

PHARMACEUTICS

M. S. (Pharm.)

Course no.	Course Name	Credits
Semester I		
CORE SUBJECTS (ALL COMPULSORY)		
PE-510	Pharmaceutical Preformulation	1
PE-520	Biopharmaceutics and Pharmacokinetics	2
PE-530	Pharmaceutical Packaging Technology	1
PE-540	Global regulatory considerations for Pharmaceutical Product Development	1
PA-520	Advanced Analytical Techniques in Pharmaceutical R&D	1
GE-510	Biostatistics	2
GE-520	Fundamentals of Intellectual Property (IP) and Technology Management	1
GE-511	Seminar	0.5
LG-510	General Laboratory Experience	2.5
ELECTIVE SUBJECTS (FOR 4 CREDITS)		
EL-501	Biochemical Engineering Fundamentals	2
EL-502	Biotechnology in Pharmaceutical Sciences	1
EL-503	Industrial safety and green chemistry	1
EL-504	Computer Application in Biomedical Engineering	1
EL-505	Biological System Analysis and Control	1
EL-506	Productivity in management and reengineering (Neha	1
EL-507	Biosynthesis of Natural Products	1
EL-508	Chemotherapy of Parasitic and Microbial Infections	1
	Choose any core courses of other department (BT/MC/MD/PA/PC/PE)	
Total Credits		16
Semester II		
CORE SUBJECTS (ALL COMPULSORY)		
PE-620	Controlled Drug Delivery Systems	2
PE-630	Pharmaceutical Product Development – I	1
PE-640	Pharmaceutical Product Development – II	1
PE-650	Targeted Drug Delivery Systems	2
PE-660	Solid State Pharmaceutics	1
PE-670	Models for Testing of Drug Delivery Systems (1 Credits)	1
PC-610	Pharmacological Screening and Assays (1 Cr)	1
GE-611	Seminar	0.5
LS-610	General Lab Experience in the Area of Specialization	2.5
ELECTIVE SUBJECTS (FOR 4 CREDITS)		

EL-601	Biomechanics	2
EL-602	Mathematical Methods in Biomedical Engineering	1
EL-603	Logistics & distribution	1
EL-604	Total quality control	1
EL-605	Lean system, 6 sigma	1
EL-606	Introduction to Ayurveda and Polyherbal Formulations	1
EL-607	Chemotherapy and Immunopharmacology	2
EL-608	Pharmacovigilance and Medical Writing	2
	Choose any core courses of other department (BT/MC/MD/PA/PC/PE)	
	Total Credits	16
Semester III Project (22 weeks)		
TH- 598	Synopsis	
TH-599	Presentation	
	Total credits	8
Semester IV		
TH-698	Thesis	
TH-699	Thesis Defense	
	Total credits	10
TOTAL CREDITS (I TO IV SEMESTERS)		50

PHARMACEUTICS

M. S. (Pharm.)

Semester-I

PE-510

Pharmaceutical Preformulation (1 Credit)

- 1. Preformulation studies:** Timing and goals of preformulation studies, Various preformulation parameters, Preformulation studies of various types of drug substances including small molecules, proteins, and peptides. Fundamental and derived properties in preformulation profiling. Preformulation work-sheet.
- 2. Role of preformulation in drug discovery and drug development:** material properties in the lead selection, 'drug ability' of new chemical entities, *in silico* and high throughput preformulation studies. Preformulation as support for formulation development, identification of 'developmental challenges' during pharmaceutical development, dosage form specific studies.
- 3. Drug-excipient interaction:** Drug-excipient interaction and incompatibilities like physical, chemical, and therapeutic, analytical techniques to characterize drug-excipient incompatibility. Excipient selection
- 4. Drug Stability Programs** Determination of Expiry date (shelf life) and Overage calculations. Stability indicating assays and ICH guidelines for Stability
- 5. Salt selection:** Role of salt selection in drug discovery and development, theoretical concepts for selection of counterions for salt formation, 'pKa rule' for salt formation, a decision tree for salt selection, appropriate case studies.
- 6. Rheology:** Concept of Viscoelastic, Methods for evaluation of viscosity, Newtonian/ non-Newtonian flow properties, thixotropy and their applications in the development of dosage form, implications of viscosity on the performance of liquid dosage forms like suspensions and emulsions, advanced techniques/equipment employed in the rheological characterization of pharmaceutical products.
- 7. Solubilization:** BCS classification system: Role in formulation designing, 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 solid forms like amorphous state.
- 8. Dissolution:** Theories of dissolution, release rates, and constants, selection of discriminatory dissolution media and QC release media, bio-relevant media (FaSSiF & FeSSiF), Mechanisms of drug release from conventional and controlled release dosage forms, Dissolution data handling and correction factors, calculation of similarity factor (f_2), Dissolution equipment with special emphasis on USP dissolution apparatus IV, Dissolution testing, validation of dissolution apparatus and IVIVC.

