Guidelines

for

Competency Based Training Programme

in

DNB- PHARMACOLOGY

NATIONAL BOARD OF EXAMINATIONS

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CONTENTS

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.

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.

(i) Knowledge:

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

i) Basic principles of pharmacology (including molecular pharmacology); understanding of basic sciences relevant to Pharmacology

ii) Process of new drug development

iii) Clinical pharmacology (including clinical pharmacokinetics, individualization of drug therapy, drug use in special categories, adverse drug reactions and drug- drug interactions)

iv) Systemic pharmacology

v) Principles of essential drugs and rational use of medicines

vi) Pharmacoeconomics

vii) Pharmacoepidemiology

viii) Pharmacovigilance

ix) Pharmacogenomics

x) Research methodology (animal as well as clinical)

xi) Biostatistics

xii) Commonly used laboratory techniques, analytical methods and instrumentation

xiii) Major national health problems and programs

xiv) Drug regulations in India and abroad and National Drug Policy

xv) Teaching technology

xvi) Methods of communication and medical writing.

xvii) Plan and conduct lecture, demonstration, practical tutorial classes for students of medical and allied disciplines.

xviii) Estimation of drug levels in blood and other biological fluids using suitable chemical assay techniques and interpret the same in therapeutic / toxicological context

xix) Would be able to participate in the team involved in the preclinical and clinical drug discovery process in pharmaceutical / academic setup.

xx) Preparation of protocols to conduct experimental studies in animal and human drug trials

(ii) Skills:

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

(i) Performing commonly employed experiments and clinical techniques in Pharmacology and drug research

(ii) Plan and conduct toxicity studies and clinical trials

(iii)Formulate and undertake research projects independently including statistical analyses

(iv)Perform a number of service activities e.g. therapeutic drug monitoring, pharmacovigilance, pharmacoeconomics and pharmacoepidemiology

(v) 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.

(vi) 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).

(vii) Be proficient in use of computers in various aspects of their day to day work

(viii) Be able to analyze and evaluate a research paper

(ix) Be able to formulate and conduct problem based teaching/learning exercises

(x) Be capable of various managerial skills e.g. Drug store management in a hospital; organization of workshops/training programs etc.

(xi) Be aware of the legal and ethical issues involved in drug development and research.

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

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.

ELIGIBILITY CRITERIA FOR ADMISSIONS TO THE PROGRAMME

(A) DNB Pharmacology Course:

1. Any medical graduate with ***MBBS*** qualification , who has qualified the ***Entrance Examination*** conducted by NBE and fulfill the eligibility criteria for admission to DNB ***Broad Specialty*** courses at various NBE accredited Medical Colleges/ institutions/Hospitals in India is eligible to participate in the Centralized counseling for allocation of DNB **Pharmacology** seats purely on merit cum choice basis.

2. Admission to 3 years post MBBS DNB **Pharmacology** course is only through ***Entrance Examination*** conducted by NBE and Centralized Merit Based Counseling conducted by National Board of Examination as per prescribed guidelines.

Duration of Course: 3 Years

Every candidate admitted to the training programme shall pursue a regular course of study (on whole time basis) in the concerned recognized institution under the guidance of recognized post graduate teacher for assigned period of the course.

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.

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:

1. Basic & molecular pharmacology
2. Biochemical pharmacology
3. Clinical pharmacology
4. Clinical Pharmacokinetics
5. Drugs acting on Synaptic & Neuroeffector junctional sites
    a) Autonomic Nervous System
    b) Peripheral Nervous System
    c) Central Nervous System
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. Evidence based medicine and rational use of medicine
21. Herbal Drug
22. Drug delivery systems
23. Heavy metals and heavy metal antagonists
24. Non-metallic toxicants – Air pollutants, pesticides etc.
25. Research methodology and biostatistics
26 Environmental Pharmacology
27. Basic and Clinical Toxicology
28. Pharmacoeconomics

29. Pharmacoepidemiology
30. Pharmacovigilance
31. Pharmacogenomics
32. Gene therapy
33. Stem cell research
34. Pharmacometrics-Methods of Evaluation
35. 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

1. 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.

2. In vitro Experiments:

A) Dose Response curves of agonists on various biological tissues
B) 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 on cumulative DRC)

• Langendorff's heart preparation (Study of different drugs on isolated perfused rabbit heart).

C) 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

C) 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 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

4. 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

a) Schedule Y
b) ICH-GCP Guidelines
c) ICMR GCP Guidelines
d) 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.

