



# **SYLLABUS**

## **Ph.D. Pharmaceutics**

**CREDIT SYSTEM FOR Ph.D. STUDENTS**  
**(In accordance with NIPER Ordinance)**

1. The student who has pursued the M.S. (Pharm.) degree from NIPER shall be required to complete Doctoral courses of minimum 12 credits
  
2. The student with qualifications from other Institutes [i.e. other than NIPER(s)] shall be required to complete a minimum of 28 credits, out of these 16 credits shall be from specialization and remaining 12 credits shall be from Doctoral courses.

<b>NIPER Students (Total 12 Credits)</b>	<b><u>Odd Semester</u></b> 01 Compulsory Subject (02 Credits)	<ul style="list-style-type: none"> <li>• These credits will be obtained from Doctoral Courses.</li> </ul>
	<b><u>Even Semester</u></b> 01 Compulsory Subject (02 Credits)	

<b>Non - NIPER Students (Total 28 Credits)</b>	<b><u>Odd Semester</u></b> 01 Compulsory Subject (02 Credits)	<ul style="list-style-type: none"> <li>• The student shall be required to complete a minimum of 28 credits, out of these 16 credits shall be from specialization and remaining 12 credits shall be from Doctoral courses.</li> </ul>
	<b><u>Even Semester</u></b> 01 Compulsory Subject (02 Credits)	

## GUIDELINES FOR SUBJECT SELECTION – Ph.D. PROGRAMME

<b><u>Compulsory Subjects for all departments (Total Credits : 04)</u></b>			
<b>Total Credits for NIPER Students</b>		<b>04</b>	
<b>Total Credits for Non NIPER Students</b>		<b>04</b>	
<b>Odd Semester</b>			
<b>S.No.</b>	<b>Subject Code</b>	<b>Subject</b>	<b>Credit</b>
1.	GE 710	Research and Publication Ethics	02
<b>Even Semester</b>			
<b>S.No.</b>	<b>Subject Code</b>	<b>Subject</b>	<b>Credit</b>
2.	GE 820	Research Methodology	02
<i>NOTE: Earning credits in aforementioned subjects is mandatory and the earned credits will be counted in preparation of final result.</i>			
<b><u>Doctoral Courses Offered By Various Departments</u></b>			
<b>Total Credits for NIPER Students</b>		<b>08</b>	
<b>Total Credits for Non NIPER Students</b>		<b>24</b>	
<b>Medicinal Chemistry : Odd Semester</b>			
<b>S.No.</b>	<b>Subject Code</b>	<b>Subject</b>	<b>Credit</b>
1.	MC 710	Stereo selective and Stereospecific Synthesis	02
2.	MC 720	Synthetic Strategies in the Total Synthesis of Complex Organic Molecules	02
3.	MC 730	Organometallic and Sustainable Chemistry in the Synthesis of Pharmaceuticals	02
<b>Total Credits</b>			<b>06</b>
<b>Medicinal Chemistry : Even Semester</b>			
<b>S.No.</b>	<b>Subject Code</b>	<b>Subject</b>	<b>Credit</b>
1.	MC 810	Principles of Peptide Chemistry	02
2.	MC 820	Carbohydrates: Occurrences, Structure, Reactions, Syntheses, Functions and Applications in Present Day Drugs	02
3.	MC 830	Advanced Topics in Drug Action and Drug Design	02
<b>Total Credits</b>			<b>06</b>

