sharma S, Velpandian T. Illustrated Reviews Pharmacology. Wolter Kluver, South Asian Edition, 2019.

10. Medhi B, Prakash A. Practical Manual of Experimental & Clinical Pharmacology. Jaypee Brothers Medical Publishers, 2nd edition, 2017.

11. 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, 10th edition, 2012.

12. Cheston B Cunha, Burke A Cunha. Antibiotic essentials. Jaypee Brothers Medical Publishers 17th edition, 2021.

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).