	Course No.	Course Name	Credits
Semester – I			
	PE-510	Dosage Form Design Parameters	1
**	PE-520	Biopharmaceutics and Pharmacokinetics	2
***	MC-510	Basics of Drug Action	2
***	MC-511	Spectral Analysis	2
*	NP-510	Separation Techniques	1
**	BT-510	Biotechnology in Pharmaceutical Sciences	1
*	GE-510	Biostatistics	2
**	GE-520	Fundamentals of Intellectual Property (IP) & Technology Management	1
	GE-511	Seminar	1
	LG-510	General Laboratory Experience	3
		Total Credits	**16**
Semester - II			
	PE-620	Drug Delivery Systems	2
	PE-630	Pharmaceutical Product Development-I	2
	PE-640	Pharmaceutical Product Development-II	2
	PE-650	Biomaterials	2
	PE-660	Solid State Pharmaceutics	1
*	PC-610	Drug Metabolism	1
*	PC-611	Pharmacological Screening and Assays	1
	GE-611	Seminar	1
	LS-610	General Lab Experience in the Area of Specialization	2
		Total Credits	**14**
Semester – III			
Projects (22 weeks)			
	TH-598	Synopsis	5
	TH-599	Presentation	3
		Total Credits	**8**
Semester – IV			
	TH-698	Thesis	9
	TH-699	Defence of Thesis	3
		Total Credits	**12**
		Grand Credits (I to IV Semesters)	**50**

SEMESTER - I

PE-510 : Dosage form Design Parameters (1 Credit)

1. **Physiochemical aspects:**
   a) pKa
   b) Partition Coefficient
   c) Solubility
   d) Reaction kinetics and mechanisms
2. **Biological aspects:**
   a) Role of physiochemical parameters on drug absorption and their implications.
   b) Routes of administrations and implication on bioavailability.
   c) Physiochemical aspects of drugs and first pass metabolism.
3. **Dissolution:**
   a) Theories of dissolution, release rates and constants.
   b) Mechanisms of conventional release and controlled release.
   c) Dissolution data handling and correction factors.
   d) Dissolution equipment.
   e) IVIVC

Recommended Books:

1. Martin's Physical Pharmacy and Pharmaceutical Scinces by P.J. Sinko
2. Pharmaceutical Dosage Forms and Drug Delivery, by Mahato R.I. and Narang A.S

**PE-520 : Biopharmaceutics and Pharmacokinetics (2 Credit)

1. **Introduction:** Definitions, ADME, concentration time profile, plotting the data, different fluid compartments and blood flow rate compartment models, biological half life, elimination rate constant. Biopharmaceutics and pharmacokinetics in drug research.
2. **GIT Absorption of drugs:** Mechanism, physico-chemical, biological and pharmaceutical factors affecting drug absorption through GIT. Techniques for the GIT absorption assessment.
3. **Drug disposition:** Total body clearance, renal clearance, mechanism of clearance, clearance ratio, factors affecting renal clearance, hepatic clearance, volume of distribution and its significance.
4. **Protein and tissue binding:** Factors affecting protein binding, kinetics of protein binding, determination of rate constant and different plots (direct, scatchard and reciprocal), Implication of protein binding on pharmacokinetic parameters.
5. **Bioavailability and bioequivalence:** Definitions, federal requirements, methods of determination of bioavailability using blood and urinary excretion data. Protocol design for bioavailability assessment. Methods for bioequivalence determination.
6. **Pharmacokinetic characterization of drugs:** Pharmacokinetics of drugs following one/ two compartment open models with first order elimination kinetics as applied to rapid intravenous injection, Intravenous transfusion and oral administration. Determination of absorption rate constant using Wagner-Nelson, Loo Riegelman methods. Flip-flop models, method of residual. Urinary excretion data and its application in pharmacokinetic characterization of drugs. Pharmacokinetics of multiple dosing.

7. **Dosage regimen:** Dosage regimen adjustment in patients with renal and hepatic diseases. Drug dosage in elderly, children and obese patients.
8. **Non Linear Pharmacokinetics:** Various causes of non-linearity, Michaelis-Menten kinetics, In-vivo estimation of Km and Vm. Case studies.
9. **Physiologic pharmacokinetics models:** Mean Residence Time; Statistical Moment Theory; Application and limitations of physiologic pharmacokinetic models.
10. **Miscellaneous Topics:** Chronopharmacokinetics, Drug toxicity and forensic pharmacokinetics, kinetics of maternal-fetal drug transfer, pharmacokinetics v/s pharmacological/ clinical response, metabolic kinetics.

