YENEPOYA

(DEEMED TO BE UNIVERSITY)
Recognized under Sec 3(A) of the UGC Act 1956
Accredited by NAAC with 'A' Grade

YENEPOYA (DEEMED TO BE UNIVERSITY)

Deralakatte, Mangaluru -575018

REGULATIONS AND CURRICULUM GOVERNING POSTGRADUATE PROGRAM (MD) IN PHARMACOLOGY

(REVISED CURRICULUM – AMENDED UP TO 2019)

ATTESTED

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NOTIFICATION – 34-ACM/2019 dtd. 20.02.2019

Sub:- Implementation of Competency Based Medical Education PG Curriculum

Ref. : Resolution of the Academic Council at its 34th Meeting held on 08.02.2019 vide Agenda 33

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The Academic Council at its 34th Meeting held on 08.02.2019 and subsequently the 45th meetings of Board of Management held on 09.02.2019 have accepted the proposal for implementation of Competency Based Medical Education (CBME) for the PG Curricula of the following programs as per the MCI Norms.

1. MD in Pathology
2. MD in General Medicine
3. MD in Anaesthesiology
4. MD in Paediatrics
5. MD in Respiratory Medicine
6. MD in Radio-diagnosis
7. MD in Anatomy
8. MD in Physiology
9. MD in Biochemistry
10. MD in Microbiology
11. MD in Pharmacology
12. MD in Forensic Medicine
13. MD in Psychiatry
14. MD in Dermatology
15. MD in Community Medicine
16. MS in General Surgery
17. MS in OBG
18. MS in Otorhinolaryngology
19. MS in Ophthalmology
20. MS in Orthopaedics

This revised curriculum shall come into effect from the academic year 2019-2020 onwards.

REGISTRAR

Yenepoya (Deemed University)
University Road, Deralakatte
Mangalore 575 018

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 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. S/he should be able to explain Drugs and Cosmetics Act, in addition to clinical trial procedures.

2. 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.

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. Cognitive domain

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 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

7. Acquire knowledge on pharmacoepidemiology, including drug utilization studies.

8. 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.

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 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.

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 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 pA_2 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

I. PG SYLLABUS

COURSE CONTENT

Theory

I. Basic and General Pharmacology

Basic Principles of Pharmacodynamics and Kinetics, including Molecular Pharmacology, Historical aspects of drug discovery, development of new drugs and its evaluation in animals and man, gene based therapy and drug abuse, Pharmacoepidemiology.

II. Clinical Pharmacology

Principles of clinical Pharmacokinetics and their application in drug treatment, clinical trials, therapeutic drug monitoring, adverse drug reaction monitoring, principles of rational drug use. Essential drug concept, Adverse drug interaction; Drug information; Route of medicinal plants.

III. Chemical Pharmacology

Structure activity relationship of important classes of drugs, Basic principles of Analytical Techniques including Spectrophotometry, Chromatography and Radio Immuno Assay.

IV. Systemic Pharmacology and Therapeutics

Drug effects on various organ systems, including anticancer drugs and Immunosuppressants, Drug treatment of disease conditions. Screening procedures for various drug categories in human and animals.

V. Toxicology

Drug poisoning and their management, Environmental, occupational and Industrial Toxicology

*Drugs in Calamities

VI. Biostatistics

Basic principles and their application in drug research

VII. Recent advances in Pharmacology

VIII. Special problems - drug use in different age groups, Pregnancy and disease conditions.

IX. Research Methodology:

[The candidate shall get acquainted with various aspects of biomedical research, so as to enable him to undertake and supervise research projects]

Basic principles and related aspects. Ethical issues related to research on human subjects and animals. Ethical guidelines of ICMR, INSA and Breeding and Experiments on Animals [Control and supervision] Rules 1998.

Practicals:

Objective: A Candidate, after passing the M.D. Pharmacology examination should possess skills in testing the effects of drugs on the various experimental systems specified below. The candidate should also be well versed in interpreting and analyzing the observations and data obtained from studies.

A. Experiments on Laboratory Animals

1. Discussion on Bioassay charts of isolated tissue preparation.
    (a) Rats:- Colon, Uterus, Fundus of stomach, phrenic nerve-diaphragm.
    (b) Guinea Pigs:- Ileum, tracheal chain.
    (c) Frogs:- Rectus muscle, sciatic nerve-gastrocnemius muscle preparation.
2. Demonstration of techniques.

B. Chemical Experiments

1. Sample tests for detecting the chemical nature of drugs.
2. Monitoring of drug levels in body fluids. Candidates should acquaint with the techniques of monitoring drug levels, using systems like Spectrophotometry and immunoassays.

C. Clinical Pharmacology

* Drug Audit in our Hospital

a. Drug prescription analysis for their rationality
b. Drug utilization studies

METHODS OF TRAINING

1. Group discussions, Seminars, Symposia, Journal Clubs and Case discussions. Lectures/lecture demonstrations may be arranged for selected topics in pharmacology as well as in allied disciplines
2. Every candidate during his postgraduate studies, shall actively and regularly participate in undergraduate training programme.

