Curriculum

DNB Broad Specialty

Pharmacology

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I. PROGRAMME GOAL & OBJECTIVES

1. PROGRAMME GOAL

The future prospects for a medical pharmacologist may be in academics, pharmaceutical industry/clinical research organization, research institution and in regulatory bodies, scientific writer or science manager. Accordingly, a DNB student in Pharmacology should be competent to meet the job requirements at all these places.

2. PROGRAMME OBJECTIVES

Keeping in view the possible functions of a medical post-graduate in Pharmacology, the postgraduate student in pharmacology should acquire the following capabilities under the described domains.

a. Knowledge:

Possess a sound knowledge of the subject in the following areas:

- Basic principles of pharmacology (including molecular pharmacology); understanding of basic sciences relevant to Pharmacology
- Process of new drug development
- Clinical pharmacology (including clinical pharmacokinetics, individualization of drug therapy, drug use in special categories, adverse drug reactions and drug- drug interactions)
- Systemic pharmacology
- Principles of essential drugs and rational use of medicines
- Pharmacoeconomics
- Pharmacoepidemiology
- Pharmacovigilance
- Pharmacogenomics
- Research methodology (animal as well as clinical)
- Biostatistics
- Commonly used laboratory techniques, analytical methods and instrumentation
- Major national health problems and programs
- Drug regulations in India and abroad and National Drug Policy
- Teaching technology

- Methods of communication and medical writing.
- Plan and conduct lecture, demonstration, practical tutorial classes for students of medical and allied disciplines.
- Estimation of drug levels in blood and other biological fluids using suitable chemical assay techniques and interpret the same in therapeutic / toxicological context

- Would be able to participate in the team involved in the preclinical and clinical drug discovery process in pharmaceutical / academic setup.
- Preparation of protocols to conduct experimental studies in animal and human drug trials

b. Skills:

The student should acquire the skills that are commensurate with the expected knowledge as outlined above. Some of the desirable skills are:

- Performing commonly employed experiments and clinical techniques in Pharmacology and drug research
- Plan and conduct toxicity studies and clinical trials
- Formulate and undertake research projects independently including statistical analyses
- Perform a number of service activities e.g. therapeutic drug monitoring, pharmacovigilance, pharmacoeconomics and pharmacoepidemiology
- Perform various teaching and training activities for undergraduate and post- graduate medical students and others with a sound understanding of the modern tools of teaching technology.
- Be conversant with the adequate communication skills of both the written and verbal nature (e.g. publishing scientific papers, training doctors, paramedics, patients and public regarding relevant aspects of pharmacotherapy).
- Be proficient in use of computers in various aspects of their day to day
- Be able to analyze and evaluate a research paper
- Be able to formulate and conduct problem-based teaching/learning Exercises
- Be capable of various managerial skills e.g. Drug store management in a hospital; organization of workshops/training programs etc.
- Be aware of the legal and ethical issues involved in drug development and research.

- Be able to constitute and conduct the proceedings of various committees e.g. IAEC, IEC, DTC etc.

c. Attitude

The students should have developed an attitude to be objective, scientifically oriented and ethical towards drugs, drug use and drug research. They should also become a lifetime learner so as to be regularly updated about the advances in the field of Pharmacology.

II. TEACHING AND TRAINING ACTIVITIES

The fundamental components of the teaching programme should include:

1. Case presentations & discussion- once a week
2. Seminar – Once a week
3. Journal club- Once a week
4. Grand round presentation (by rotation departments and subspecialties)- once a week
5. Faculty lecture teaching- once a month
6. Clinical Audit-Once a Month
7. A poster and have one oral presentation at least once during their training period in a recognized conference.

The rounds should include bedside sessions, file rounds & documentation of case history and examination, progress notes, round discussions, investigations and management plan) interesting and difficult case unit discussions.

The training program would focus on knowledge, skills and attitudes (behavior), all essential components of education. It is being divided into theoretical, clinical and practical in all aspects of the delivery of the rehabilitative care, including methodology of research and teaching.