Recommended Books:

1. Applied Biopharmaceutics & Pharmacokinetics, by Shargel, L., S. Wu-Pong
2. Biopharmaceutics and Pharmacokinetics: An Introduction by Notari, R. E.
3. Introduction to Biopharmaceutics, by Gibaldi, M.
4. Biopharmaceutics and Relevant Pharmacokinetics, by Wagner, J. G.
5. Textbook of Biopharmaceutics and Clinical Pharmacokinetics by Niazi, S.K.
6. Handbook of Bioequivalence Testing, by Niazi, S. K.
7. Modeling in Biopharmaceutics, Pharmacokinetics, and Pharmacodynamics: Homogeneous and Heterogeneous Approaches, by Macheras, P. and A. Iliadis
8. Comparative Pharmacokinetics: Principles, Techniques and Applications, by Riviere, J. E
9. Foundations of Pharmacokinetics, by Rescigno, A.
10. Clinical Pharmacokinetics and Pharmacodynamics: Concepts and Applications, by Rowland, M. and T. N. Tozer

***MC-510 : Basics of Drug Action (2 credits)

1. **Structure**: 2D vs 3D. Structure vs. Electronic structure. Electronic structure of ketenes and its importance in reactivity. Diels-Alder reaction, Symmetry using group theory. Graph theory and 2D structure.
2. **Energy**: Energy concept and its importance in drug action. First, Second and Third laws of thermodynamics and the principles derived from these laws which are of significance to drug action.
3. **Thermodynamics**: Free energy and Relationship between thermodynamics and statistics. Importance of chemical potential in drug action. Thermodynamic cycle. Statistical thermodynamics in predicting the structure of biomolecules and their interaction with drug molecules. Macromolecular vs. micromolecular correlation using thermodynamics and statistical thermodynamics.
4. **Interactions**: Inter- and intramolecular interactions. Weak interactions in drug molecules. Chirality and drug action. Covalent, ion-ion, ion-dipole, Hydrogen bonding, C-H hydrogen bonding, dihydrogen bonding, Van der Waals interactions and the associated energies.
5. **Receptorology**: Drug-receptor interactions, Receptor theories and drug action: Occupancy Theory, Rate Theory, Induced Fit Theory, Macromolecular perturbation theory, Activation-Aggregation theory. Topological and stereochemical consideration.
6. **Enzyme Kinetics**: enzyme kinetics in drug action. Do all molecules of an enzyme have same kinetics? Mechanisms of enzyme catalysis, Electrostatic catalysis and desolvation. Covalent catalysis, Acid-base catalysis, Strain / distortion in enzyme catalysis. Coenzyme catalysis.
7. **Enzyme Inhibition**: Drug action through enzyme inhibition. Examples based on PDE4, GSK3, etc. Theories of enzyme inhibition and inactivation. Enzyme activation of drugs prodrugs.
8. **Nucleic acids**: NA as targets for drug action. NA-interactive agents. Classes of drugs that interact with nucleic acids. Intercalation, NA-alkylation, NA-strand breaking and their importance in drug action.

9. **Drug likeness**: Drug like molecules and theories associated with the recognition of drug like properties. Physical organic chemistry of Drug metabolism, drug deactivation and elimination.

10. **Drug action after Metabolism**: Phase I and Phase II transformations. Concept of hard and soft drugs. Chemistry of ADME and Toxicity properties of drugs.

Recommended Books:

1. The Organic Chemistry of Drug Design and Drug Action by R.B. Silverman
2. C.J. Coulson, Molecular Mechanism of Drug Action by C.J. Coulson
3. A primer of Drug Action by R.M. Julien
4. Drug-Receptor Thermodynamics by R.B. Raffa
5. Principles of Drug Action by W.B. Pratt, P. Taylor
6. Medicinal Chemistry How Drugs Act and Why by A. Gringauz
7. Principles of Molecular recognition by A.D. Buckingham
8. Quantitative molecular pharmacology and Informatics by M. Lutz
9. Physical Biochemistry by K.E.V. Holde
10. Free energy calculations in rational drug design by M. Rami Reddy

***MC-511 : Spectral Analysis (2 credits)

1. **Ultra Violet (UV) and visible spectroscopy:**
   a) Energy levels and selection rules: Definitions, molecular orbital approach for energy absorption, various modes of transitions.
   b) Correlation of structural variation with UV absorption: Factors influencing the position and intensity of absorptions, Inductive and resonance effects, effect of ring size, influence of stereochemical factors.
   c) Predicting UV absorption: Woodward- Fieser, Fieser-Kuhn and Nelson rules.
   d) Other factors: Non-conjugative effect, solvent effect, S-Cis band.

2. **Infrared (IR)spectroscopy:**
   a) Characteristic regions of the spectrum: Various modes of vibrations, Energy levels.
   b) Correlation of structure with IR spectra: Influence of substituents, ring size, hydrogen bonding, vibrational coupling and field effect on frequency.
   c) Applications: Determination of stereochemistry. Spectral interpretation with examples.