<b>Pharmaceutics : Odd Semester</b>			
<b>S.No.</b>	<b>Subject Code</b>	<b>Subject</b>	<b>Credit</b>
1.	PE 710	Implications of Solid State Properties in Drug Delivery	02
2.	PE 720	Advanced Polymeric Formulations	02
3.	PE 730	Advanced Delivery Approaches for Neurological Disorders	02
<b>Total Credits</b>			<b>06</b>
<b>Pharmaceutics : Even Semester</b>			
<b>S.No.</b>	<b>Subject Code</b>	<b>Subject</b>	<b>Credit</b>
1.	PE 810	Novel Approaches for Targeted Drug Delivery	02
2.	PE 820	Advanced Materials as Theranostics	02
3.	PE 830	Cosmeceutical Formulation Development	02
<b>Total Credits</b>			<b>06</b>
<b>Pharmacology and Toxicology : Odd Semester</b>			
<b>S.No.</b>	<b>Subject Code</b>	<b>Subject</b>	<b>Credit</b>
1.	PC 710	Signalling Mechanisms of Receptors and Neurotransmitters in Brain	02
2.	PC 720	Basics and Advances in Neuorscience	02
3.	PC 820	Pharmacological Interventions for Ischemic Brain Injury	02
4.	PC 830	Parasitology/Microbiology, Community & Pharmacy	02
<b>Total Credits</b>			<b>08</b>
<b>Pharmacology and Toxicology : Even Semester</b>			
<b>S.No.</b>	<b>Subject Code</b>	<b>Subject</b>	<b>Credit</b>
1	PC 840	Regulatory Toxicology And Drug Safety Evaluation	02
2	PC 860	Epigenetics and Diseases	02
3	PC 870	Preclinical Pharmacological Models Of Screening	02
<b>Total Credits</b>			<b>06</b>
<b>Regulatory Toxicology : Odd Semester</b>			
<b>S.No.</b>	<b>Subject Code</b>	<b>Subject</b>	<b>Credit</b>
1	RT 710	Recent advances in Regulatory Toxicology	02
<b>Total Credits</b>			<b>02</b>

<b>Biotechnology : Odd Semester</b>			
<b>S.No.</b>	<b>Subject Code</b>	<b>Subject</b>	<b>Credit</b>
1	BT 710	Interfacial Enzymology	02
2	BT 720	Therapeutic and Diagnostic approaches in Neglected Tropical Diseases	02
<b>Total Credits</b>			<b>04</b>
<b>Biotechnology : Even Semester</b>			
<b>S.No.</b>	<b>Subject Code</b>	<b>Subject</b>	<b>Credit</b>
1	BT 810	Protein Structure and Stability	02
2	BT 820	Host-Pathogen Interaction in Infectious Disease	02
3	BT 830	Targeting metabolic disorders by Natural Products	02
4	GE 830	Cell Based Therapies	02
5	GE 840	Cell-Based Therapies: Laboratory Experience Prerequisite: GE 830 Cell-Based Therapies	02
<b>Total Credits</b>			<b>10</b>

All the PhD Students have to complete 12 credits from the doctoral courses mentioned above. Further, the Non NIPERian students shall be required to earn 16 credits more from specialization of the concerned department. For these 16 credits, the PhD student may also refer to subjects of M.S. (Pharm.) Programme of the concerned department.

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## Ph.D. Pharmaceutics

Course Code	Course Name	Credits
<b>Odd Semester</b>		
PE 710	Implications of Solid State Properties in Drug Delivery	2
PE 720	Advanced Polymeric Formulations	2
PE 730	Advanced Delivery Approaches for Neurological Disorders	2
	<b>Total Credits</b>	<b>06</b>
<b>Even Semester</b>		
PE 810	Novel Approaches for Targeted Drug Delivery	2
PE 820	Advanced Materials as Theranostics	2
PE 830	Cosmeceutical Formulation Development	2
	<b>Total Credits</b>	<b>06</b>

## Ph.D. Pharmaceutics Odd Semester

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

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

### PE 720 - Advanced Polymeric Formulations (2 Credits)

1	<b>Introduction to polymers:</b> Classification based on origin, chemical structure and degradation mechanism. Overview of polymer synthesis. Solution properties including gelling behavior. Water soluble, swellable and insoluble polymers useful for delivering small and large molecular bioactives (drug/ gene/ protein/ short peptides/ antibodies). Polymer nanomedicines. Commercialized technologies.
2	<b>Natural polymers:</b> Proteins and pharmaceutically relevant polysaccharides (alginate, chitosan, hyaluronic acid and dextran). Physical modifications (blends, composites and interpenetrating networks). Chemical modifications to achieve stimuli responsiveness (pH, temperature and redox) and cell/tissue-specific targeting. Formulation-development with modified polysaccharides. Drug-polymer conjugates. Protein as carriers.
3	<b>Synthetic and semisynthetic polymers:</b> Introduction to random, graft, and branched polymers. Degradable synthetic polymers of biomedical interest. Substitution and modification processes and relevant characterization techniques (scattering, thermal and rheological). Application in delivery and targeting of bioactives. Biodegradation - mechanisms.
4	<b>Polymer-based multimodal theranostic and regenerative platforms:</b> Multimodality in context to particulate formulations. Amphiphilic polymers and their self-assembly to form micelles, polymersomes and other higher order aggregates. Polymer based scaffolds and miniaturized devices. Development, characterization and application of regenerative and biomimetic formulations. Degradation kinetics, and tests of biocompatibility and safety.