1. 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.

2. 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.

3. 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.

4. 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.

5. 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.

6. 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

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

8. 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.

9. 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

THESIS PROTOCOL & THESIS

The candidates are required to submit a thesis at the end of three years of training as per the rules and regulations of NBE.

Guidelines for Submission of Thesis Protocol & Thesis by candidates

Research shall form an integral part of the education programme of all candidates registered for DNB degrees of NBE. The Basic aim of requiring the candidates to write a thesi protocol & thesis/dissertation is to familiarize him/her with research methodology. The members of the faculty guiding the thesis/dissertation work for the candidate shall ensure that the subject matter selected for the thesis/dissertation is **feasible, economical** and **original**.

Guidelines for Thesis Protocol

The protocol for a research proposal (including thesis) is a study plan, designed to describe the background, research question, aim and objectives, and detailed methodology of the study. In other words, the protocol is the 'operating manual' to refer to while conducting a particular study.

The candidate should refer to the NBE Guidelines for preparation and submission of Thesis Protocol before the writing phase commences. The minimum writing requirements are that the language should be clear, concise, precise and consistent without excessive adjectives or adverbs and long sentences. There should not be any redundancy in the presentation.

The development or preparation of the Thesis Protocol by the candidate will help her/him in understanding the ongoing activities in the proposed area of research. Further it helps in creating practical exposure to research and hence it bridges the connectivity between clinical practice and biomedical research. Such research exposure will be helpful in improving problem solving capacity, getting updated with ongoing research and implementing these findings in clinical practice.

Research Ethics: Ethical conduct during the conduct and publication of research is an essential requirement for all candidates and guides, with the primary responsibility of ensuring such conduct being on the thesis guide. Issues like Plagiarism, not maintaining the confidentiality of data, or any other distortion of the research process will be viewed seriously. The readers may refer to standard documents for the purpose.

The NBE reserves the right to check the submitted protocol for plagiarism, and will reject those having substantial duplication with published literature.

PROTOCOL REQUIREMENTS

1. All of the following will have to be entered in the online template. The thesis protocol should be restricted to the following word limits.

- Title : 120 characters (with spacing) page
- Synopsis [structured] : 250-300
- Introduction : 300-500
- Review of literature : 800-1000
- Aim and Objectives : Up to 200
- Material and Methods : 1200-1600
- 10-25 References [ICMJE style]

2. It is mandatory to have ethics committee approval before initiation of the research work. The researcher should submit an appropriate application to the ethics committee in the prescribed format of the ethics committee concerned.

Guidelines for Thesis

1. The proposed study must be approved by the institutional ethics committee and the protocol of thesis should have been approved by NBE.

2. The thesis should be restricted to the size of 80 pages (maximum). This includes the text, figures, references, annexures, and certificates etc. It should be printed on both sides of the paper; and every page has to be numbered. Do not leave any page blank. To achieve this, following points may be kept in view:

    a. The thesis should be typed in 1.5 space using Times New Roman/Arial/ Garamond size 12 font, 1" margins should be left on all four sides. Major sections viz., Introduction, Review of Literature, Aim & Objectives, Material and Methods, Results, Discussion, References, and Appendices should start from a new page. Study proforma (Case record form), informed consent form, and patient information sheet may be printed in single space.
    b. Only contemporary and relevant literature may be reviewed. Restrict the introduction to 2 pages, Review of literature to 10-12 pages, and Discussion to 8-10 pages.
    c. The techniques may not be described in detail unless any modification/innovations of the standard techniques are used and reference(s) may be given.
    d. Illustrative material may be restricted. It should be printed on paper only. There is no need to paste photographs separately.

3. Since most of the difficulties faced by the residents relate to the work in clinical subject or clinically-oriented laboratory subjects, the following steps are suggested:
    a. The number of cases should be such that adequate material, judged from the hospital attendance/records, will be available and the candidate will be able to collect case material within the period of data collection, i.e., around 6-12 months so that he/she is in a position to complete the work within the stipulated time.
    b. The aim and objectives of the study should be well defined.
    c. As far as possible, only clinical/laboratory data of investigations of patients or such other material easily accessible in the existing facilities should be used for the study.
    d. Technical assistance, wherever necessary, may be provided by the department concerned. The resident of one specialty taking up some problem related to some other specialty should have some basic knowledge about the subject and he/she should be able to perform the investigations independently, wherever some specialized laboratory investigations are required a co-guide may be co-opted from the concerned investigative department, the quantum of laboratory work to be carried out by the candidate should be decided by the guide & co-guide by mutual consultation.