3. **Nuclear Magnetic Resonance (NMR)spectroscopy:**
   a) Fundamentals: Physical basis, magnetic nuclei, resonance, relaxation processes, signal-sensitivity.
   b) Instrumentation: Continuous-Wave (CW) instrument, Pulsed Fourier Transform (FT) instrument, Functions, Relation with sensitivity, Sampling.
   c) ^{1}H NMR, correlation of structure with spectra:Chemical environment andshielding, chemical shift and originof its concept, reference compound, local diamagnetic shielding and magnetic anisotropy, relation with chemical shift, chemical and magnetic non-equivalence, spin-spin splitting and its origin, Pascal's triangle, coupling constant, mechanism of coupling, integral, NMR solvents and their residual peaks, protons on heteroatoms, quadrupole broadening and decoupling, effect of conformations and stereochemistry on the spectrum, Karplus relationship, diastereomeric protons,Heteronuclear coupling to ^{19}F and ^{31}P, virtual coupling, long range coupling-epi, peri, bay effects. Shift reagents-mechanism of action, spin decoupling and double resonance.Explanation of spectra of some compounds and drugs.
   d) ^{13}C NMR, correlation of structure with spectra: Chemical environment, shielding and carbon-13 chemical shift, calculation, proton-coupled ^{13}C Spetra, Proton-decoupled ^{13}C spectra, Nuclear Overhauser Enhancement (NOE), Problem with integration, Distortionless Enhancement by Polarization Transfer (DEFT), Heteronuclear coupling for carbon to deuterium, carbon to ^{19}F, carbon

to ^{31}P.Explanation of spectra of some compounds and drugs.

4. **Mass spectrometry (MS):** Molecular ion and metastable peak, fragmentation patterns, nitrogen and ring rules, McLafferty rearrangement, electron and chemical ionization modes, applications.

Recommended Books:

1. Spectroscopy by Donald L Pavia, Gary M Lampman, George S Kriz, James A Vyvyan
2. Organic spectroscopy by William Kemp
3. Spectroscopic Methods in Organic Chemistry by Dudley H. Williams & Ian Fleming
4. Spectrometric Identification of Organic Compounds by Robert M. Silverstein, Francis X. Webster & David J. Kiemie
5. Applications of Absorption Spectroscopy of Organic Compounds by Dyer
6. Fundamentals of Molecular Spectroscopy by Colin N. Banwell & Elaine M. McCash
7. Spectroscopy by Pavia, Donald L. Lampman, Gary M. Kriz, George S.

*NP-510 : Separation Techniques (1 credit)

1. **Separation Techniques:** Need for learning separation techniques, separation techniques in natural product research and drug discovery, extraction techniques.
2. **Chromatography:** General principles, classification of chromatographic techniques, normal and reverse phase, bonded phase chromatography, stationary phases, activity of stationary phases, elutropic series, and separation mechanisms.
3. **Column Chromatography and Short Column Chromatography:** Column packing, sample loading, column development, detection.
4. **Flash Chromatography and Vacuum Liquid Chromatography:** Objectives, optimization studies, selecting column and stationary phases, selecting suitable mobile phases, automated flash chromatography, and reverse phase flash chromatography.
5. **High Performance Liquid Chromatography:** Principles, instrumentation, peak shapes, capacity factor, selectivity, plate number, plate height, resolution, band broadening, pumps, injector, detectors, columns, column problems, gradient HPLC, HPLC solvents, trouble shooting, sample preparation, method development.
6. **Planar Chromatography - TLC/HPTLC/OPLC:** Basic principles, sample application, development of plates, visualization of plates, 2D TLC, densitometry, Over pressure layer chromatography.
7. **Counter Current Chromatography:** Basic principles, droplet counter current chromatography, centrifugal partition chromatography, choice of solvents for SP and MP.
8. **Gas Chromatography:** Principles, instrumentation, split-splitless injector, head space sampling, columns for GC, detectors, quantification.
9. **Biochromatography:** Size exclusion chromatography, ion exchange chromatography, ion pair chromatography, affinity chromatography general principles, stationary phases and mobile phases.
10. **Hyphenated Techniques:** Introduction to GC-MS and LC-MS techniques and their applications in natural products.

Recommended Books:

1. Methods in Biotechnology, Natural Product Isolation by Sarker, Latif, Gray
2. Methods in Biotechnology, Natural Product Isolation by Richard Canell
3. Various Reviews and Research Papers

