



SYLLABUS

Ph.D.

PHARMACEUTICS

**NATIONAL INSTITUTE OF PHARMACEUTICAL EDUCATION AND RESEARCH
GUWAHATI**

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Ph.D. Syllabus

PHARMACEUTICS

Course No.	Course Name	Credits
Semester-I		
PE-710	Implications of Solid State Properties in Drug Delivery (Prerequisite to course PE-660)	2
PE-720	Technological Aspects of Oral Modified Release Formulations	2
*CS-701	Research Methodology (Compulsory)	2

Course No.	Course Name	Credits
Semester-II		
PE-810	Novel Approaches for Targeted Drug Delivery	2
PE-820	Advanced Drug Delivery System	2
*CS-801	Research and Publication Ethics (Compulsory)	2

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

Ph.D. Syllabus SEMESTER - I

PE-710:- Implications of Solid State Properties in Drug Delivery (2 Credits)

1. **Barriers to Drug Delivery:** Aqueous solubility, permeability, first pass metabolism.
2. **Solid State Properties and Biopharmaceutics:** Implications of molecular level and particle level solid state properties on aqueous solubility, permeability, first pass metabolism.
3. **Molecular level of Solid State and Drug Delivery:** (a) Polymorphs-thermodynamic properties, solubility advantage. (b) Co-crystals-crystal engineering aspects, synthons exploited in pharmaceuticals, phase behavior, solubility behavior. (c) Amorphous phase-thermodynamic and kinetic properties, physical stability, solubility advantage, challenges in use of amorphous phase, stabilization strategies and surface behavior of amorphous form.
4. **Particle level of solid state and drug delivery:** (a) Particle size reduction to micron and nano size-Nanocrystals, polymeric nanocrystalline solid dispersions, small molecule assisted nano-crystalline solid dispersions. (b) Crystal habit-surface anisotropy and its impact on dissolution behavior.

PE-720:- Technological Aspects of Oral Modified Release Formulations (2 Credits)

1. Human anatomy physiology and CR products.
2. Types, selection of drug candidates.
3. Strategies involved in development and marketing.
4. Selection of polymer: Polymer characterization, polymer properties influencing drug permeation, factors influencing kinetics of solute release
5. Osmotic drug delivery systems.
6. Relevance of chrono-therapeutics: Site-specific absorption and metabolism, software Solutions.
7. Intellectual property opportunities: Existing patented technologies.
8. Formulation and technology development processes for oral MR formulations.
9. Scale up issues in oral MR products: SUPAC technology transfer protocols.
10. Setting up of specifications for API: Excipients and drug product; Dissolution specifications; Regulatory aspects

Ph.D. Syllabus SEMESTER - II

PE-810:- Novel Approaches for Targeted Drug Delivery (2 Credits)

1. **Principles of drug targeting and molecular basis of targeted drug delivery:** Receptor mediated endocytosis; Different levels of targeting-first order, second order and third order targeting; Different types of targeting-active and passive targeting.
2. **Disease based targeting approaches:** Novel approaches to target diseases and disorders such as cancer and infectious diseases, exploitation of disease environment for the targeted delivery of therapeutics.
3. **Organ based targeting:** Novel strategies for CNS, pulmonary, liver, and colon targeting.
4. **Cell/Organelles based targeting:** Mitochondria, Nuclear targeting, lymphatics/M cells, liver parenchymal cells/macrophages, hepatocytes and bone marrow cells.
5. **Physico-chemical approaches of targeting:** Stimuli responsive: Magnetically, thermal and pH assisted drug delivery systems, Chemical drug delivery (prodrugs), Lipid-drug/Polymer drug conjugates.
6. **Carrier based approach for targeted drug delivery:** Functionalized liposomes, polymeric and lipid nanoparticles, liquid crystalline nanoparticles, polymeric micelles, functionalized carbon nanotubes and inorganic nanoparticles.
7. **Gene Delivery:** Barriers to gene delivery, novel approaches based on viral and non viral vectors for site specific gene delivery, their advantages and limitations, siRNA delivery.
8. **Advanced characterization techniques for nanocarriers:** Nanoscale characterization techniques, Biophysical characterization of nanoparticles and In vivo imaging techniques Fluorescence Gamma scintigraphy, X rays.
9. **Miscellaneous Topics:** Emerging roles of Emulsomes, transferosomes, ethosomes, bilosomes, virosomes etc. for drug/ macromolecule delivery.
10. **Nanotoxicology and regulatory issues:** Toxicity and regulatory hurdles of nanocarriers, Nanotoxicity in lungs.

PE-820:- Advanced Drug Delivery Systems (2 Credits)

1. **Dendrimers: a versatile targeting platform:** Dendrimers in biomedical applications; Characterization of dendrimers; Dendrimer–drug interactions; Dendrimer biocompatibility and toxicity; Supramolecular structures from dendrons and dendrimers; Dendrimers in gene delivery; Targeted drug delivery with dendrimers.
2. **Drug-eluting stents: an innovative multidisciplinary drug delivery platform.** Role of stent design and coatings on restenosis and thrombosis; Mechanisms of controlled drug release from drug-eluting stents; Factors governing local pharmacokinetics; The Taxus™ drug eluting stent; Zotarolimus (ABT-578) eluting stents; Clinical experience

and applications of drug-eluting stents in the noncoronary vasculature, bile duct and esophagus.

3. Polymer drug conjugates (PDCs) in drug delivery: Need of PDCs as polymeric prodrugs in drug delivery; Polymers used in PDCs; linkers, Design of PDCs, Factors affecting PDCs; PDCs in cancer therapy.

4. Mucoadhesive polymeric drug delivery systems: Mucoadhesive polymers: strategies, achievements and future challenges; basics and underlying mechanisms of mucoadhesion; mucoadhesion tests for polymers and polymer-coated particles to design optimal mucoadhesive drug delivery systems; Nasal mucoadhesive drug delivery; buccal mucoadhesive drug delivery; mucoadhesive polymers in ocular drug delivery.

(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