4. The clinical residents are not ordinarily expected to undertake experimental work or clinical work involving new techniques, not hitherto perfected OR the use of chemicals or radioisotopes not readily available. They should; however, be free to enlarge the scope of their studies or undertake experimental work on their own initiative but all such studies should be feasible within the existing facilities.

5. The DNB residents should be able to freely use the surgical pathology/autopsy data if it is restricted to diagnosis only, if however, detailed historic data are required the resident will have to study the cases himself with the help of the guide/co-guide. The same will apply in case of clinical data.

6. Statistical methods used for analysis should be described specifically for each objective, and name of the statistical program used mentioned.

General Layout of a DNB Thesis:

- **Title-** A good title should be brief, clear, and focus on the central theme of the topic; it should avoid abbreviations. The Title should effectively summarize the proposed research and should contain the PICO elements.

- **Introduction-** It should be focused on the research question and should be directly relevant to the objectives of your study.

- **Review of Literature -** The Review should include a description of the most relevant and recent studies published on the subject.

- Aim and Objectives - The 'Aim' refers to what would be broadly achieved by this study or how this study would address a bigger question / issue. The 'Objectives' of the research stem from the research question formulated and should at least include participants, intervention, evaluation, design.

- **Material and Methods-** This section should include the following 10 elements: Study setting (area), Study duration; Study design (descriptive, case-control, cohort, diagnostic accuracy, experimental (randomized/non-randomized)); Study sample (inclusion/exclusion criteria, method of selection), Intervention, if any, Data collection, Outcome measures (primary and secondary), Sample size, Data management and Statistical analysis, and Ethical issues (Ethical clearance, Informed consent, trial registration).

- **Results-** Results should be organized in readily identifiable sections having correct analysis of data and presented in appropriate charts, tables, graphs and diagram etc.

- **Discussion–**It should start by summarizing the results for primary and secondary objectives in text form (without giving data). This should be followed by a comparison of your results on the outcome variables (both primary and secondary) with those of earlier research studies.

- **Summary and Conclusion-** This should be a précis of the findings of the thesis, arranged in four paragraphs: (a) background and objectives; (b) methods; (c) results; and (d) conclusions. The conclusions should strictly pertain to the findings of the thesis and not outside its domain.

- **References-** Relevant References should be cited in the text of the protocol (in superscripts).

- **Appendices -**The tools used for data collection such as questionnaire, interview schedules, observation checklists, informed consent form (ICF), and participant information sheet (PIS) should be attached as appendices. Do not attach the master chart.

Competencies

General screening and evaluation

•Analgesics, antipyretics,anticonvulsants, anti-inflammatory drugs, 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
- Antihelminthics
- Antiparkinsonism
- Alzheimers disease
- Pyrogen testing
- Sedatives & hypnotics

Bioassay

- Bioassay methods
- General & statistical considerations
- Methods of bioassay for: Acetylcholine, skeletal neuromuscular junction blockers, adrenaline, noradrenaline, histamine, 5HT, hormones, insulin, vasopressin/oxytocin, estrogen, progestins, ACTH
- Competitive antagonism-pA2 values
- Radio immunoassay: Basic Concepts & applications, ELISA
- 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, item analysis etc.

Thesis Protocol Submission to NBE

1. DNB candidates are required to submit their thesis protocol within 90 days of their joining DNB training.

2. Enclosures to be submitted along with protocol submission form:
   a) Form for Thesis Protocol Submission properly filled.
   b) Thesis Protocol duly signed.
   c) Approval letter of institutional Ethical committee. *(Mandatory, non receivable of any one is liable for rejection)*

Thesis Submission to NBE

1. As per NBE norms, writing a thesis is essential for all DNB candidates towards partial fulfillment of eligibility for award of DNB degree.
2. DNB candidates are required to submit the thesis before the cut-off date which shall be 30th June of the same year for candidates appearing for their scheduled December final theory examination. Similarly, candidates who are appearing in their scheduled June DNB final examination shall be required to submit their thesis by 31st December of preceding year.
3. Candidates who fail to submit their thesis by the prescribed cutoff date shall NOT be allowed to appear in DNB final examination.
4. Fee to be submitted for assessment (In INR): 3500/-
5. Fee can be deposited ONLY through pay-in-slip/challan at any of the Indian bank branch across India. The challan can be downloaded from NBE website www.natboard.edu.in
6. Thesis should be bound and the front cover page should be printed in the standard format. A bound thesis should be accompanied with:
   a. A Synopsis of thesis.
   b. Form for submission of thesis, duly completed

c. NBE copy of challan (in original) towards payment of fee as may be applicable.
d. Soft copy of thesis in a CD duly labeled.
e. Copy of letter of registration with NBE.