Theoretical: The theoretical knowledge would be imparted to the candidates through discussions, journal clubs, symposia and seminars. The students are exposed to recent advances through discussions in journal clubs. These are considered necessary in view of an inadequate exposure to the subject in the undergraduate curriculum.

Symposia: Trainees would be required to present a minimum of 20 topics based on the curriculum in a period of three years to the combined class of teachers and students. A free discussion would be encouraged in these symposia. The topics of the symposia would be given to the trainees with the dates for presentation.
Clinical: The trainee would be attached to a faculty member to be able to pick up methods of history taking, examination, prescription writing and management in rehabilitation practice.

Bedside: The trainee would work up cases, learn management of cases by discussion with faculty of the department.

Journal Clubs: This would be a weekly academic exercise. A list of suggested Journals is given towards the end of this document. The candidate would summarize and discuss the scientific article critically. A faculty member will suggest the article and moderate the discussion, with participation by other faculty members and resident doctors. The contributions made by the article in furtherance of the scientific knowledge and limitations, if any, will be highlighted.

Research: The student would carry out the research project and write a thesis/ dissertation in accordance with NBE guidelines. He/ she would also be given exposure to partake in the research projects going on in the departments to learn their planning, methodology and execution so as to learn various aspects of research.

III. SYLLABUS

The post-graduate students in D.N.B. (Pharmacology) shall undergo a 3 - year (6 terms of 6 months each) training that will comprise of the following:

1. Theory: (lectures, seminars, group discussion, journal review, etc.)
2. Practical training
3. Thesis and Dissertation
4. Teaching Skills

THEORY

Theory covering the following broad topics:

a. Basic & molecular pharmacology

b. Biochemical pharmacology
c. Clinical pharmacology
d. Clinical Pharmacokinetics
e. Drugs acting on Synaptic & Neuroeffector junctional sites
    - Autonomic Nervous System
    - Peripheral Nervous System
    - Central Nervous System
f. Drugs modifying renal function
g. Drugs acting on cardiovascular system and haemostatic mechanisms
h. Reproductive Pharmacology
i. Pharmacology of endocrines
j. Agents effecting calcification and bone turnover
k. Autacoids and related pharmacological agents
l. Gastrointestinal drugs
m. Pharmacology of drugs affecting the respiratory system
n. Chemotherapy of microbial and parasitic diseases
o. Chemotherapy of neoplastic disease
p. Dermatological pharmacology
q. Ocular pharmacology
r. Immunomodulators – immunosuppressants and immunostimulants
s. Pharmacology of drugs used in metabolic syndromes
t. Evidence based medicine and rational use of medicine
u. Herbal Drug
v. Drug delivery systems
w. Heavy metals and heavy metal antagonists
x. Non-metallic toxicants – Air pollutants, pesticides etc.
y. Research methodology and biostatistics
z. Environmental Pharmacology
aa. Basic and Clinical Toxicology
bb. Pharmacoeconomics
cc. Pharmacoepidemiology
dd. Pharmacovigilance
ee. Pharmacogenomics
ff. Gene therapy
gg. Stem cell research
hh. Pharmacometrics-Methods of Evaluation
ii. Medical education techniques and technology

General Pharmacological Principles & Allied Sciences

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 relationships, Physiological and biochemical basis 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.

Systemic Pharmacology, Chemotherapy and Therapeutics

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.

Experimental Pharmacology, Bioassay and Statistics

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. Drug screening methods.

Instrumentation in Drug Analysis

Qualitative testing, titrimetric analysis. Beer and Lambert's law. Basis and working principle of colorimeter, ultraviolet, atomic absorption spectrometers, Fluorescence spectroscopy, NMR, and Mass Spectroscopy. Basics of Chromatography. Partition, absorption and ion exchange chromatography.

Clinical Pharmacology Recent Advances

Development of new drugs, protocol designing, phases, methodology and ethics of clinical trials, clinical pharmacokinetics and phramcodynamic 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.

