

Course & Curriculum for PG

COURSE CONTENT

Each post-graduate student in M.D (Pharmacology) shall undergo a 3 - year (6 terms of 6 months each) training as mentioned below.

1. Theory: (lectures, seminars, journal club /review, therapeutic club, group discussion etc.)

2. Practical training in:

Experimental Pharmacology:

In vitro (including bioassays), in vivo (including common methods of drug evaluation) experiments and toxicity tests

Chemical Pharmacology:

Identification of drug/toxin by using chemical, biological and analytical tests.

Quantitative estimation- Use of colorimeter, spectrophotometer, flame photometer &/or other advanced analytical Equipment as applicable

Clinical Pharmacology:

- Evaluation of drugs in healthy volunteers as well as patients
- Critical evaluation of drug literature, pharmacoeconomics, pharmacovigilance and pharmacoepidemiology etc.

3. Dissertation on a suitable problem

4. Training in undergraduate teaching

5. Computer training

A 3 month rotating posting will be allowed in the allied subjects, including two weeks posting in emergency (casualty) department. A limited period (maximum 2 weeks) of internship during the course may also be

allowed in a pharmaceutical company/contract research organization or a state/national research laboratory/organization.

The syllabus will be based broadly on the following:

(A) KNOWLEDGE:

TEACHING -LEARNING ACTIVITIES

The P G students are to be encouraged to largely carry out self learning with the help of libraries and teachers. Preponderance of didactic teaching is to be avoided. They are expected to actively seek knowledge and skills on their own initiative. Sound knowledge of general and systemic pharmacology including therapeutics of graduate level is to be acquired by self-study and by participating in the teaching of graduate students.

The following self- learning sessions for PG students will be held.

1. P.G. Lectures, Seminars, Journal Club and therapeutic club:

- Postgraduate lectures are to be held once a week in systemic pharmacology to update various aspects of basic pharmacology and applied therapeutics. These lectures will be delivered by faculty members /PG teachers of pharmacology department. Topics of interest common to PGs of other basic and/or clinical disciplines (e.g. medical statistics, teaching technology, communication skills, information technology, biomedical ethics, human behaviour) may be covered. Some proposed topics for multidisciplinary integrated teaching are annexed **(Annexure 6A)**.
- Seminars: Seminar shall be presented to update newer developments in pharmacology/emerging trends/ novel mechanisms of drug action etc. Each PG student should present at least 4-6 seminars every year and actively participate in seminars presented by other PGs.
- Journal club: To familiarize with research methodologies and analysis of results.
- Therapeutic club: To critically analyze the day to day development in therapeutics and application of new drugs.

2. Practical exercises: The PG students will perform experimental pharmacology and chemical pharmacology exercises once a week under the supervision of a faculty member, with/without the help of

animals, various principles/ mode of drug action/ screening of drugs/ drug analysis using various techniques should be performed to develop practical skills to conduct similar experiments in future. The faculty members will also hold a group discussion on the exercise after its completion. It is completed. The PG students will repeat the experiment until they acquire adequate skill and dexterity in the technique. The PGs will be encouraged to acquaint themselves and develop confidence in handling laboratory animals and equipment/instruments. The PGs will maintain a detailed record of the exercises performed by them and get it checked by a faculty member concerned and by Head of the department.

3. Thesis (Dissertation): Each PG student will carry out research work under the supervision of a faculty member of the Pharmacology Department who is recognized PG teacher as per M.C.I. guidelines. One or more co-guides may be appointed from the same or other departments when the work involves multidisciplinary participation. The purpose of this activity is to train the student in all aspects of scientific research and scientific communication, which includes identification of a problem/lacuna in knowledge, hypothesis formulation, literature search, study designing, learning the techniques and execution of the study, data collection, statistical analysis, drawing inferences and writing up the thesis/papers. In a nutshell this will be “an exercise from ideation to publication”. The thesis will be submitted to VN South Gujarat University, Surat and will be analyzed by suitable experts in that field. *The acceptance of the thesis by the institute will be a prerequisite for the candidate to be allowed to appear in the final examination.*

4. Teaching:

The PG students shall participate in all aspects of graduate teaching, specially practicals, demonstrations and tutorials. In the first/second term they should attend the class conducted by senior group teachers. Subsequently they should be given independent charge of a group. One or two graduate lecture classes will also be allocated to each PG student in the 2nd and 3rd year of course, which will be attended by a faculty member to give constructive suggestions for improvement.

5. Intradepartmental postings

Each PG student shall be posted by rotation to the different sections/laboratories of the Pharmacology department viz. experimental pharmacology, chemical pharmacology, clinical pharmacology, pharmacy, Pharmacovigilance centre (ADR monitoring centre) and animal house. A 2 weeks part time basis (morning session 9.00 a.m. to 1.00 p.m.) to the hospital pharmacy shall be arranged so that the PG student could learn drug procurement, storage, record keeping, dispensing and quality control. A record of the observations made and lessons learnt shall be maintained by the students.