POSTINGS IN OTHER DEPARTMENTS

A candidate of the M.D. Degree course in Pharmacology, needs to be well versed in the applied aspects of pharmacology and therapeutics. Actual postings in the wards of the clinical departments will help the candidate get acquired with the patterns of drug use, rational drug therapy, adverse drug reactions and interactions etc., Such postings will also help him gain confidence in interacting with the clinicians, which will be needed if he chooses to be clinical pharmacologist in his future career. The following clinical postings are recommended:

Department	**Period of posting
General medicine	**1 week**
Pediatrics	**1 week**
Anesthesiology & I.C.U	**1 week**
Dermatology	**1 week**
Psychiatry	**1 week**

These postings shall be during the initial phase of the studies.

**The duration of the clinical postings for MD (2016 batch onwards) students has been increased to 10 weeks.

Department	**Period of postings**
General Medicine	3 Weeks
Respiratory Medicine	1 Week
Pediatrics	2 Weeks
Dermatology	1 Week
Psychiatry	1 Week
Anesthesiology & I. C.U	2 Weeks

To have 2 weeks external postings such as visit to industry/CRO can be included in MD Pharmacology syllabus.

Schedule of work time table.

I YEAR:

1ST to 3rd month: Search and Identification of topic for dissertation in consultation with guide and use of library, Satellite search etc., and preparation of synopsis.

4th to 6th month: Study of Methodology of experiments, Animal Lab, maintenance of Animals, study of instruments for experimentation, Analytical chemistry, submission of synopsis to the University for Registration.

7th to 10th month - Literature Survey, preparation of reference cards, collection of relevant literature and journal work.

Apart from this, the students shall attend all the theory classes, practical's, tutorial and other teaching activities. They should also maintain work diary and duly get it countersigned by head of the department.

II YEAR & III YEAR

Candidates should do all the experiments mentioned in the course content on weekly basis and also continue the experimental work of the dissertation if any, candidates should participate in seminar, journal clubs on weekly basis and file the seminars done to be presented as a book.

They should undergo training in teaching skills. They should also maintain a daily log book of their work in the department for 3 years.

II. MONITORING PROGRESS OF P.G. STUDENTS

1. Work diary/ Log book: Every candidate shall maintain a work diary and record his/her participation in the training programme conducted by the department such as journal reviews, seminars etc. Special mention to be made of the presentations made by the candidate as well as the laboratory experiments conducted. The log book shall be scrutinized and certified by the Head of department every term.

2. The department will conduct periodic tests which may include written paper, practicals and viva voce. Records and marks obtained in such tests will be maintained by head of department and sent to the university.

DISSERTATION

a. Every candidate is required to carry out work on a selected research project under the guidance of a recognized postgraduate teacher. The results of such work shall be submitted in the form of a dissertation.
b. The dissertation is aimed to train the candidate in pharmacological research methods and techniques. It includes identification of a problem, formulation of a hypothesis, search and review of relevant literature, getting acquainted with recent advances, designing of research study, collection of data, critical analysis of results and drawing conclusions.
c. The dissertation is to be submitted at least six months before the final examination as notified by the university to the Controller of Examinations.
d. The dissertation shall be valued by three examiners. Prior acceptance of the dissertation shall be a precondition for a candidate to appear for the final examination.

SCHEME OF EXAMINATION

A. THEORY WRITTEN EXAMINATION- 100×4= 400 MARKS

There shall be four question papers, each of three hours duration, carrying 100 marks.

Question paper pattern:-

I. Long Essay (2 questions)	20 × 2	**40 marks**
II. Short Essay (6 questions)	10 × 6	**60 marks**
	Total	**100 marks**

Details of distribution of topics for each paper will be as follows:

Paper 1: General Pharmacology including Biostatistics

- Sources of drugs, Dosage forms, Special drug delivery system, Route of administration, Pharmacokinetics- Absorption, Distribution, Metabolism, Excretion, Pharmacodynamic- Mechanism of drug action, Combination of drugs and their effects
- Adverse drug reaction, Drug interaction, Factors modifying drug action, Dose
- Biostatistics- Meta-analysis, ANOVA, T-test, Randomization, P Value, Chi square test, Standard error & deviation

Paper 2: Clinical Pharmacology

- Clinical pharmacology- BA, BE studies, TDM, HPLC, Pharmacovigilance, Pharmacogenetics, Pharmaco-epidemiology, Pharmaco-economics, P-drugs, Essential drugs, Gene therapy, stem cell therapy, Drug shelf life
- Preclinical studies, Clinical trials- Placebo, Micro-dosing, Package insert
- Regulatory bodies- FDA, IAEC/CPCSEA, Human ethics committee, Drug schedules.
- Experimental pharmacology- Bioassay, Dose response curve, Radioimmunoassay
- Drug screening method- Analgesics, Anti-inflammatory, Anti epileptic, Anti depressant, Anxiolytic, Antihypertensive, Anti-diabetic, Anti-asthamatic, Local anaesthetic, Antiemetic, Anti-anginal, Peptic ulcer.