Clinical Trials

- Clinical trial for a new investigational drug in India. Methods involved in the assessment of drugs in human volunteers and bio-equivalence studies. Key points in drafting protocol for a large scale multicentric drug trial in India.
- Practical skills: Draft a protocol to conduct phase II clinical trial for a newly discovered non-steroidal anti-inflammatory drug.

Therapeutic Drug Monitoring (TDM)

- Basic principles of TDM. Therapeutic index. Trough level monitoring and dosage adjustments. Practical skills: Calculation of the next dosage of drug to the patient whose plasma drug level has been estimated Therapeutic audit: Drug utilization studies, essential drug concept, rational prescribing
- Drug delivery systems: sustained release, enteric coated formulations and liposome etc.
- Pharmacovigilance, Pharmacoeconomics, Pharmacogenetics and Drug Information

PRACTICALS

- Experimental Pharmacology: In vitro (including bioassays), in vivo (including common methods of drug evaluation) experiments and toxicity tests
- Biochemical Pharmacology: Identification of drug/toxin by using chemical, biological and analytical tests.

Clinical Pharmacology:

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

Experimental Pharmacology

General:

- Study of basic instruments used for isolated tissue experiments
- Study of basic animal techniques
- Techniques for injection of drugs and collection of blood samples, feeding of animals, etc.
- 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.

In vitro Experiments:

- Dose Response curves of agonists on various biological tissues
- Effects of drugs on various biological tissues like:
  - Isolated Rabbit/Guinea-pig/Rat Intestine
  - Isolated rat uterus
  - Isolated Guinea pig tracheal chain (histamine and histamine antagonists cumulative DRC)
  - Langendorff's heart preparation (Study of different drugs on isolated perfus rabbit heart)
- Bioassay (by using different methods):
  - 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 / estrogen primed rat uterus
- Demonstration of competitive antagonism using suitable in vitro methods
- Determination of EC50, ED50, pD2 and pA2 values of drugs

In vivo Experiments:

- Study of drugs using various psychopharmacological techniques
- Effect of mydiatrics 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

Anaesthetized animal studies:

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

Biochemical Pharmacology

- Introduction to simple analytical Methods-Basic principles and applications
- Quantitative estimation using Colorimetry and Spectrophotometry, flame photometry, HPLC, ELISA etc.
- Toxicological Studies using chemical and biological tests
- Identifying toxic drugs using chemical and biological tests (alkaloids, glycosides, steroids, barbiturates, salicylates)

Clinical Pharmacology

- Preparation of protocol for human experiments/clinical trials
  - Schedule Y
  - ICH-GCP Guidelines
  - ICMR GCP Guidelines
  - ICMR Genetic Guidelines
- Preparation of patient information sheet and Informed consent form for human experiments
- Evaluation of promotional drug literature
- Preparation of "Drug Information Sheet" (WHO criteria)
- Preparing standard operative practice for Bioavailability and bioequivalence studies
- Interpretation of bioavailability parameters with the help of given pharmacokinetics data

Clinical Pharmacy

- Dosage forms and calculations

- Evaluation of fixed dose combinations
- Instructions for use of dosage forms
- Communication skills regarding use of drugs

Computer Skills

- Use of audio-visual aids
- Use of computers in education, communication and research
- Use of computers for simulated experiments

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

Biostatistics

- 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
- And any other Statistical methodology as applicable
- Statistical software

Others

- Dissertation on a suitable problem
- Training and teaching skills

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.

P.G. Lectures, Seminars & Journal Club: These are to be held once a week and are to include talks delivered by qualified faculty members of Pharmacology as well as allied disciplines. Topics of interest common to PGs of other basic and/or clinical disciplines (e.g. statistics, educational science, communication skills, information technology, biomedical ethics, and human behavior) could be covered in programs drawn out jointly with other departments. Suggested topics for multidisciplinary teaching (Appendix 1), PG lectures (Appendix 2) and PG seminars, experimental methods discussion. A timetable of these programs should be drawn every 6 months. Each PG student should present at least 4-6 seminars every year and actively participate in seminars presented by other PGs.