6. Posting in allied disciplines:

Each PG student should be posted for 2 weeks each to the physiology, biochemistry, Microbiology, and medicine departments on part time basis to learn the techniques and instrumentation being used in these departments. This will also include two weeks posting in emergency (casualty) department. The schedule for these postings shall be finalized every year in consultation with these departments.

7. Ward rounds: In consultation with major clinical departments, arrangement shall be made so that the PG students of pharmacology attend the ward rounds once a week to get an exposure to the trends in the use of drugs and learn cases of interest for discussion with faculty of pharmacology.

8. Conferences/Workshops

The PG students shall be encouraged to attend national/regional pharmacology conferences. Attendance at a minimum one conference during the 3 year course is mandatory. Credits should be given for attending more conferences and making poster/oral presentations at these. At least one research paper shall be Published/Communicated/Accepted in suitable medical journal.

THEORY SHALL COVER THE FOLLOWING BROAD TOPICS (SUBDIVIDED FOR LECTURE PURPOSE):

1. Basic & molecular pharmacology
2. Biochemical pharmacology
3. Clinical pharmacology
4. Clinical Pharmacokinetics
5. Drugs acting on Synaptic & neuroeffector junctional sites
6. Drugs modifying renal function
7. Drugs acting on cardiovascular system and haemostatic mechanisms
8. Reproductive Pharmacology
9. Pharmacology of endocrines
10. Agents effecting calcification and bone turnover
11. Autacoids and related pharmacological agents
12. Gastrointestinal drugs
13. Pharmacology of drugs affecting the respiratory system
14. Chemotherapy of microbial and parasitic diseases
15. Chemotherapy of neoplastic disease
16. Dermatological pharmacology
17. Ocular pharmacology

18. Immunomodulators – immunosuppressants and immunostimulants
19. Pharmacology of drugs used in metabolic syndromes
20. Drug delivery systems
21. Heavy metals and heavy metal antagonists
22. Non-metallic toxicants – Air pollutants, pesticides etc.
23. Research methodology and biostatistics
24. Literature search.
25. Pharmacogenomics
26. Gene therapy
27. Stem cell research
28. Pharmacometrics-Methods of Evaluation

MULTIDISCIPLINARY TOPICS

1. Biostatistics: Sampling techniques, randomization, sample size estimation, scales of measurement, data display, measures of central tendency (mean, mode, median) dispersion of data (variance, standard deviation, standard error), bias, tests of significance, selection of tests and their applicability, correlation, regression analysis, statistical software.
2. Literature search: different methods (including computer database) with their advantages and limitations
3. Organization of data; data checking, data cleaning, transformation of data, raw and derived data
4. Formulation of research topic, study design, blinding procedures, protocol writing, placebos
5. Good laboratory practices (GLP) and good clinical practices (GCP)
6. Ethical principles of animal and human experimentation, ethical clearance procedures, consent forms and information sheets, publication ethics
7. Educational sciences: Teaching-learning concepts, teaching-learning methods, learning resource materials, audio visual aids, educational objectives and curriculum development, communication skills, evaluation methods (assay type and multiple-choice questions), item analysis etc.
8. Use of computer in biomedical research; computer assisted learning; computer based illustration and data presentation.
9. Care and breeding of laboratory animals

10. Human behavior

11. Scientific writing and publication skills

GENERAL SCREENING AND EVALUATION OF:

- Analgesics, antipyretics and anti-inflammatory drugs
- anticonvulsants, , antidepressants, antianxiety & antipsychotics
- antiarrhythmics,
- Hypotensives/antihypertensives,
- hypocholesterolaemic agents,
- diuretics,
- adrenergic blocking drugs
- Gastric acid secretion/antiulcer drugs
- Antitussives, bronchodilators
- Local Anaesthetics
- Oxytocics, antifertility agents
- Hypoglycemics/antidiabetics
- Antileprosy
- Anti-TB
- Anti-Cancer
- Antihistaminics
- Antimalarials
- Anti-HIV
- Anthelmintics
- Antiparkinsonism
- Alzheimers disease
- Pyrogen testing
- Sedatives & hypnotics

BIOASSAY

- Bioassay methods
- General & statistical considerations
- Methods of bioassay for:

Acetylcholine, neuromuscular blockers, adrenaline, noradrenaline,
histamine, 5HT, hormones, insulin, vasopressin/oxytocin, estrogen, progestins, ACTH

- Competitive antagonism-pA₂ values
- Animal experiments – Legal and Ethical considerations

Educational Science:

- Teaching learning concept
- Teaching learning methods including problem based learning (PBL)
- Learning resource materials
- Instructional aids
- Educational objectives and curriculum development
- Communication skills
- Evaluation methods (Essay type, SAQs, MCQs etc)

(B) EXPERIMENTAL SKILLS.

[1] Experimental Pharmacology

1. General:

- 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 e.g.