7. A declaration of thesis work being bonafide in nature and done by the candidate himself/herself at the institute of DNB training need to be submitted bound with thesis. It must be signed by the candidate himself/herself, the thesis guide and head of the institution, failing which thesis shall not be considered.

The detailed guidelines and forms for submission of Thesis Protocol & Thesis are available at www.natboard.edu.in.thesis.php.

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
6. 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.
7. In the absence of production of log book, the result will not be declared.

Leave Rules

1. DNB/FNB Trainees are entitled to avail leave during the course of DNB/FNB training as per the Leave Rules prescribed by NBE.
2. A DNB/FNB Trainees can avail a maximum of 30 days of leave in a year excluding regular duty off/ Gazetted holidays as per hospital/institute calendar/policy. This leave shall be processed at the institutional level.
3. Any kind of study leave is not permissible to DNB/FNB Trainees.
4. Under normal circumstances leave of one year should not be carried forward to the next year. However, in exceptional cases such as prolonged illness, the leave across the DNB/FNB training program may be clubbed together with prior approval of NBE.
5. Unauthorized absence from DNB/FNB training for more than 7 days may lead to cancellation of registration and discontinuation of the DNB/FNB training and rejoining shall not be permitted.
6. Any Leave availed by the candidate other than the eligible leave (30 days per year) shall lead to extension of DNB /FNB training. The training institute has to forward such requests to NBE along with the leave records of the candidate since his/her joining and supporting documents (if any) through the Head of the Institute with their recommendation/comments. NBE shall consider such requests on merit provided the seat is not carried over and compromise with training of existing trainees in the Department.
7. Any extension of DNB/FNB training beyond the scheduled completion date of training is permissible only under extra-ordinary circumstances with prior approval of NBE. Such extension is neither automatic nor shall be granted as a matter of routine.
8. DNB/FNB trainees are required to complete their training by a prescribed cutoff date (as per information bulletin of Exit exam) for being eligible to DNB/FNB Exit examination.
9. The eligibility for DNB/FNB Final Examination shall be determined strictly in accordance with the criteria prescribed in the respective information bulletin.
10. Candidates join on or after 2018 can avail Maternity / Paternity leave, as per the Central or State Government policies, whichever is applicable to DNB/FNB training institute.

11. DNB/FNB trainees are eligible for stipend either during the leave period or extension of training period as per the policies of DNB/FNB training institute and prevailing rules.

EXAMINATION

FORMATIVE ASSESSMENT

Formative assessment includes various formal and informal assessment procedures by which evaluation of student's learning, comprehension, and academic progress is done by the teachers/ faculty to improve student attainment. Formative assessment test (FAT) is called as "Formative "as it informs the in process teaching and learning modifications. FAT is an integral part of the effective teaching .The goal of the FAT is to collect information which can be used to improve the student learning process.

Formative assessment is essentially positive in intent, directed towards promoting learning; it is therefore part of teaching. Validity and usefulness are paramount in formative assessment and should take precedence over concerns for reliability. The assessment scheme consists of Three Parts which has to be essentially completed by the candidates.

The scheme includes:-

Part I:- Conduction of theory examination
Part-II :- Feedback session on the theory performance
Part-III :- Work place based clinical assessment

Scheme of Formative assessment

PART – I	**CONDUCT OF THEORY EXAMINATION**	Candidate has to appear for Theory Exam and it will be held for One day.
PART – II	**FEEDBACK SESSION ON THE THEORY PERFORMANCE**	Candidate has to appear for his/her Theory Exam Assessment Workshop.
PART – III	**WORK PLACE BASED CLINICAL ASSESSMENT**	After Theory Examination, Candidate has to appear for Clinical Assessment.

The performance of the resident during the training period should be monitored throughout the course and duly recorded in the log books as evidence of the ability and daily work of the student

1. Personal attributes:

- **Behavior and Emotional Stability:** Dependable, disciplined, dedicated, stable in emergency situations, shows positive approach.
- **Motivation and Initiative:** Takes on responsibility, innovative, enterprising, does not shirk duties or leave any work pending.