Books and References Recommended:

1. Aulton's *Pharmaceutics The Design and Manufacture of Medicines*, Michael E. Aulton and Kevin M. G. Taylor, Elsevier, 5th Edition, 2018.
2. Bentley's *Textbook of Pharmaceutics An Adaptation*, Sanjay K. Jain and Vandana Soni, Elsevier, 2012.
3. *Drug Stability Principles and Practices*, Jens T. Carstensen and C. T. Rhodes, Marcel Dekker, 3rd Edition, 2000.
4. *Handbook of Preformulation Chemical, Biological, and Botanical Drugs*, Sarfaraz K. Niazi, CRC Press, 2nd Edition, 2019.
5. *Integrated Pharmaceutics Applied Preformulation, Product Design, and Regulatory Science*, Antoine Al-achi, Mali Ram Gupta, William Craig Stagner, Wiley, 2013.
6. *Modern Pharmaceutics Volume 1 & 2*, Alexander T. Florence, Juergen Siepmann, Informa Healthcare, 5th Edition, 2009.
7. *Molecular Biopharmaceutics Aspects of drug characterisation, drug delivery and dosage form evaluation*, Bente Steffansen, Birger Brodin, Carsten Uhd Nielsen, Pharmaceutical Press, 2010.
8. *Pharmaceutical Formulation The Science and Technology of Dosage Forms*, Geoffrey D. Tovey, Royal Society of Chemistry, 2018.
9. *Pharmaceutical Preformulation and Formulation A Practical Guide from Candidate Drug Selection to Commercial Dosage Form*, Mark Gibson, Informa Healthcare, 2nd Edition, 2009.

10. Preformulation in Solid Dosage Form Development, Moji Christianah Adeyeye, Harry G. Brittain, Informa Healthcare, 2008.
11. Tekade RK (Editor), *Dosage Form Design Considerations*, Volume -I, Publisher: ELSEVIER, ISBN: 978-0-12-814423-7, Place of Publication: USA
12. Tekade RK (Editor), *Dosage Form Design Parameters*, Volume – II, Publisher: ELSEVIER, ISBN: 9780128144213, Place of Publication: USA

Course outcomes:

After the successful completion of the course, students should be able to:

- i. Demonstrate the timing for initiating the preformulation activity to expedite the overall drug development process.
- ii. Derive the compatibility information of various excipients with the drug substance as well as the compatibility of one excipient in the presence of others to arrive at the most stable dosage form.
- iii. Identify the most suitable form of drug substance to be used in dosage form development.
- iv. Demonstrate the importance of rheology in liquid and semisolid dosage forms for optimized performance.
- v. Derive the shelf life of dosage form based on the stability study to meet the required therapeutic outcome consistently over the derived shelf life.
- vi. Demonstrate the importance of dissolution in choosing the most appropriate dosage form, among others, for the desired therapeutic outcome.

PE-520

Biopharmaceutics and Pharmacokinetics (2 credits)

1. **Introduction:** Definitions, ADME, concentration-time profile, plotting the data, different fluid compartments and blood flow-rate compartment models, biological half-life, Drug biotransformation: Pathways of drug metabolism, drug-metabolizing enzymes, Factors affecting drug metabolism and drug response, elimination rate constant, renal clearance, Total body clearance
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, the volume of distribution, and its significance.
4. **Protein and tissue binding:** Factors affecting protein binding, the kinetics of protein binding, determination of the rate constant, and different plots (direct, Scatchard, and reciprocal), Implication of protein binding on pharmacokinetic parameters.
5. **Bioavailability and bioequivalence:** Definitions, the purpose of Bioavailability requirements, factors influencing bioavailability, federal requirements, methods of determination of bioavailability using blood, and urinary excretion data. Protocol design for bioavailability assessment. Problems in Bioavailability & Bioequivalence studies, Criteria for waiver of Bioavailability, Methods for bioequivalence determination. Criteria for establishing Bioequivalence requirements.
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. Pediatric pharmacokinetic, Pharmacokinetics of multiple dosing, Pharmacokinetic Softwares like GastroPlus® SimCYP®, Phoenix WinNonlin®, and SAS for calculating pharmacokinetic parameters.
7. **Dosage regimen:** Individualization of drug dosage regimen, Therapeutic Drug Monitoring, Design of dosage regimen, Dosage regimen adjustment in patients with renal and hepatic diseases. Drug dosage in the elderly, children, and obese patients.
8. **Non-Linear Pharmacokinetics:** Various causes of non-linearity, Michaelis-Menten kinetics, In-vivo estimation of K_m , and V_m . Case studies.

