

MGM INSTITUTE OF HEALTH SCIENCES (Deemed University u/s 3 of UGC Act, 1956) Grade 'A' Accredited by NAAC Sector-01, Kamothe, Navi Mumbai - 410 209 Tel 022-27432471, 022-27432994, Fax 022 - 27431094

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MGM 06 MD Pharmacology

Program Outcomes:

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

CO1. **Acquisition of knowledge:** 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. She/he should be able to explain Drugs and Cosmetics Act, in addition to clinical trial procedures.

CO2. **Teaching and training:** 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.

CO3. **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. Cognitive domain

- 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. Explain pharmacodynamics and pharmacokinetics of drugs.
- 3. Describe mechanisms of drug-drug interactions and their clinical importance.
- 4. Apply and integrate knowledge of pathophysiology of diseases and its modulation by drugs.
- 5. Acquire knowledge on pharmacogenetics and pharmacogenomics
- 6. Acquire knowledge on principles of pharmacoeconomics
- Acquire knowledge on pharmacoepidemiology, including drug utilization studies.
- Aquire knowledge and understanding of principles of Good clinical practice (GCP) and Good laboratory practice (GLP) guidelines

- 9. Acquire knowledge on essential medicines
- 10. Acquire knowledge on pharmacovigilance
- 11. Acquire knowledge and apply the principle of biostatistics in the evaluation and interpretation of drug safety and efficacy studies
- 12. Describe how to evaluate, analyse and monitor preclinical and clinical data in drug discovery
- 13. Able to integrate principles of immunology in biochemistry.
- 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 guide students.
- 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 of Instrumentation.
- Demonstrate knowledge about recent advances and trends in research in the field of pharmacology and clinical pharmacology.
- 19. Acquire knowledge on generic drugs and generic prescription.
- 20. Acquire knowledge on rational use of drugs and prescription auditing
- 21. Aquire knowledge about antimicrobial stewardship programs and strategies for containment of antibiotic resistance
- 22. Acquire knowledge on animal toxicity studies
- 23. Acquire knowledge on common poisoning
- 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 clinical trial
 - Scales of measurement, data display, measures of central tendency (mean, median, mode)
 - Dispersion of data (variance, standard deviation)
 - Selection of tests (of significance) and their applicability
 - Correlation and regression analysis
 - Basics of systematic reviews and meta-analysis

B. Affective domain

- 1. Effectively explain to patients, the effects and side effects of drugs, including the need for medication adherence.
- 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 healthcare professionals.

- 4. Demonstrate ethical behavior and integrity in one's work.
- 5. Demonstrate ability to generate awareness about the use of generic drugs in patients.
- 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 professional development.

C. Psychomotor domain

- 1. Able to predict efficacy and adverse effects associated with use of drugs, along with causality assessment.
- 2. Demonstrate skills for prescription writing.
- 3. Perform major *in vivo* and *in vitro* animal experiments.
- 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 and research.
- 6. Determine levels of common poisons in blood
- 7. Demonstrate presentation skills at academic meetings, publications and writing research projects for funding agencies.
- 8. Be able to analyze and evaluate a research paper

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 affective disorders.
- 2. Administration of drugs by various routes (subcutaneous, intravenous, intraperitoneal) in experimental animals
- 3. Collection of blood samples and oral gavage in experimental animals
- 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 intestine
 - ii) Isolated rat uterus
- 6. Determination of EC50, ED50, pD2 and pA2 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 using animal 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. Estimate toxic drug levels using chemical and biological tests (alkaloids, glycosides, steroids, barbiturates, salicylates) by commonly used methods)
- 12. Clinical pharmacology
 - i) Prepare protocol for a clinical trial
 - ii) Prepare Informed consent form and participant information sheet for research involving human participants
 - iii) Report Serious Adverse Effect (SAE)
 - iv) Evaluate promotional drug literature
 - v) Prepare "Drug Information Sheet" (WHO criteria)
 - vi) Interpret bioavailability parameters with the help of given pharmacokinetics data
 - 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

COURSES OUTCOME

Syllabus

The course contents should cover the following broad topics:

- 1. Basic and molecular pharmacology
- 2. Drug receptors and Pharmacodynamics
- 3. Pharmacokinetics (Absorption, Distribution, Metabolism and Excretion)
- 4. Biotransformation
- 5. Pharmacogenomics and Pharmacogenetics
- 6. Autonomic Pharmacology
- 7. Drugs acting on Smooth muscles
- 8. Clinical pharmacology
- 9. Drug development and Regulations
- 10. Clinical Pharmacokinetics
- 11. Drugs acting on Synaptic and Neuroeffector Junctional sites
- 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 of abuse)

- 13. Drugs modifying renal function
- Drugs acting on cardiovascular system and haemostatic mechanisms
 (Antihypertensives, Antianginal, Antiarrhythmics, Drugs used in heart failure, Drugs used in Dyslipidemias, Fibrionolytics, Anticoagulants, Antiplatelets
- 15. Reproductive Pharmacology
- 16. Agents effecting calcification and bone turnover
- Autacoids and related pharmacological agents (NSAIDs) and drugs used in Rheumatoid arthritis and Gout
- 18. Gastrointestinal drugs
- Pharmacology of drugs affecting the respiratory system (drugs used in Bronchial Asthma and COPD)
- 20. Antimicrobial, antiparasitics, disinfectants, antiseptics
- 21. Chemotherapy of neoplastic disease
- 22. Antiviral drugs
- 23. Drugs used in Autoimmune disorder and Graft versus Host Disease)
- 24. Dermatological pharmacology
- 25. Ocular pharmacology
- 26. Use of drugs in pregnancy
- 27. Perinatal and Pediatric Pharmacology
- 28. Geriatric Pharmacology
- 29. Immunomodulators immunosuppressants and immunostimulants
- 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 their inhibitors)
- 31. Drug delivery systems
- 32. Heavy metal poisoning
- 33. Non-metallic toxicants air pollutants, pesticides etc.
- 34. Research methodology and biostatistics
- 35. Literature search.
- 36. Pharmacogenomics, Pharmacovigilance (ADR reporting),pharmacoeconomics (cost-effectiveness study) and pharmacoepidemiology
- 37. Over the counter drugs
- 38. Dietary supplements and herbal medicines
- 39. Pharmacometrics methods of drug evaluation.
- 40. General screening and evaluation of:
 - Analgesics, antipyretics, anticonvulsants, anti-inflammatory drugs, antidepressants, antianxiety and antipsychotics, sedatives, muscle

relaxants, antihypertensives, hypocholesterolaemic agents, antiarrhythmics, diuretics, adrenergic blocking drugs

- Drugs used in peptic ulcer diseases/Prokinetic agents/ antiemetics
- Antitussives, /anti-asthma agents
- Local Anaesthetics
- Oxytocics, antifertility agents
- Antidiabetics

Behavioral pharmacology models and evaluation of drugs affecting learning and memory

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 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, ethical approval
- Regulatory Guidelines (CPCSEA) and alternatives to animal experimentation

42. 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).

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