**PE-730: Advanced Delivery Approaches for Neurological Disorders (2 Credits)**

1	<b>Introduction to brain delivery:</b> Anatomy and physiology of brain. Basic idea of neurological disorders (neurodegenerative diseases, brain tumors, seizures). Physiological barriers of the brain. Internalization, Pgp/efflux. Conventional treatment and current challenges. Overcoming the physiological barriers of the brain (intranasal drug delivery, convection-enhanced diffusion and intrathecal/intraventricular drug delivery systems).
2	<b>Enhanced delivery of therapeutic molecules across the vascular barriers</b> Chemical delivery systems: Lipid-mediated transport, prodrug approach and lock-in system Biological delivery systems: Re-engineered pharmaceuticals to cross the BBB via specific endogenous transporters localized within the brain capillary endothelium Disruption of the BBB: Modification of tight junctions to cause a controlled and transient increase in the permeability of brain capillaries; Application of molecular Trojan horses: Peptidomimetic monoclonal antibodies to transport large molecules (e.g. antibodies, recombinant proteins, nonviral gene medicines or RNA interference drugs) across the BBB Particulate drug carrier systems.
3	<b>Delivery approaches and challenges:</b> Peroral and alternative routes of administration. Delivery of phytomolecules for neurodegenerative disorders. Targeting to cytosolic structures. Limitations and hurdles. Concept of nose-to-brain delivery. Landscape study of intranasal route. Challenges and limitations. Devices for intranasal administration. Regulatory guidelines for intranasal formulations.
4	<b>Regulatory landscape for brain delivery:</b> Current therapeutics for neurological diseases covering API and biologicals. Excipients limit for brain delivery. US-FDA, OECD and EMA guidelines related to brain therapeutics.

**Recommended Books:****PE 720**

1	Introduction to Polymers by Robert J. Young, Peter A. Lovell, Published by CRC Press.
2	Block Copolymers: Synthetic Strategies, Physical Properties, and Applications by Nikos Hadjichristidis, Stergios Pispas, George Floudas, Published by Wiley- Interscience.
3	Introduction to Synthetic Polymers by Ian M. Campbell. Published by Oxford University Press.
4	Polymers in Drug Delivery Edited by Ijeoma F. Uchegbu, Andreas G. Schatzlein, Published by CRC Press.
5	Scientific journals.

**PE 730**

1	ICH ( <a href="http://www.ich.org">www.ich.org</a> ), OECD ( <a href="http://www.oecd.org">www.oecd.org</a> ) and WHO ( <a href="http://www.who.int">www.who.int</a> ) guidelines.
2	Nanomaterial Drug Delivery for Neurodegenerative Diseases. Academic Press.
3	Handbook of Pharmaceutical Excipients. Ninth edition. American Pharmacists Assn.
4	Scientific journals.



## Ph.D. Pharmaceutics Even Semester

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

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

### PE-820: Advanced Materials as Theranostics (2 Credits)

1	<b>Carbon Materials:</b> Different carbon materials including porous materials (graphene, fullerene, carbon nanotubes, carbon dots, nanodiamonds). Physicochemical properties (structure, morphology, electrical, and photothermal properties). Characterization techniques (spectroscopic, thermal, electron microscopic and other advanced techniques). Bioconjugation approaches. Tissue distribution and accumulation. Anti-oxidant properties relevant to biological applications. Theranostic applications in cancers, life-style disorders and neurodegenerative diseases.
2	<b>Lipid Materials:</b> Acylglycerols, phospholipids, glycolipids, aminolipids and lipopeptides, phytosterol surfactants. Marine phospholipids. Lipid-based drug