**BT-510 : Biotechnology in Pharmaceutical Sciences (1 credit)

1. **Biotechnology in pharmaceutical Sciences perspective:** Biology in drug discovery; Traditional drug discovery vs rational drug discovery; rational drug discovery pipeline; concept of target based drug design and target discovery; role of plant biotechnology in edible vaccine development.
2. **Genomics in target discovery:** Concept of genome, genes and gene expression; genome sequencing and sequence comparison methods (microarray); comparative genomics and expression genomics for target discovery of communicable disease and lifestyle disease.
3. **Systems and methods of molecular biology:** Isolation and validation of targets; PCR, RT-PCR nucleic acid isolation; cloning vectors (some examples), enzymes used in molecular cloning methods (some examples); cloning and characterization of biopharmaceuticals.
4. **Protein expression systems:** Gene expression in bacteria, yeast, insect and mammalian cells.
5. **Enzyme purification and assay:** Various protein purification methods; enzyme based assay for small molecule screening.
6. **Bioprocess technology:** *Upstream process:* Introduction to microbial growth, media formulation; sterilization, inoculum preparation.
7. **Bioprocess technology:** *Fermentation:* Fermentation process design, operation and characteristics of fermentation processes; batch, fed-batch and continuous culture systems, instrumentation and bioprocess control.
8. **Downstream process:** Introduction to various downstream process operations in biopharmaceutical manufacturing such as centrifugation, filtration, tangential flow filtration, cell disintegration, solvent-solvent extraction, supercritical fluid extraction etc.
9. **Biotechnology in pharmaceutical industry:** Major areas of biotechnology in the pharmaceutical industry such as antibiotics, vaccines, diagnostics, antibodies, biopharmaceuticals (insulin, interferon, GSF, CSF and therapeutic proteins etc.); commercial aspects, priorities for future biotechnological research.
10. **Industrial enzymes in drug development:** Penicillin amidase, lipase, oxidoreductase, nitrilase, protease etc.; use of all these enzymes for enantioselective synthesis of pharmaceutically important drugs/drug intermediates, future directions.

Recommended Books:

1. Analysis of Genes and Genomes by Richard J Reece. John Wiley & Sons
2. Molecular Biotechnology by Principles and Applications of Recombinant DNA by Bernard R. Glick, Jack J. Pasternak and Cheryl L. Patten, ASM Press
3. Principles of Fermentation Technology by P F Stanbury, A. Whitaker, S. J. Hall. Butterworth-Heinemann.
4. Bioprocess Engineering Principles by Pauline M. Doran, Academic Press
5. Pharmaceutical Biotechnology by Concepts and Applications by Gary Walsh, John Wiley & Sons

*GE-510 : Biostatistics (2 credits)

1. **Statistics:** Introduction, its role and uses. Collection; Organization; Graphics and pictorial representation of data; Measures of central tendencies and dispersion. Coefficient of variation.
2. **Probability:** Basic concepts; Common probability distributions and probability distributions related to normal distribution.
3. **Sampling:** Simple random and other sampling procedures. Distribution of sample mean and proportion.
4. **Estimation and Hypothesis Testing:** Point and interval estimation including fiducial limits. Concepts of hypothesis testing and types of errors. Student- t and Chi square tests. Sample size and power.
5. **Experimental design and analysis of variance:** Completely randomized, randomized blocks. Latin square and factorial designs. Post- hoc procedures.
6. **Correlation and regression:** Graphical presentation of two continuous variables; Pearson's product moment correlation coefficient, its statistical significance. Multiple and partial correlations. Linear regression; Regression line, coefficient of determination, interval estimation and hypothesis testing for population slope. Introduction to multiple linear regression model. Probit and logit transformations.
7. **Non-parametric tests:** Sign; Mann-Whitney U; Wilcoxon matched pair; Kruskal wallis and Friedman two way anova tests. Spearman rank correlation.
8. **Statistical techniques in pharmaceutics:** Experimental design in clinical trials; Parallel and crossover designs. Statistical test for bioequivalence. Dose response studies; Statistical quality control.

Recommended Books:

1. Fundamentals of Biostatistics by Bernard Rosner
2. Pharmaceutical Statistics: Practical and Clinical Applications by Bolton and Bon
3. Statistical Misconceptions by Huck

**GE-520 : Fundamentals of Intellectual Property (IP) and Technology Management (1credit)

1. **Intellectual property:** Concepts and fundamentals; Concepts regarding intellectual property (IP), intellectual property protection (IPP) and intellectual property rights (IPR); Economic importance, mechanisms for protection of intellectual property-patents, copyrights, trademark; Factors effecting choice of IP protection; Penalities for violation; Role of IP in pharmaceutical industry; Global ramifications and financial implications.
2. **Trade related aspects of intellectual property rights:** Intellectual property and international trade; Concept behind WTO (World Trade Organisation), WIPO (World Intellectual Property Organisation) GATT (General Agreement on Tariff and Trade), TRIPs (Trade Related Intellectual Property Rights), TRIMS (Trade Related Investment Measures) and GATS (General Agreement on Trade in Services); Protection of plant and animal gentic resources; Biological materials; Gene patenting; Biotechnology / drug related IPR issues; Status in India and other developing countries; Case studies and examples; TRIPS issues on herbal drugs.
3. **Nuts and bolts of patenting, copyright and trademark protection criteria for patentability, types of patents; Indian Patent Act, 1970; WTO and modifications under TRIPS:** Filing of a patent application; Precautions before patenting-disclosures / non-disclosures, publication-article / thesis; Prior art search-published patents, internet search patent sites, specialized services-search requests, costs; Patent

