

Study & Evaluation Scheme

of

Doctor of Medicine MD (Pharmacology) 2011-12



TEERTHANKER MAHAVEER MEDICAL COLLEGE & RESEARCH CENTRE
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P.G. Curriculum M.D. Pharmacology

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Curriculum

M.D. Pharmacology

Curriculum

M.D. Pharmacology

The composition of the department in terms of faculty strength; other staff, laboratory Equipment and number of PG residents will be as per MCI regulations.

1. Goals

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

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
- 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 animal 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.
- Develop skills as a self-directed learner, recognize continuing educational needs; use appropriate learning resources and be able to critically analyze relevant published literature
- Design protocol for clinical trials
- Incorporate knowledge of information technology in medical sciences
- 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.

3. Syllabus

3.1. Theory:-

General Pharmacology: - Principles & Applied Sciences

- Important landmarks in the growth and development of Pharmacology, Important contributions of renowned Indian and foreign Pharmacologists
- Principles and modes of drug administration, source, nature and preparations Of drugs
- Qualitative and Quantitative Pharmacokinetics
- Pharmacodynamics
- Drugs interactions, Adverse drug reactions
- Methods of new drug development
- Factors modifying drug response
- Pharmacogenetics and pharmacogenomics
- Structure-activity relationship of important group of drugs
- Preclinical evaluation of new drugs and toxicity studies

– Systemic Pharmacology

- Autonomic nervous system
- Central nervous system
- Cardiovascular system
- Hematopoietic system
- Respiratory system
- Autacoids
- Gastrointestinal system
- Renal pharmacology
- Endocrine pharmacology
- Chemotherapy
- Miscellaneous: Vitamins, heavy metals, vaccines & sera, antiseptics etc.

3.2 Practical

– Clinical Pharmacology & Therapeutics

- Rational basis of therapeutics (P-drug concept, Essential drugs)
- Rational use of drugs
- Human and Population Pharmacokinetics
- Clinical drug evaluation
- Clinical trial designing
- Clinical trial ethics
- Medico-legal aspects of clinical trials
- Pharmacovigilance
- Drugs and Cosmetics Act
- Data archiving and management
- Drug audit (Pharmacoepidemiology, Pharmacoeconomics)
- Evidence Based Medicine
- Statutory and legal requirements for conduct of clinical trials (including drug schedules)

Experimental Pharmacology

- Study of some basic instruments used for isolated tissue experiments.

- Study of some basic animal techniques:
 - Techniques for injection of drugs and collection of blood samples, feeding of animals etc.
 - Different laboratory animals and their application in experimental pharmacology, breeding data, housing and animal feeds.
 - Preparation and administration of a drug solution in appropriate strength and volume.
- Study design
 - Biostatistics
 - Bioassay
 - CPCSEA
 - Alternatives to animal experiments (cell culture, cell lines)
 - Screening for Pharmacological activity with special reference to the following activities:
 - Analgesic-Antipyretic
 - Anticonvulsant
 - Sedative-hypnotics
 - Anti-depressant
 - Anti-parkinsonian
 - Diuretic
 - Anti-inflammatory
 - Local anesthetic
 - Handling of animals, collection of blood and urine samples.
 - Assembly of organ bath and setting of thermostat.
 - Isolated tissue preparations:
 - To prepare log dose response curve of a suitable drug on:
 - Guinea pig ileum.
 - Frog rectus abdominis
 - Rabbit ileum
 - Rat colon
 - To perform four-point bioassay of a suitable drug on:
 - Guinea pig ileum
 - Frog rectus abdominis
 - To study the stimulatory and depressant effects of drugs on rabbit gut.
 - To study the effect of coronary vasodilator drug on perfused rabbit heart (Langendroff's technique).
 - Study of local anesthetics by various animal techniques.
 - Determination of pA₂ value of acetylcholine on guinea pig ileum.
 - To study the effect of unknown drugs using rabbit eye.
 - Screening Tests on animals to study the following activities:
 - Motor in-coordination
 - Anxiolytic effect
 - Anticonvulsant effect
 - Diuretic activity

- Analgesic effect
- Conditioned Avoidance Response
- Anti-inflammatory effect
- Clinical/human experiments:
- **Computer Aided Learning (CAL) Program:**
- Proficiency in using CAL programs for demonstration of effects of drugs on animals.

Chemical Laboratory:

- To do chemical estimation of various drugs including sulphonamides and salicylates, chemical identification of alkaloids, glycosides and basic chemical parameters like blood sugar levels, blood urea levels, lipid profile etc.
- Introduction to simple analytical methods-Basic principles and applications.
- Quantitative estimation using Colorimetry and Spectrophotometry.
- Toxicological studies using chemical and biological tests.