Practical exercises: The PG students will perform experimental pharmacology and chemical pharmacology exercises once a week under the supervision of a faculty member, who will also hold a group discussion on the exercise after it is completed. On other days, PGs should repeat the experiment until they acquire adequate skill and dexterity in the technique. The PGs should be encouraged to develop confidence in handling laboratory animals and instruments. The PGs will maintain a detailed record of the exercises performed by them and get it checked by a faculty member.

Teaching: The PG students is to participate in all aspects of graduate teaching, especially practical, demonstrations and tutorials. In the first 6 months they should be attached to senior group teachers. Subsequently they should be given independent charge of a group. One or two graduate lecture classes should also be allocated to each PG student in the 2nd and 3rd year of course. A faculty member should attend these lectures and give constructive suggestions for improvement.

Intradepartmental postings: Every PG student should be posted by rotation to the different sections/laboratories of the Pharmacology department, viz. experimental pharmacology, chemical pharmacology and drug assay, clinical pharmacology including ADR monitoring and drug information service, toxicology. A two weeks part time posting to the hospital pharmacy should 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 should be maintained by the students in logbooks.

Posting in allied disciplines: Every PG student should be posted for two 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. The schedule for these postings should be drawn every year in consultation with these departments.

Ward rounds: In consultation with major clinical departments, arrangement should be made 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

Hospital Posting: One month of casualty posting will be compulsory.

Conferences/Workshops: The PG students should 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 / Abstract should be Published/Accepted.

Desirable: A six month rotating posting is desirable in the allied subjects, a limited period (maximum three months) of internship during the course and they may also be allowed training in a pharmaceutical company / contract research organization or a state/national research laboratory / organization

Biostatistics, Research Methodology and Clinical Epidemiology

Ethics

Medico legal aspects relevant to the discipline

Health Policy issues as may be applicable to the discipline

IV. COMPETENCIES

General screening and evaluation

1. Analgesics, antipyretics, anticonvulsants, anti-inflammatory drugs, antidepressants, antianxiety & antipsychotics antiarrhythmics,

Hypotensives/ antihypertensives, hypocholesterolaemic agents, diuretics, adrenergic blocking drugs

2. Gastric acid secretion/antiulcer drugs
3. Antitussives, bronchodilators
4. Local Anaesthetics
5. Oxytocics, antifertility agents
6. Hypoglycemics/antidiabetics
7. Antileprosy,
8. Anti-TB,
9. Anti-Cancer
10. Antihistaminics
11. Antimalarials
12. Anti-HIV
13. Antihelminthics
14. Antiparkinsonism
15. Alzheimers disease
16. Pyrogen testing
17. Sedatives & hypnotics

Bioassay

1. Bioassay methods
2. General & statistical considerations
3. Methods of bioassay for: Acetylcholine, skeletal neuromuscular junction blockers, adrenaline, noradrenaline, histamine, 5HT, hormones, insulin, vasopressin/ oxytocin, estrogen, progestins, ACTH
4. Competitive antagonism-pA2 values
5. Radio immunoassay: Basic Concepts & applications, ELISA
6. Animal experiments – Legal and Ethical considerations

Educational Science:

1. Teaching learning concept
2. Teaching learning methods including problem based learning (PBL)
3. Learning resource materials
4. Instructional aids
5. Educational objectives and curriculum development
6. Communication skills

7. Evaluation methods (Essay type, SAQs, MCQs, item analysis etc.

V. LOG BOOK

A candidate shall maintain a log book of operations (assisted / performed) during the training period, certified by the concerned post graduate teacher / Head of the department / senior consultant.

This log book shall be made available to the board of examiners for their perusal at the time of the final examination.

The log book should show evidence that the before mentioned subjects were covered (with dates and the name of teacher(s) The candidate will maintain the record of all academic activities undertaken by him/her in log book.