application-forms and guidelines, fee structure, time frames, jurisdiction aspects; Types of patent applications- provisional, non provisional, PCT and convention patent applications; International patenting-requirement procedures and costs; Financial assistance for patenting- introduction to schemes by NRDC and TIFAC; Publication of patents-gazette of India, status in Europe and US; Patent annuity; Patent attomeys technical aspects, criteria for selection, addresses, fee, rights and responsibilities of a patentee; Practical aspects regarding maintaining of a PATENT FILE; Patent infrigment- meaning, scope, litigation, case studies and examples; Patenting by research students, lecturers and scientists-University / organisational rules in India and abroad; Thesis research paper publication, credit sharing by workers, financial incentives; Useful information sources for patents related information-internet sites, brouchers, periodicals, CD roms; Significance of copyright protection for researchers; Indian Copyright Law and digital technologies-Beme convention, WIPO copyright treaty (WCT), WIPO performance and Phonogram Treaty (WPPT); Protection for computer data bases, multi media works; Trade marks legislation and registration system in India-an introduction, meaning of trademark criteria for eligibility; filling application for trademark registration; Trade secrets-scope modalities and protection; Case studies-drug related patents infringments.

4. **Technology development / transfer / commercialisation related aspects:** Technology development-meaning; Drug related technology development; Toxicological studies, bioequivalence (BU), clinical trials-phase-I, phase-II and phase-III; Approved bodies and agencies; Scale-up, semi-commercialisation and commercialisation-practical aspects and problems; Significance of transfer of technology (TOT), bottlenecks; Managing technology transfer-guidelines for research students, scientists and related personnal; TOT agencies in India-APCTD, NRDC, TIFAC, BCIL, TBSE/SIDBI; TOT related documentation-confidentiality agreements, licensing, MOUs, legal issues; Compulsary licensing excess to medicine issues; DOHA declaration, POST WTO product patent regime from 2005; Challenges for Indian pharmaceutical industry in the context of globalisation of IP; Drug registration and licensing issues-national and global; Drug master file submissions, SOPS; Related registration and marketing issues; Case studies-antiretroviral drugs and others.

5. **Funding sources for commercialization of technology:** Preparation of a project report, financial appraisal, business models; GOI schemes and incentives; NRDC, TePP, HGT, TDB schemes. PATSER; Venture capitalists, banks. Incubator concept-Case studies with respect to IIT, CCMB, IMTECH, NIPER. Documentation and related aspects.

6. **Ethics and values in IP:** IP and ethics-positive and negative aspects of IPP; Societal responsibility; Avoiding unethical practices; Echo-responsibility-economic, social and environmental benifits of modern biotechnology; Voluntary adoption of pollution control strategies.

Recommended Books:

1. Law Relating to Intellectual Property by B.L.Wadhera
2. IPR Handbook for Pharma Students and Researchers by P.Bansal
3. The Patents Act, 1970 (Bare Act with Short Notes) (New Delhi: Universal Law Publishing Company Pvt. Ltd. 2012)
4. Patent Agent Examination by Sheetal Chopra and Akash Taneja
5. Making Innovation Happen- A simple and Effective Guide to Turning Ideas into Reality by Michael Morgan
6. Making Breakthrough Innovation Happen by Porus Munshi
7. Innovation X- Why a Company's Toughest Problems are its Greatest Advantage by Adam Richardson
8. Legal Drafting for the Layman by Nabhi Kumar Jain
9. How to Write and Publish a Scientific Paper by Rober A Day
10. Concise Law Dictionary-with Legal Maxims, Latin Terms and Words and Phrases by Justice Y.V.Chandrachud
11. Biomedical Research- From Ideation to Publication by G.Jagadeesh and others

GE-511 : Seminar (1 credit)

1. Introduction, information retrieval systems.
2. Writing term papers and reports.
3. Organization of scientific material, thesis, dissertation and references.
4. Reading research papers.
5. Skill in oral presentation.

Each student has to present a seminar before end of the semester.

LG-510 : General Laboratory Experience (3 Credits)

1. **Analytical Techniques (75 hours)**
   a. Spectral Analysis workshop (45 hours)
   b. Separation Techniques (30 hours)
2. **Computer and application in pharmaceutical sciences (100 hours):** Introduction to computers, basic unit and functions, H/W and S/W, operating systems, word processing, spread sheet, graphic programs, dbase, windows, statistical S/W programs and packages. Steps involved in S/W development, computer languages with emphasis to FORTRAN language and programming, hands on experience in pharmaceutical software systems. Use of computers in information retrieval systems.
3. **Pharmacology (25 hours):** Animal handling, route of administration of drugs, dose response relationship, acute toxicity testing of drug, analgesic activity of a compound, estimation of protein and haematological parameters.
4. **Biotechnology for pharmaceutical sciences (20 hours):**
   Day-1: Preparation for plasmid miniprep.
   Day-2: Plasmid miniprep and restriction digestion.
   Day-3: Gel electrophoresis and molecular weight calculation.
   Day-4: Discussion of result and viva.
5. **Specialization (50 hours):**
   a) To prepare granules by dry granulation using Roller compactor.
   b) To optimize wet granulation process and perform scale up using Rapid Mixer Granulator (RMG)
   c) Study the dissolution behaviour/drug release pattern of various conventional, sustained release, enteric coated and nanoparticulate dosage form and establishment of dissolution kinetics. Study of various factors affecting dissolution/ drug release.
   d) Study of drug protein binding and effect of competitive agent on binding kinetics.
   e) Plotting and interpretation of pharmacokinetics data and calculation of various pharmacokinetic parameter.