Statistics

Use of calculators and electronic spread sheets for understanding of:

- Elements of data collection and presentation of data
- Measures of central tendency and dispersion
- Non parametric tests
- Parametric tests (including ANOVA)
- Correlation and regression
- Sampling techniques, randomization, sample size estimation.
- Scales of measurement, data display, and 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.
- Statistical software.

Clinical Pharmacy

- Dosage forms and calculations
- Evaluation of fixed dose combinations and Rational Drug Therapy.
- Instructions for use of dosage forms.
- Preparing instructions for patients regarding use of some drugs.

Computer Skills:

- Use of audio-visual aids.
- Use of computers in biomedical research.
- Computer assisted learning.

- Computer based illustration and data presentation.

Research Methodology:

- Literature search and bibliography.
- Data management and presentation.
- GCP and GLP.
- Formulation of research topic, study design, blinding procedures and protocol writing.
- Ethical principles of animal & human experimentation. Publication ethics.

4. Teaching Program

Acquisition of practical competencies being the keystone of postgraduate Medical education, postgraduate training is skill oriented.

Learning in postgraduate program is essentially self directed and primarily emanating from clinical and academic work. The formal sessions are merely meant to supplement this core effort.

4.1. Teaching sessions

The postgraduate students should attend all undergraduate classes taken by their teachers and colleagues and should also be involved in supervised undergraduate teaching. In addition, there should be daily sessions of formal teaching. Each MD student has to present seminars, Journal clubs, Drug Reviews and perform practicals. He/she should be allotted time for thesis related work.

4.2. Teaching Schedule

Following is the suggested departmental teaching schedule:

Item Frequency

1. Thesis work Once a week
2. Journal club/Drug review Once a week
3. Practical
(Experimental/Chemical/Human)
Once a week
4. Seminar Once a week
5. Statistical exercise Once a fortnight
6. Pharmacokinetic exercise Once a fortnight
7. Theory test Once a month
8. Grand viva Once a year

Note:

- All PGs are supposed to attend the sessions.
- All the teaching sessions shall be assessed by the faculty members at the end of each session and marks should be given out of 10 (for participant) & 100 (for presenter) and kept in the office for the purpose of calculation of internal assessment
- Attendance of the residents at various sessions (including central sessions) should be at least 75%

5. a. Skills:

The candidates should be conversant with the following techniques:

- Weighing technique (chemicals & animals)
- Handling of equipment
- Handling of small animals including various anaesthetic techniques.
- Recording of blood pressure (In vivo and Computer Assisted Learning program)
- Administration of drugs/chemicals to animals (parenteral and enteral routes)
- Screening of drugs using appropriate models
- Isolated tissue preparations for log dose response curve and bioassay
- Use of Cartesian and log graph paper
- Use of various methods to evaluate drug effects in humans

- Elementary principles of common chemical techniques such as colorimeter, spectrophotometer, flame photometer etc.
- Use of appropriate statistical techniques to analyze the results

b. Posting :

Postgraduates will be posted in Medicine and Pediatrics during first year

6. Thesis

- Every candidate shall carry out work on an assigned research project under the guidance of a recognized Postgraduate Teacher; the project shall be written and submitted in the form of a Thesis.
- Every candidate shall submit thesis plan to the University within the timeframe specified by the university.
- Thesis shall also be submitted to the University within the time frame stipulated by the University.
- The student will: (i) identify a relevant research question; (ii) conduct a critical review of literature; (iii) formulate a hypothesis; (iv) determine the most suitable study design; (v) state the objectives of the study; (vi) prepare a study protocol; (vii) undertake a study according to the protocol; (viii) analyze and interpret research data, and draw conclusions; (ix) write a research paper

7. EVALUATION

Dissertation:

- Assessment by 2 independent assessors.
- Acceptance of dissertation for appearing at Final Examination

Day to day evaluation will be based on:

- Regularity in attendance (minimum attendance 80% per term).
- Performance in Seminars, journal reviews etc.
- Performance in practical exercises.
- Participation record keeping: The student will keep regular record of all activities in the form of a log book including attendance of lectures, seminars, conferences / workshops, records of paper presented and a practical journal.