	delivery systems (nanoemulsion/dispersion systems, self-emulsifying formulations). Advantages, limitations and application of lipid-based formulations in cancers, life-style disorders and neurodegenerative diseases.
3	<b>Inorganic Materials:</b> Biomedically relevant metallic nanoparticles (gold, silver, selenium). Mesoporous nanomaterials. Metal-organic frameworks and other nanocomposites. Superparamagnetic nanoparticles. Application in the diagnosis of cancers, life-style disorders and neurodegenerative diseases.
4	<b>Hybrid materials:</b> Type and classification of hybrid nanomaterials. Methods of fabrication (polymer-lipid, protein-inorganic substrates. Hybrid quantum dots. Applications in cancers, life-style disorders and neurodegenerative diseases.
<b>PE-830: Cosmeceuticals Formulation Development (2 Credits)</b>	
1	<b>Cosmeceuticals-Biology:</b> Introduction of cosmeceutical formulations. Skin types based on sensitivity to UV light, hydration state and lipid content. Problems unique to baby's skin. Age associated morphological and histological changes in human skin. Immunological mechanism of skin allergy. Anatomy of nail. Structure and properties of hair, hair-fall aetiology and current treatment approaches.
2	<b>Cosmetics and Cosmeceuticals – Formulation Science:</b> Formulation building blocks for different product formulations of cosmetics/cosmeceuticals: surfactants, emollients, rheological additives, antimicrobials and preservatives. Colored cosmetics including lipsticks, kajals, eye shadows etc. Examples from marketed cosmeceutical products.
3	<b>Design and Development of Advanced Cosmeceutical Formulations:</b> Nanogel, nanoemulsion, emulgel, nanoemulgel, cubosomes, liposomes, niosomes, ethosomes, phytosomes, exosomes in cosmeceutical formulation development. Herbal cosmeceuticals. Anti-ageing and anti- wrinkle formulations. Case studies from journal papers. Patents and marketed formulations.
4	<b>Evaluation of Cosmeceutical Formulations:</b> In process quality control and finished products quality control. Quality control test for containers, closures and secondary packing materials. Regulatory aspects. Schedules of D&C act relevant to cosmetics and cosmeceutical formulations. Requirements of consumers and patients with regard to cosmetics and cosmeceuticals, respectively.
<b>Recommended Books:</b>	
<b>PE 820</b>	
1	J. Abraham, S. Thomas, N K Kalarikkal. Handbook of Carbon Nanotubes. Springer Publication.
2	M. Endo, S. Iijima and M.S. Dresselhaus. Carbon Nanotubes Elsevier Publication.
3	M. Naito, M. Hosokawa, T. Yokoyama, Ki Nogi. Nanoparticle Technology Handbook Elsevier Publication.
4	K. Tanaka, S. Iijima. Carbon Nanotubes and Graphene, Elsevier Publication.
5	J. C. Arnault Nanodiamonds. Elsevier Publication.
6	P. Bracke, H. Schurmans, J. Verhoest. Inorganic Fibres & Composite Materials: A Survey of Recent Developments. 1st Edition. Elsevier Publication.

7	A.R. Unnithan, ARK Sasikala, C. Park, C. Kim, Biomimetic Nanoengineered Materials for Advanced Drug Delivery 1st Edition, Elsevier Publication.
<b>PE 830</b>	
1	Harry's Cosmeticology. 8th edition.
2	Handbook of cosmetic science and Technology A.O. Barel, M. Paye and H.I. Maibach. 3rd edition.
3	Poucher's perfume cosmetics and Soaps, 10th edition. Hilda Butler, 10th Edition.
4	Handbook of Cosmetic Science and Technology, 5 <sup>th</sup> Edition.
5	CTFA directory.
6	Indian Pharmacopoeia, British Pharmacopoeia, United State Pharmacopoeia, National Formulary.
7	Good laboratory Practice Regulations – Allen F. Hirsch, Volume 38, Marcel Dekker Series, 1989.
8	ICH guidelines.
9	Articles published in journals indexed in JCR, patents, Suppliers catalogue on specialized cosmetic excipients.