Note : * Common in all disciplines

** Common between Pharmaceutics and Pharmacology & Toxicology

*** Common between Pharmaceutics and Medicinal Chemistry

SEMESTER - II

PE-620 : Drug Delivery Systems (2 credits)

1. **Influence of Drug Properties and Routes of Drug Administration on the design of sustained and controlled release systems:** Rationale for controlled drug delivery, physiochemical properties and biological factors influencing the design and performance of sustained/controlled release products.
2. **Biopharmaceutic and pharmacokinetic aspects of PO CRDDS:** Strategies and design, factor effecting controlled release drug delivery systems, Computation of desired release rate and dose for CRDDS, Pharmacokinetic design for DDS; in-vitro/in-vivo considerations, Intermittent zero order and first order release.
3. **Peroral controlled-release delivery:** Design and fabrication of oral systems, dissolution controlled release, diffusion controlled release, diffusion and dissolution controlled release, ion-exchange resins, pH-independent formulations, osmotically controlled release, altered density formulations, Case studies.
4. **Parenteral drug delivery:** Major routes of parenteral administration; selection, design and development, biopharmaceutics of sustained/controlled release parenteral drug products, polymer microspheres and their biocompatibility and dispersed DDS.
5. **Transdermal/skin drug delivery systems:** Principles of skin permeation, factors affecting percutaneous absorption of drugs, sorption promoters, absorption enhancement by energy input - iontophoresis, sonophoresis and electroporation, pharmacokinetics of skin permeation, development and evaluation of transdermal devices, Case studies.
6. **Implantable Therapeutic Systems:** Introduction, Historical Development, Approaches to development of Implantable therapeutic systems, Benefits of controlled drug administration via implantation, Medical aspects of Implantation.
7. **Drug targeting:** Different levels of targeting-first order, second order and third order targeting, active and passive targeting, EPR effect, receptor mediated endocytosis, prodrug based drug targeting, brain targeting, tumor targeting.
8. **Overview of different carrier systems for drug delivery:** Microparticles, liposomes, niosomes, polymeric nanoparticles, solid lipid nanoparticles, carbon nanotubes etc.
9. **Protein/peptide drug delivery systems:** Enzyme, epithelial/endothelial barriers, pharmacokinetics, different routes of delivery, practical considerations.
10. **Regulatory Assessement of controlled release products:** Potential pharmacodynamic and bioavailability problems of oral controlled release products, dissolution rate assessment, biopharmaceutic considerations in the regulatory assessment.

Recommended Books:

1. Drug Delivery Systems, by K K Jain.
2. Pharmaceutical Perspectives of Cancer Therapeutics, by Y Lu and R.I. Mahato.
3. Targeted Delivery of Small and Macromolecular Drugs, by A.S. Narang and R.I. Mahato.
4. Controlled Drug Delivery, Fundamentals and Applications, by Robinson and Lee.
5. Controlled Drug Delivery Concepts & Advances, by SP Vyas and RK Khar.
6. Targeted and Controlled Drug Delivery: Novel Carrier Systems, by SP Vyas and RK Khar

PE-630 : Pharmaceutical Product Development-I (2 credits)

1. **Preformulation studies:** Preformulation studies of drug substances, proteins and peptides. Fundamental and derived properties in pre-formulation profiling, Preformulation work sheet.
2. **Role of pre-formulation in drug discovery:** Material properties in lead selection, high throughput pre-formulation studies, 'drugability' of new chemical entities, tools to assist in lead selection.
3. **Role of preformulation in drug development:** Preformulation as a support for formulation development, identification of challenges during formulation development, dosage form specific studies.
4. **Salt selection:** Role of salt selection in drug discovery and development, theoretical concepts for selection of counter ions for salt formation, 'pKa rule' for salt formation, decision tree for salt selection, case study.
5. **Complexation:** Metal and organic molecular complexes, inclusion compounds with reference to cyclodextrins, chemical characteristics of inclusion complexes, applications in solubilization / taste masking / enhancement of permeability / enhancement of oral bioavailability, methods of preparation ofcyclodextrin complexes.
6. **Solubilization:** Solubility and solubilization of non-electrolyte, drug solubilization in surfactant systems, use of co-solvents for development of liquid formulations, solid-state manipulations including use of metastable forms like amorphous state and drug derivatization.
7. **Rheology:** Thixotropy, methods for evaluation of viscosity, implications of viscosity on performance of liquid dosage forms like suspensions and emulsions.
8. **Micromeritics:** Particle size distribution, evaluation methods including advanced techniques like atomic force microscopy, significance of particle size in different dosage forms including aerosols, parenterals and solid dosage forms.
9. **Development of dosage forms:** Four stage development including preformulation/ prototype development / scale up studies / commercialization, biological basis and opportunities, dosage form and its implications; Manipulation of physiological processes.
10. Case studies will be discussed after each topic with current literature, case study dealing with use of preformulation data for lead selection and dosage form decisions