Final (summative) evaluation:

(A) Theory:

Total 4 papers of 100 marks each. Each question paper to have 5 questions and each question to have 2 parts. Division of topics may be as follows:

Paper-1: General Pharmacological Principles & Allied Sciences

100 marks

Theories and mechanism of drug action, Pharmacokinetic principles and parameters, Factors modifying drug action, Pharmacogenetics, Chronopharmacology, Adverse effects of drugs, Drug dependence, Toxicology, Dose response relationships, Structure-activity relationship, Physiological and biochemical basic of drug action, Etiopathogenesis of diseases relevant to therapeutic use of drugs, basic microbiology, Immunology and molecular biology, History of Pharmacology, sources of drug information and use of information technology.

Paper-2 systemic Pharmacology, Chemotherapy and Therapeutics

100 marks

Pharmacology of drugs acting on autonomic, peripheral and central nervous systems; cardiovascular, endocrine, respiratory, renal, gastrointestinal and haemopoietic systems, treatment of diseases affecting these systems. Pharmacology of anti-microbial and anti-parasitic drugs and treatment of infective diseases; cancer chemotherapy, immunopharmacology, gene therapy and evidence based medicine.

Paper-3 Experimental Pharmacology, Bioassay and Statics

100 marks

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. Drugs screening methods.

Paper-4 Clinical Pharmacology Recent Advances

100 marks

Development of new drugs, protocol designing, phases, methodology and ethics of clinical trials, clinical pharmacokinetics and pharmacodynamic studies, post marketing surveillance, therapeutic drug monitoring, pharmacovigilance, ADR monitoring, Drug information service, drug utilization studies, therapeutic audit, essential drug concept and rational prescribing, GLP and GMP. Recent advances in understanding of mechanism of drug action and treatment of diseases; new drugs and new uses of old drugs.

400 marks

(B) PRACTICAL

400 marks

a) Long Experiment:

100 marks

Demonstrating effects of drugs/interpretation of results in anesthetized animal

b) Short experiment

100 marks

- Isolated tissue experiment (Bioassay of drugs)
- In vivo experiment

c) Any two exercises from the following :

100 marks

- Critical appraisal of a published paper.
- Evaluation of drug literature.
- Protocol designing.
- Designing a Proforma for ADR monitoring.
- Assessment of preclinical toxicity data.
- Analysis of rational and irrational formulations.
- Any other similar exercises
- Therapeutic Drug monitoring

d) Grand Viva

100 marks

- Microteaching 20 marks
- Discussion of general and systemic pharmacology 20 marks
- Principles of general and systemic pharmacology 40 marks
- Recent advances in pharmacology & drug therapy 20 marks

8. Job Responsibilities

- To maintain a log book on daily basis
- To maintain daily record of post graduate activities including:
- Practical exercises
- Statistics exercises
- Pharmacokinetic exercises
- PG teaching schedule
- To maintain the laboratory equipment allotted to them
- To prepare and organize undergraduate and postgraduate practical's

9. Suggested Books & Journals

9.1. Core books

Title of Book

Author

- | | |
|--|------------------------------|
| • Goodman & Gilman's The Pharmacological Basis of Therapeutics | Goodman and Gilman |
| • Basic and Clinical Pharmacology | BG Katzung |
| • Pharmacology | Rang, Dale, Ritter and Moore |
| • Essential of Medical Pharmacology | K.D.Tripathi |
| • Principles of Pharmacology | KK Sharma & HL Sharma |

9.2. Reference books

- | | |
|---|--------------------------------------|
| • Applied Therapeutics | Kimble, Young, Corelli and Alldredge |
| • Basic Statistical Methods | Downie and Heath |
| • Clinical Pharmacology | Bennett and Brown |
| • Fundamentals of Experimental Pharmacology | Ghosh M.N. |
| • Principles of Pharmacology | Paul L Munson |
| • Screening Methods | Vogel and Vogel |
| • Text books of Pharmacology | Bowman and Rand |

9.3. Monographs

- Martin Dale's Extra Pharmacopoeia
- Other Pharmacopoeias

9.4. Journals:

- Annual Review of Pharmacology and Toxicology
- British Journal of Pharmacology
- British Medical Journal
- Drugs
- European Journal of Clinical Pharmacology
- Indian Journal of Pharmacology
- Japanese Journal of Clinical Pharmacology
- Journal of Anesthesiology and Clinical Pharmacology
- Journal of Association of Physicians of India
- The Lancet
- The New England Journal of Medicine
- Trends in Pharmacological Sciences

10. Model Test Papers

MODEL QUESTION PAPER

MD (Pharmacology)

Paper-I

Clinical and other Basic Sciences as related to Pharmacology

Max. Marks: 100

Time: 3 hrs

- **Attempt ALL questions**
- **Answer each question & its parts in SEQUENTIAL ORDER**
- **ALL questions carry equal marks**
- **Illustrate your answer with SUITABLE DIAGRAMS**

I Discuss briefly the status of hormone replacement therapy in post menopausal women.