1. Personal profile of the candidate
2. Educational qualification/Professional data
3. Record of case histories
4. Procedures learnt
5. Record of case Demonstration/Presentations
7. Every candidate, at the time of practical examination, will be required to produce performance record (log book) containing details of the work done by him/her during the entire period of training as per requirements of the log book. It should be duly certified by the supervisor as work done by the candidate and countersigned by the administrative Head of the Institution.
8. In the absence of production of log book, the result will not be declared.

VI. RECOMMENDED TEXT BOOKS AND JOURNALS

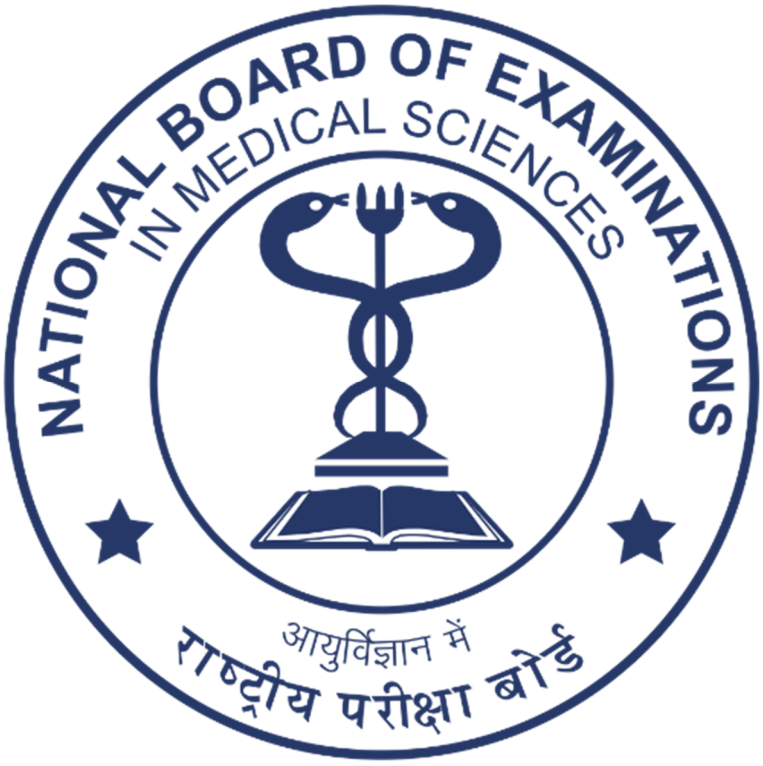
1. TEXT BOOKS

a. Goodman Gillman's The Pharmacological basis of therapeutics. Latest Ed. Hardman JG, Limbird LE (Tenth Edition) McGraw Hill press New York.
b. Basic and Clinical Pharmacology Latest edition by Katzung
c. Drug Discovery and Evaluation – Pharmacological assays. (1997) Ed.Vogel HG & Vogel WH. Springer-New York.

d. Fundamentals of experimental pharmacology. Latest Ed.Ghosh MN. Scientific book agency, Calcutta.
e. Text book of receptor pharmacology. Latest Eds. Forman JC, Johansen TJ CRC Press, New York
f. Basic & Advances Biostatistics – A Indrayan
g. Oxford Handbook of Medical Biostatistics

2. REFERRED JOURNALS

a. Annual Review of Pharmacology and Toxicology Pharmacological Reviews
b. Trends in Pharmacological Sciences
c. Indian Journal of pharmacology
d. Indian Journal of Physiology and Pharmacology
e. Annals of Pharmacotherapy
f. J Pharmacology and Experimental Therapeutics
g. Journal of Ethnopharmacology,
h. Nature
i. Science
j. European Journal of Clinical Pharmacology
k. BJCP and other pharmacology related journals.
l. BJP
m. Clinical Pharmacology and Therapeutics



आयुर्विज्ञान में राष्ट्रीय परीक्षा बोर्ड

स्वास्थ्य एवं परिवार कल्याण मंत्रालय, भारत सरकार

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