Recommended Books:

1. Performulation in Solid Dosage Form Development, Edited by Moji Christianah Adeyeye and Harry G. Brittain
2. Handbook of Performulation, Edited by Sarfaraz K. Niazi
3. Handbook of Pharmaceutical Salts, Edited by P.Heinrich Stahl and Camille G. Wermuth

PE-640 : Pharmaceutical Product Development-II (2 credits)

1. **Formulation additives:** Study of different types of additives e.g. antioxidants and preservatives, coloring and flavouring agents, emulsifying and suspending agents, basic materials for ointment bases, diluents and pharmaceutical solvents, regulatory perspectives: GRAS, IIG; new developments in excipient science, functional and co-processed excipients, international patented excipients. Implication of quantitative selection of each excipient in product development.
2. **Drug-excipient interaction:** Drug-excipient interaction and incompatibilities, physical, chemical, pharmaceutical and therapeutic, analytical techniques to characterize drug-excipient incompatibility.
3. **Solid dosage forms:** Tablets, benefits, improved tablet production, advances in materials, material handling and granulation; process automation. Processing problems in tablet and troubleshooting. Specialized tablets:

Formulation and evaluation of effervescent, orodispersible and chewable tablets.

4. **Tablet coating:** Coating pans, sugar coating, film coating, advanced coating technologies, aqueous based film coating, solvent free coating, coating defects.
5. **Liquid and poly-disperse systems:** Suspensions: theoretical considerations, flocculated and deflocculated suspensions, adjuvants utilized, evaluation of suspension stability. Emulsions: descriptive theory of emulsification, formulation aspects, stability evaluation, advances in emulsion technology-multiple, micro and nano emulsions.
6. **Sterile products and admixtures:** Formulation development, vehicles and other additives, containers and closures, evaluation of stability and sterility, requirements of facilities for production, recent advances and developments.
7. **Aerosols:** Components of aerosol package, containers, nebulizers, pressured metered dose inhalers, dry powder inhalers, formulation aspects, types of propellants used, stability testing of pharmaceutical aerosols, Quality control and testing evaluation of pharmaceutical aerosols.
8. **Package development:** Package types for different dosage forms, packaging materials like glass and plastic, selection of proper material, labelling, preformulation screening of package components, regulatory perspectives.
9. **Design of materials and product specifications:** Factory design, laying down and optimization of material and product specifications, process and in-process controls
10. **Documentation protocols:** Forms and maintenance of records in product development department including clinical batches.

Recommended Books:

1. Handbook of Pharmaceutical Excipients, by Rowe, R.C., P. J. Sheskey
2. Pharmaceutical Excipients: Characterization by M. Dekker. Bugay, D. E. and W. P. Findlay
3. Pharmaceutical Manufacturing Handbook: Production and Processes, by Gad, S. C
4. Selected Pharmaceutical Excipients: Physicochemical Properties, Analytical Techniques Utilized and their Excipient-Excipient Interactions by Rane, S. C.
5. Encyclopedia of Pharmaceutical Technology, by Swarbrick, J. and J. C. Boylan
6. Packaging of Pharmaceuticals and Healthcare Products, by Lockhart, H. and F. A. Paine
7. Pharmaceutical Packaging Technology, by Dean, D. A., R. Evans
8. Pharmaceutical Packaging Handbook, Informa Healthcare by Bauer, E. J.
9. Pharmaceutical Manufacturing Handbook: Regulations and Quality, Wiley-Interscience by Gad, S. C. WHO Publications:
10. Quality Assurance of Pharmaceuticals: A Compendium of Guidelines and Related Materials.
11. Good Manufacturing Practices and Inspection, World Health Organization.
12. Modern Pharmaceutics, Marcel Dekker by Banker, G.S. and C. T. Rhodes
13. Pharmaceutical Dosage Forms, by Lieberman, H. A. and L. Lachman
14. Pharmaceutical Dosage Forms: Parenteral Medications, by Avis, K. E., H. A. Lieberman

PE-650 : Biomaterials (2 credits)

1. **Introduction to biomaterials:** Fundamentals of polymer science and polymer classification.
2. **Synthesis and modification methods of biomaterials:** Polymerization methods, polymer fabrication.
3. **Physical and chemical chracterization techniques of biomaterials:** Thermal, spectroscopic, microscopic and laser based techniques.
4. **Manipulating biomaterials in various forms depending upon end use specification:** Hydrogels, micro and nano particles, films, fibres.
5. **Host reaction to biomaterials and their evaluation:** Inflammation, wound healing, foreign body

response, systematic toxicity

6. **Biocompatibility testing of biomaterials:** In vitro assessment of tissue compatibility, invivo assessment of tissue compatiability, testing blood materials interactions.
7. **Degradation of biomaterials in biological environment:** Chemical and biochemical degradation of polymers; Degradative effects of biological environment.
8. **Use of polymers in controlled release of active agents:** Diffusion controlled devices, solvent-controlled devices and chemically controlled devices.
9. **Regulatory considerations:** Assessment of safety and long term toxicity evaluation, toxicity considerations on repetitive accumulation of polymeric materials.
10. **Pharmaceutical and biomedical applications:** Drug delivery, tissue engineering.