Paper 3: Systemic Pharmacology

- ANS, CVS, Diuretics, Blood, CNS, Autacoids, RS.

- Drug acting on uterus, GIT, Endocrine, Immune Pharmacology, Gout, RA, Vaccine, Vitamins – antioxidants, Enzymes
- Antibacterial, Antifungal, Antiviral, Cancer chemotherapy, Therapeutic gases-hyperbaric oxygen, Antiseptics & Disinfectants
- Drugs used in extreme ages-Paediatric, geriatric, Drugs used in pregnancy & lactation.
- Ocular pharmacology, Drugs used in Dermatology.
- Toxicology- Heavy metal poisoning, animal bites, Hepato toxic drugs, Nephro toxic drugs.

Paper 4: Recent Advances in Pharmacology

B. PRACTICAL EXAMINATION - 200 MARKS

Practicals are to be held for minimum of 2 days, along with viva voce.

I. Experimental pharmacology

a. Discussion of Bioassay charts (Rat colon/Rat ileum/G.pig ileum)
b. Interpretation and discussion of Graphs (Dog B.P, Frog heart, Frog rectus abdominus muscle, Rabbit eye used in experiments)
c. Animal handling and demonstration of technique (Rat oral feeding, Mouse oral feeding, Mice intraperitoneal)
d. Discussion of screening methodology using instruments

II. Chemical pharmacology

Identification of any one substance by chemical testing for alkaloids/ glycosides/ steroids/ other drugs.

III. Clinical pharmacology

a. Promotional literature comments
b. Scientific paper evaluation
c. Case discussion - ADR Reporting and causality assessment

IV. Pedagogy

Student is asked to make a presentation on the topic on the second day for 8 to 10 minutes.

V. Grand viva voce

1. Viva voce examination

Students will be examined by all the examiners together about student's knowledge and comprehension of the prescribed course contents, analytical approach, expression and interpretation of data. It includes discussion on dissertation.

2. Dissertation presentation.

I.	**Theory**	**400**
	Paper- 1 Paper- II Paper- III Paper- IV	100 100 100 100
II	**Practicals**	**200**
	A. Experimental pharmacology	**100**
	a. Discussion of Bioassay charts (Rat colon/Rat ileum/G.pig ileum) b. Interpretation and discussion of Graphs (Dog B.P, Frog heart, Frog rectus abdominus muscle, Rabbit eye used in experiments) c. Animal handling and demonstration of technique (Rat oral feeding, Mouse oral feeding, Mice intraperitoneal) **d.** Discussion of screening methodology using instruments	40 20 20 20
	B. Chemical pharmacology	**20**
	Identification of any one substance by chemical testing for alkaloids/ glycosides/ steroids/ other drugs.	
	C. Clinical pharmacology	**60**

	a. Promotional literature comments b. Scientific paper evaluation c. Case discussion - ADR Reporting and causality assessment	20 20 20
	Pedagogy	**20**
III	**Viva voce**	**100**
	Dissertation presentation **Grand viva voce**	25 75
	Total	**700 Marks**

RECOMMENDED BOOKS AND JOURNALS

Books (Latest editions):

1. Goodman and Gillman's Pharmacological basis of therapeutics-12th edition
2. Lange Katzung Basic & Clinical/ Katzung Bertram G-14th Ed
3. Pharmacology and Pharmacotherapeutics – R S Satoskar - 25th edition
4. Essentials of Medical Pharmacology-K D Tripati- 8th edition
5. Principles of Pharmacology- H .L. Sharma & K .K Sharma- 3rd edition
6. Principles of Pharmacology : 4/E 2016/ Golan-2nd Ed
7. Lippincott Illustrated Reviews: Pharmacology : 6/E 2014/ Whalen Karen-5th ed- Author Michelle A Clark
8. Netter's Illustrated Pharmacology Updated Edition/2013/RAFFA-1st Ed
9. Clinical Pharmacology, 2012/-Bennett-11th Ed
10. Drug Screening Methods : 3/E 2016/ Gupta SK
11. Practical Manual of experimental and Clinical Pharmacology- -Bikash Medhi-2nd edition

Journals:

1. Journal of Pharmacology and Experimental Therapeutics
2. Journal of Pharmacy and Pharmacology.
3. Drug [monthly journal Published by Adis international]
4. Clinical Pharmacology and therapeutics
5. Indian Journal of Pharmacology
6. Annual Review of Pharmacology [last 5 years]
7. Trends in Pharmaceutical sciences
8. Indian Journal of Physiology and Pharmacology.

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