II Describe the clinical significance of apoptosis. Discuss the mechanism of action of drugs modifying apoptosis.

III Discuss the management of nosocomial infections.

IV Describe the composition of blood substitutes and explain their therapeutic uses.

V Outline the present status of purinergic receptors.

VI Describe the pharmacotherapy of obesity.

VII Define antimicrobial resistance and discuss methods for its prevention.

VIII Elaborate the modern approaches to receptor characterization and classification.

IX Discuss the current approaches in the management of osteoporosis.

X Discuss briefly the pathophysiological basis of the management of essential hypertension with the help of suitable illustrations.

MODEL QUESTION PAPER
MD (Pharmacology)
Paper-II
General & Systemic Pharmacology

Max. Marks:100

Time: 3 hrs

- **Attempt ALL questions**
- **Answer each question & its parts in SEQUENTIAL ORDER**
- **ALL questions carry equal marks**
- **Illustrate your answer with SUITABLE DIAGRAMS**

I Give an account of the drugs modifying the Renin-angiotensin system. Discuss the clinical implications with special reference to cardiovascular system.

II Explain the cell-cycle. Discuss the clinical implications of the drugs acting on different phases of cell-cycle.

III Define selective estrogen receptor modulators. Discuss their therapeutic implications.

IV Discuss the current therapeutic status of metronidazole in different diseases.

V Enumerate newer antiepileptic drugs. Discuss their current therapeutic status in seizure and non-seizure disorders.

VI Classify antidepressant drugs. Give an account of adverse effects of typical and atypical antidepressants.

VII Discuss the principles of safe and effective antibacterial drug therapy.

VIII Define half life of a drug following first order kinetics. Discuss its derivation and clinical importance.

IX Define therapeutic index and discuss its importance in therapeutics.

X Define pA₂ value. Describe the method of its calculation giving suitable examples.

MODEL QUESTION PAPER
MD (Pharmacology)
Paper-III
Experimental & Clinical Pharmacology

Max. Marks:100

Time: 3 hrs

- **Attempt ALL questions**
- **Answer each question & its parts in SEQUENTIAL ORDER**
- **ALL questions carry equal marks**
- **Illustrate your answer with SUITABLE DIAGRAMS**

I Define placebo. Give an outline of ethical considerations for its use in clinical trials.

II Explain the role of genetic engineering in new drug development.

III Define LD50 and ED50. Discuss the methods for their calculation.

IV What is the significance of sample size in biomedical research? Give the methods to calculate sample size using an appropriate hypothetical example.

V Define the term 'transgenic animals'. Elaborate on their use in drug research.

VI Enumerate the drug schedules. Give a detailed account of Schedule Y.

VII Discuss the significance of randomization in clinical trials. Elaborate on the practicable methods of randomization.

VIII Outline the evaluation of diuretic activity of a new compound in animal models.

IX Discuss the phases of clinical trials. Give an outline of Phase V clinical trial plan.

X Outline the evaluation of a lead compound for its hypolipidemic activity in animal models.

MODEL QUESTION PAPER
MD (Pharmacology)
Paper-IV
Recent Advances in Pharmacology

Max. Marks:100

Time: 3 hrs

- **Attempt ALL questions**
- **Answer each question & its parts in SEQUENTIAL ORDER**
- **ALL questions carry equal marks**
- **Illustrate your answer with SUITABLE DIAGRAMS**

I Discuss the recent advances in CRIE (Chemotherapy and Radiation Induced Emesis)

II Define monoclonal antibodies. Describe the rationale for their use in therapeutics.

III Give an outline of the pathophysiology of bronchial asthma. Discuss the recent advances in its management.

IV Compare the cyclo-oxygenase enzymes. Discuss the current status of COX-2 inhibitors in therapy.

V Give an account of pharmacotherapy of cutaneous leishmaniasis.

VI Describe the ethical considerations for the use of animals in biomedical research. Discuss the alternatives to animal species in research.

VII Discuss the recent advances in the management of type 2 diabetes mellitus.

VIII Give a diagrammatic representation of the synthesis of eicosanoids. Describe the newer therapeutic applications of prostaglandins.

IX Outline the pathophysiology of osteoporosis. Discuss the diagnostic and therapeutic advances in the management of osteoporosis.

X Describe the management of Premenstrual Dysphonic Disorder.