9. **Physiologic pharmacokinetics models:** Mean Residence Time; Statistical Moment Theory; Mean Absorption Time (MAT) and Mean Dissolution Time (MDT); Application and limitations of physiologic pharmacokinetic models.
10. **Miscellaneous Topics:** Chronopharmacokinetics, Drug toxicity, the kinetics of maternal-fetal drug transfer, pharmacokinetics v/s pharmacological/ clinical response, metabolic kinetics

Books and References Recommended:

1. Applied Biopharmaceutics and Pharmacokinetics, Leon Shargel, Andrew B.C. Yu, McGraw Hill Education, 7th Edition, 2016.
2. Basic Pharmacokinetics and Pharmacodynamics *An Integrated Textbook and Computer Simulations*, Sara E. Rosenbaum, Wiley, 2nd Edition, 2017.
3. Biopharmaceutics and Pharmacokinetics: An Introduction, Robert E. Notari, Fourth Edition, CRC Press, 1987.
4. Biopharmaceutics and Relevant Pharmacokinetics, John G. Wagner, Drug Intelligence Publications, 1971.
5. Clinical Pharmacokinetics and Pharmacodynamics: Concepts and Applications, by Rowland, M. and T. N. Tozer
6. Comparative Pharmacokinetics Principles, Techniques and Applications, Jim E. Riviere, Wiley-Blackwell, 2nd Edition, 2011.
7. Drug Disposition and Pharmacokinetics from Principles to Applications, Stephen H. Curry and Robin Whelpton. Wiley-Blackwell, 2011.
8. Essential Pharmacokinetics A Primer for Pharmaceutical Scientists, Thorsteinn Loftsson, Academic Press (Elsevier), 2015.
9. Essentials of Pharmacokinetics and Pharmacodynamics, Thomas N. Tozer and Malcolm Rowland, Wolters Kluwer, 2nd Edition, 2016.
10. Evaluation of Drug Candidates for Preclinical Development Pharmacokinetics, Metabolism, Pharmaceutics, and Toxicology, Chao Han, Charles B. Davis and Binghe Wang, Wiley, 2010.
11. Handbook of Bioequivalence Testing, Sarfaraz Niazi, Informa Healthcare, 2007.
12. Introduction to Biopharmaceutics, by Gibaldi, M.
13. Modeling in Biopharmaceutics, Pharmacokinetics, and Pharmacodynamics: Homogeneous and Heterogeneous Approaches, Panos Macheras and Athanassios Iliadis, Springer, 2nd Edition, 2016.
14. Tekade RK (Editor), *Dosage Form Design Considerations*, Volume -I, Publisher: ELSEVIER, ISBN: 978-0-12-814423-7, Place of Publication: USA
15. Tekade RK (Editor), *Dosage Form Design Parameters*, Volume – II, Publisher: ELSEVIER, ISBN: 9780128144213, Place of Publication: USA

Course outcomes:

After the successful completion of the course, students should be able to:

- i. Explain various dosage form parameters affecting the pharmacokinetic parameters
- ii. Describe the basic concepts in biopharmaceutics and Pharmacokinetics
- iii. Elucidate the biopharmaceutical factors associated with various routes of administration
- iv. Explain the absorption, distribution, metabolism, and elimination of drugs from the human body
- v. Select the correct pharmacokinetic model based on plasma level or urinary excretion data that best describes the process of drug absorption, distribution, metabolism and elimination (ADME)
- vi. Determine the effect of Pharmacokinetic (ADME) parameters on the biological effects of the drug
- vii. Plan biopharmaceutical studies and use the obtained data in the development of new drugs or dosage forms
- viii. Calculate various pharmacokinetic parameters from plasma and urinary excretion data
- ix. Design dosage regimens for patients based on calculated pharmacokinetic parameters
- x. Design Bioavailability and Bioequivalence studies of new drugs or dosage forms

PE-530

Pharmaceutical Packaging Technology

(1 Credit)

1. **Concepts in Pharmaceutical Packaging:** Functions of packaging, Packaging materials with particular reference to Glass, Plastics and polymers, metals, and paper. Package system, package design Research, Packaging management
2. **Containers and closures:** Basis of the closure system, Types, and mechanism of the closure system Sealing and adhesion techniques, Materials used for closure systems. Introduction and applications of

Glass containers, Plastic containers, Collapsible tubes, Aerosol containers, Closures, Liners, and Rubber stoppers. Ancillary materials used in packaging