- (a) Rat tail vein injection.
- (b) Administration of drugs to rats and guinea pig by gastric cannula.
- (c) Collection of blood from rat tail and guinea pig saphenous vein.
- (d) Collection of blood by cardiac puncture in rat.
- (e) Injection of drugs through marginal ear vein of rabbits.
- (f) Intra-peritoneal and subcutaneous injection to rats and mice.
- (g) Demonstration of catalepsy in rats.
- Techniques of Euthanasia
- Different laboratory animals and their application in experimental pharmacology, breeding data, housing and maintenance and animal feeds
- Preparation and administration of a drug solution in appropriate strength and volume.

2. In vitro Experiments:

- A) Dose Response curves of agonists on various biological tissues
- B) Effects of drugs on various biological tissues e.g.
 - Isolated Rabbit/Guinea-pig/Rat Intestine
 - Isolated rat uterus
 - Isolated Guinea pig tracheal chain (histamine and histamine antagonists on cumulative DRC)
- C) Bioassay (by using different methods) e.g.
 - Adrenaline on Rabbit/Guinea-pig/Rat intestine/duodenum
 - Histamine on Guinea-pig ileum / Tracheal chain
 - Acetylcholine on rat colon
 - Mepyramine on guinea pig ileum
 - 5-HT on rat fundus strip and estrogen primed rat uterus
- D) Demonstration of competitive antagonism using suitable in vitro methods
- E) Determination of EC₅₀, ED₅₀, pD₂ and pA₂ values of drugs

3. In vivo Experiments:

- Study of drugs using various psychopharmacological techniques
- Effect of mydiatics and miotics on rabbit eye
- Study of CNS stimulants and depressants using photoactometer
- Study of antiepileptic drugs by using animal models of epilepsy
- Study of analgesics using animal methods of analgesia
- Study of anti-inflammatory drugs using carageenin induced rat paw edema and other methods if possible
- Study of histamine aerosol induced bronchospasm and its antagonism by antihistamines
- Administration of drugs by various routes
- Collection of blood from animals

4. Anaesthetized animal studies:

- Anaesthetics used in laboratory animals
- Recording of blood pressure and respiration of anaesthetized animals and Identification of unknown drug based on responses
- Sacrificing anaesthetized animals
- Demonstration of head drop with dTC and its reversal
- Study of local anesthetics by various animal techniques

Note: All the animal experiments shall be performed **as per CPCSEA guidelines** and after **approval of IAEC**. The experiments shall be **reduced, refined and replaced** with suitable alternatives acceptable and permissible as per standard /MCI norms wherever possible.

[2] Chemical Pharmacology

- Preparing standard operative practice for Bioavailability and bioequivalence studies
- Introduction to simple analytical methods-Basic principles and applications

- Quantitative estimation using Colorimetry and Spectrophotometry, flame photometry,
- Toxicological Studies using chemical and biological tests
- Identifying toxic drugs using chemical and biological tests (alkaloids, glycosides, steroids, barbiturates, salicylates)

[3] Clinical Pharmacology

(b) Exercises using equipment/instrument

- Recording of BP and heart rate in healthy human volunteers
- Effect of a minimum single dose of antihypertensive drug in human volunteers
- Recording of EEG in healthy human volunteers
- Recording of ECG and measurement of heart rate, PR interval , QT interval, ST segment depression etc in human volunteers
- Study of effect of sublingual nitroglycerine tablet on BP and heart rate.
- Study of effect of beta blockers on exercise tolerance in human volunteers utilizing bicycle ergometer.
- Spirometry and respiratory function tests and effect of bronchodilators.
- Assessment of analgesic activity in human volunteers by soda water metal bottle cap BP cuff pressure test.
- Effect of miotic, mydriatic and cyclopegic drugs in human subjects
- Effect of anticholinergic drugs on salivation, pupillary size, heart rate and memory.
- Effect of antihistaminic and diazepam on visual and auditory reaction time

(b) Exercises on clinical pharmacology as table work

- Drug related problem solving exercise
- Selection of P drug for a given condition
- Psychomotor test in volunteers using 6 digit cancellation test, digit letter symbol substitution test.
- Exercise in pharmacokinetics e.g. calculation and interpretation of bioavailability parameters with the help of given pharmacokinetics data
- Assessment of preclinical toxicity data
- Evaluation of fixed dose combination formulation (rational and irrational)
- Comment on a paper reporting clinical trial
- Research protocol designing
- Writing a protocol for a clinical trial
- Preparation of "Informed consent form" and patient information sheet
- Preparation of "Drug Information Sheet" (WHO criteria)
- Designing a proforma for ADR monitoring
- ADR reporting and causality assessment
- Evaluation / Comment on a drug advertisement/promotional literature
- Critical appraisal of a published paper
- Prescription audit
- Exercise in biostatistics

- Exercises on pharmacoeconomics

[4] Clinical Pharmacy

- Dosage forms and Instructions for use of dosage forms
- Dose calculation and setting up i.v. drip
- Preparing instructions for patients regarding use of some drugs

[5] Computer Skills:

- Use of audio-visual aids
- Use of computers in biomedical research
- Computer assisted learning
- Computer based illustration and data presentation

[6] Research Methodology:

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

[7] Biostatistics:

- Sampling techniques, randomization, sample size estimation
- 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

- Statistical software e.g. SPSS