SYLLABUS

Ph.D.

PHARMACY PRACTICE

NATIONAL INSTITUTE OF PHARMACEUTICAL EDUCATION AND RESEARCH GUWAHATI
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Ph.D. Syllabus

PHARMACY PRACTICE

Course No.	Course Name	Credits
Semester-I		
*CS-701	Research Methodology (Compulsory)	2

Course No.	Course Name	Credits
Semester-II		
*CS -801	Research and Publication Ethics (Compulsory)	2
PP-810	Advanced Pharmacy Practice	2

*Detailed Syllabus is available at Page No. 39-40

Ph.D. Pharmacy Practice
SEMESTER - II

PP-810:- Advanced Pharmacy Practice (2 Credits)

1. ***Drug Effectiveness Evaluation:*** Post-marketing surveillance, real-world evidence, observational study designs, experimental and quasi-experimental study designs, pragmatic randomized controlled trials, single-arm trials, self-controlled case-series design, case-crossover design, and mixed methods research. Confounding, biases (including immortal-time bias and channeling bias), propensity score matching, intention-to-treat analysis, per-protocol analysis, as-treated analysis, and benefit-risk assessment. Importance of machine learning, artificial intelligence, and big data mining in drug discovery and development.
2. ***Drug Safety Evaluation:*** Pharmacovigilance methods, signal detection, risk assessment, risk management, risk communication, and drug safety evaluation in special populations. The importance of pharmacogenomics for individual variation in adverse drug reactions. Regulatory requirements for pharmacovigilance, Good Pharmacovigilance Practices (GVP), and qualified person for pharmacovigilance. Ecopharmacovigilance, vaccine pharmacovigilance, hemovigilance, materiovigilance, and pharmacovigilance of biologics.
3. ***Pharmacoeconomic Evaluation:*** Pharmacoeconomic methods, budget impact analysis, health status measures, decision analysis, Markov modeling, and health technology assessment in India.
4. ***Evidence Synthesis:*** Scoping review, systematic review, meta-analysis, network meta-analysis, GRADE approach, and consensus approach.
5. ***Databases, Registries, and Guidelines:*** Spontaneous reporting databases and insurance & claims databases. Drug & disease registries and pregnancy exposure registries. ICMR ethical guidelines for human research, Good Clinical Practice (GCP, certification is mandatory) and Good Pharmacy Practice guidelines, and Drugs, Medical Devices and Cosmetics Bill 2022.
6. ***Societies and Associations:*** International Society for Pharmacoepidemiology (ISPE), International Society for Pharmacoeconomics and Outcomes Research (ISPOR), International Society of Pharmacovigilance (ISoP), Institute for Safe Medication Practices (ISMP), American College of Clinical Pharmacy (ACCP), American Society of Health-System Pharmacists (ASHP), and Board of Pharmacy Specialties (BPS).

(Syllabus for Compulsory Courses)

Semester-I

CS- 701 :- Research Methodology (2 Credits)

Unit 1: **Objectives and types of research**: Motivation and objectives, research methods vs methodology. Types of research – descriptive vs analytical, applied vs fundamental, quantitative vs qualitative, conceptual vs empirical. Introduction to drug discovery & development research, objectives, flowchart from discovery to post-marketing research, overview of research methodology in various areas of drug discovery and development research.

Unit 2: **Research formulation and Literature review**– Defining and formulating the research problem, selecting the problem, the necessity of defining the problem, the importance of literature review in defining a problem, Literature review - primary and secondary sources, reviews, monographs, patents, research databases, web as a source, searching the web, critical appraisal of literature, identifying gap areas from literature review and research databases, and development of a working hypothesis.

Unit 3: **Research design and methods**: Research design – basic principles, need of research design, features of good design, important concepts relating to research design, observation and facts, laws and theories, prediction and explanation, research databases, development of models, developing a research plan – exploration, description, diagnosis, and experimentation.

Unit 4: **Execution of the research, data collection and analysis**: Aspects of method validation, observation and collection of data, methods of data collection, sampling methods, data processing and analysis strategies and tools, data analysis with statistical packages (GraphPad Prism, SPSS for Student t-test, ANOVA, etc), hypothesis testing, generalization, and interpretation.

Unit 5: **Safety measures in the laboratory: Handling of hazardous chemicals, incompatible chemicals, flammable solvents, toxic chemicals and forms of toxic materials.** Approaches for prevention and management of fire, electrical, chemical, biological, and gaseous hazards, good laboratory practices. General safety rules, waste minimization approaches and safety practices for disposal of chemical waste, biologicals and other laboratory waste.

(Syllabus for Compulsory Courses)

Semester-II

CS- 801 :- Research and Publication Ethics (2 Credits)

Unit 1: **Research Ethics:**

a) Ethics – ethical issues, ethical committees (human & animal)
b) Ethics with respect to science and research
c) Intellectual honesty and research integrity
d) Scientific misconducts: Falsification, Fabrication, and Plagiarism
e) What is plagiarism? Similarity report software like iThenticate/ Turnitin/ Urkund.
f) Redundant publications: duplicate and overlapping publications, salami-slicing
g) Selective reporting, and misrepresentation of data

Unit 2: **Publication Ethics:**

a) Publication ethics: definition, introduction, and importance.
b) Best practices / standards-setting initiatives and guidelines: COPE, WAME, etc.
c) Conflicts of interest
d) Publication and Research misconduct: definition, concept, problems that lead to unethical behavior and vice versa, types
e) Violation of publication ethics, authorship, and contributorship
f) Identification of publication misconduct, complaints, and appeals
g) Predatory publishers and journals.
h) Journal finder/journal suggestion tools.

Unit 3: **IPR and scholarly publishing**:

Intellectual Property Rights (IPR) and patent law, commercialization, copyright, royalty, trade-related aspects of intellectual property rights (TRIPS)

Unit 4: **Report and thesis writing:**

a) Structure and components of scientific reports, types of reports, technical reports, and thesis.
b) Thesis writing – different steps and software tools (Word processing, etc) in the design and preparation of the thesis, layout, structure (chapter plan), and language of typical reports, Illustrations and tables, bibliography, referencing, and footnotes.
c) Oral presentation – planning, software tools, creating and making an effective presentation, use of visual aids, the importance of effective communication
d) Writing a research proposal and research grant
e) Scholarly publishing – IMRaD concept and design of research paper, citation and acknowledgment, reproducibility, and accountability.
f) Graphical Abstract and Artwork preparation

Unit 5: **Databases and Research Metrics**

a) Indexing databases: PubMed, Embase, etc.
b) Citation databases: Web of Science, Scopus, etc.
c) Impact Factor of the journal as per Journal Citation Report, SNIP, SJR, IPP, Cite Score, *etc*.
d) Metrics: h index, g index, i10 index, altmetrics