Recommended Books:

1. Handbook of Biodegradable Polymers, by Abraham J. Domb, David M. Wiseman
2. Biodegradable Polymers in Clinical Use and Clinical Development, by Domb, Kumar and Azra
3. Surface modification of Biomaterials: Methods Analysis and Applications, Edited by R Williams

PE-660 : Solid State Pharmaceutics (1 credit)

1. **Levels of solid state properties:** Molecular / particle / bulk level properties, inter-dependence of various levels on each other, role of different levels during pharmaceutical development and process development
2. **Molecular level:** Crystalline form, definition, concept of long range order, supramolecular arrangements, building blocks of crystals, unit cell, basic types of unit cells, demonstration of unit cells using crystal visualization softwares.
3. **Polymorphism:** Definition, significance of polymorphism in drug product performance, packing / conformational polymorphism, thermodynamics of polymorphs, enatiotropy / monotropy, concept of transition temperature, Burger and Ramberger rule.
4. **Crystallization process:** Molecular aggregation events in crystallization, energetic of crystallization, enthalpy entropy balance, types of nucleation, Ostwald's step rule, experimental protocols for polymorph screening.
5. **Implications of polymorphism in pharmaceutical development:** Regulatory concerns related to polymorphism, introduction to latest regulatory position on polymorphism.
6. **Amorphous state:** Definition, long range order versus short range order, disorder in the amorphous state, concept of glass transition temperature (Tg), thermodynamic necessity for Tg, entropy crisis.
7. **Role of amorphous state in drug delivery:** Solubility advantage, spring parachute effect during solubility studies, physical instability of the amorphous form, techniques for stabilization of amorphous form, amorphous solid dispersions.
8. **Particulate level properties:** Crystal habit, generation of different crystal habits, implications of crystal habit on product performance and processing.
9. **Bulk level:** Bulk density, compressibility, flow properties, cohesivity, electrostatics, aggregation, agglomeration, role in formulation development and processing..

Recommended Books:

1. Polymorphism in Pharmaceutical Solids Edited by Harry Brittain
2. Solid State Characterization of Pharmaceuticals Edited by Angeline and Mark Zarkrzewski
3. Crystal Engineering: A textbook, Edited by G. R. Desiraju, J. J. Vittal and A. Ramanan

PC-610 : Drug Metabolism (1 credit)

1. Biotransformation of drugs.
2. Enzymes responsible for bio-transformations, microsomal and non-microsomal mechanisms.
3. Factors influencing enzyme induction and inhibition.
4. Factors effecting drug metabolism.
5. Drug metabolism in fetus and new born.
6. Models to study drug metabolism.
7. Dose-effect relationships.
8. Excretion of drugs, biliary and fecal excretion.
9. Adverse drug reactions and drug interactions; Toxic reactions, allergic reactions, idiosyncracy.
10. Acute poisoning and its treatment.

Recommended Books:

1. Introduction to Drug Metabolism, by G. Gordon Gibson and Paul Skett
2. Drug Metabolism Handbook Concepts and Applications Edited by Ala F. Nassar, Wiley .

PC-611 : Pharmacological Screening and Assays (1 credit)

1. General principles of screening, correlations between various animal models and human situations, animal ethics.
2. Pharmacological screening models for therapeutic areas such as hypertension,' cerebral ischaemia, pain, epilepsy, depression, Parkinson's disease, Alzheimer's disease, diabetic, leishmania etc.
3. Correlation between *in-vitro* and *in-vivo* screens; Special emphasis on cell- based assay, biochemical assay, radioligand binding assay, high through put screening, high through put pharmacokinetic analysis, specific use of reference drugs and interpretation of results.

Recommended Books:

1. Drug Discovery and Evaluation: Pharmacological Assays by Vogel
2. CPCSEA guidelines.

GE-611 : Seminar (1 credit)

Students are required to submit written record and present details of the project to be pursued in semester-lll & IV This should include the purpose and basis of the project, stating aims, objectives and probable outcomes, be able to supplement these with necessary information, literature review towards it and process for the project itself.

LS-610 : General Laboratory Experience -10 hours/week (2 credits)

Preparation and evaluation of biomaterials for different DDS, development and evaluation of drug delivery systems, formulation development and evaluation.

Note : * Common in all disciplines