- **Honesty and Integrity:** Truthful, admits mistakes, does not cook up information, has ethical conduct, exhibits good moral values, loyal to the institution.
- **Interpersonal Skills and Leadership Quality:** Has compassionate attitude towards patients and attendants, gets on well with colleagues and paramedical staff, is respectful to seniors, has good communication skills.

2. Clinical Work:

- **Availability:** Punctual, available continuously on duty, responds promptly on calls and takes proper permission for leave.
- **Diligence:** Dedicated, hardworking, does not shirk duties, leaves no work pending, does not sit idle, competent in clinical case work up and management.
- **Academic ability:** Intelligent, shows sound knowledge and skills, participates adequately in academic activities, and performs well in oral presentation and departmental tests.
- **Clinical Performance:** Proficient in clinical presentations and case discussion during rounds and OPD work up. Preparing Documents of the case history/examination and progress notes in the file (daily notes, round discussion, investigations and management) Skill of performing bed side procedures and handling emergencies.

3. Academic Activity: Performance during presentation at Journal club/ Seminar/ Case discussion/Stat meeting and other academic sessions. Proficiency in skills as mentioned in job responsibilities.

FINAL EXAMINATION

The summative assessment of competence will be done in the form of DNB Final Examination leading to the award of the degree of Diplomate of National Board in Pharmacology. The DNB final is a two-stage examination comprising the theory and practical part. An eligible candidate who has qualified the theory exam is permitted to appear in the practical examination.

Theory Examination

1. The theory examination comprises of ***Four*** papers, maximum marks 100 each.
2. There are 10 short notes of 10 marks each, in each of the papers. The number of short notes and their respective marks weightage may vary in some subjects/some papers.
3. Maximum time permitted is 3 hours.
4. Candidate must score at least 50% in the aggregate of ***Four*** papers to qualify the theory examination.

5. Candidates who have qualified the theory examination are permitted to take up the practical examination.
6. The paper wise distribution of the Theory Examination shall be as follows:

Paper I: General Pharmacological Principles and Allied Sciences **Paper II:** Systemic Pharmacology, Chemotherapy and Therapeutics **Paper III:** Experimental Pharmacology, Screening of Drugs and Statistics **Paper IV:** Clinical Pharmacology and recent advances in Pharmacology

a) Practical Examination:

1. Maximum Marks: 300.
2. Comprises of Clinical Examination and Viva.
3. Candidate must obtain a minimum of 50% marks in the Clinical Examination (including Viva) to qualify for the Practical Examination.
4. There are a maximum of three attempts that can be availed by a candidate for Practical Examination.
5. First attempt is the practical examination following immediately after the declaration of theory results.
6. Second and Third attempt in practical examination shall be permitted out of the next three sessions of practical examinations placed alongwith the next three successive theory examination sessions; after payment of full examination fees as may be prescribed by NBE.
7. Absentation from Practical Examination is counted as an attempt.
8. Appearance in first practical examination is compulsory;
9. Requests for Change in center of examination are not entertained, as the same is not permissible.
10. Candidates are required not to canvass with NBE for above.

Declaration of DNB Final Results

1. DNB final is a qualifying examination.
2. Results of DNB final examinations (theory & practical) are declared as PASS/FAIL.
3. DNB degree is awarded to a DNB trainee in the convocation of NBE.

RECOMMENDED TEXT BOOKS AND JOURNALS

1. Goodman Gillman's The Pharmacological basis of therapeutics. Latest Ed. Hardman JG, Limbird LE (Tenth Edition) McGraw Hill press New York.
2. Basic and Clinical Pharmacology Latest edition by Katzung
3. Drug Discovery and Evaluation – Pharmacological assays. (1997) Ed.Vogel HG & Vogel WH. Springer-New York.
4. Fundamentals of experimental pharmacology. Latest Ed.Ghosh MN. Scientific book agency, Calcutta.
5. Text book of receptor pharmacology. Latest Eds. Forman JC, Johansen TJ CRC Press, New York
6. Basic & Advances Biostatistics – A Indrayan
7. Oxford Handbook of Medical Biostatistics

REFERRED JOURNALS

Annual Review of Pharmacology and Toxicology

Pharmacological Reviews

Trends in Pharmacological Sciences

Indian Journal of pharmacology

Indian Journal of Physiology and Pharmacology

Annals of Pharmacotherapy

J Pharmacology and Experimental Therapeutics

Journal of Ethnopharmacology,

Nature

Science

European Journal of Clinical Pharmacology

BJCP and other pharmacology related journals.

BJP

Clinical Pharmacology and Therapeutics

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