3. **Packaging Techniques and Machineries:** Pack types for different dosage forms, including parenteral, Ophthalmic, and aerosols. Types of Packaging with particular reference to- Blister and Strip packs, Film Wrappers, Bubble packs, Shrink seals, Sachet and Pouches, Tape seals, Breakable caps, Child-resistant and Tamper-evident packaging. Sealed tubes, Introduction, and applications of Form-Fill-Seal (FFS) technology.
4. **Smart Packaging for Pharmaceuticals** like PFS, Pen injectors, autoinjectors, and use of oxygen scavengers in container closure systems.
5. **Printing and Decoration of Labels and Packages.**
6. **Quality Control and Quality Assurance of Packaging Materials:** packaging specification, Stability of packages, and packaging materials. Defects in packaging, Detection of defects in packaging materials, Quality testing of formed packs, Pharmacopoeial tests and specifications closure systems, Extractables, and leachable.
7. **Hazards encountered by packaging material, drug-packaging material consideration, equipment used**
8. **Sterilization of packaging materials**
9. **Regulatory aspects of Pharmaceutical Packaging:** Requirements of labels and labeling as per Drug & Cosmetics act and rules. Product / patient information literature. Regulatory aspects of storage, handling, and distribution of packaging materials with special emphasis on cGMP and cGLP requirements.

Books and References Recommended:

1. Aulton's Pharmaceuticals *The Design and Manufacture of Medicines*, Michael E. Aulton and Kevin M. G. Taylor, Elsevier, 5th Edition, 2018.
2. Encyclopedia of Pharmaceutical Technology, James Swarbrick, Volume 1-6, Informa Healthcare, 3rd Edition, 2007.
3. Lachman Liebermans The Theory And Practice Of Industrial Pharmacy, Roop K Khar, SP Vyas, Farhan J Ahmad and Gaurav K Jain, CBS Publication, 4th Edition, 2020.
4. Modern Pharmaceutics Volume 1 & 2, Alexander T. Florence, Juergen Siepmann, Informa Healthcare, 5th Edition, 2009.
5. Pharmaceutical Packaging Handbook, Edward J. Bauer, Informa Healthcare, 2009.
6. Pharmaceutical Packaging Technology, D. A. Dean, E. R. Evans and I. H. Hall, Tylor and Francis. 2000.
7. Michael J. Akers, Sterile Drug Products Formulation, Packaging, Manufacturing, and Quality, Informa Healthcare, 2010.
8. Kit L Yam, Wiley Encyclopedia of Packaging Technology. 3rd Edition 2010, A John Wiley & Sons, Inc Publisher
9. Dean, D.A.; Evans, E.R.; and Hall I.H., *Pharmaceutical Packaging Technology*. Taylor and Francis
10. Paine, Frank A., Lockhart, H, Packaging of Pharmaceuticals and Healthcare Products, Springer House
11. Quality Control of Packaging Materials in the Pharmaceutical Industry, Kenneth Harburn, Informa Healthcare, 1990.

Course outcomes:

After the successful completion of the course, students should be able to:

- i. Explain various kinds of packaging materials like glass, plastic, elastomer.
- ii. Describe the role and function of packaging materials used for a range of pharmaceutical needs and wants.
- iii. Design solutions to packaging problems.
- iv. Relate the properties of pharmaceutical packages to conversion technologies, processing and packaging technologies and user requirements including safety, convenience and environmental issues.
- v. Evaluate the physical, chemical and mechanical properties of packages and packaging.
- vi. Describe the technology involved in the production, shaping and printing of various packaging materials and packages.
- vii. Identify an ideal packaging configuration for the dosage form
- viii. Explain the use of smart packaging like pre-filled syringes (PFS), pen injectors, autoinjector for drug delivery
- ix. Demonstrate the quality control tests needed to ensure the consistency in quality of various packaging materials.
- x. Define regulatory requirements with respect packaging materials quality control including labeling.

PE 540

Global regulatory considerations for Pharmaceutical Product Development (1 Credit)

1. **International regulatory trends in the pharmaceutical industry**
2. **Role of regulatory affairs department in the pharmaceutical organization:** regulatory audits, interactions with various other departments, single point contact with regulatory agencies.
3. **Types of regulatory filings for pharmaceutical products:** goals of regulatory registration procedures investigational new drug applications, Introduction to various types of regulatory filings.
4. **New drug applications:** stages involved in NDA, different phases of clinical trials, the purpose of IND, types, and categories of IND applications information to be given in IND applications.
5. **Chemistry, manufacturing, and control (CMC) information in NDA:** information related to drug substance like manufacturing process, specifications, description of test methods. Information related to drug product: description of method of manufacturing, specifications, and acceptable limits. Information compared to placebo.
6. **Hybrid NDA:** a difference from NDA, historical background, literature-based hybrid NDAs and other sources of information for hybrid NDA, examples of types of products considered under hybrid NDA.
7. **Abbreviated New Drug applications (ANDAs):** historical developments leading to the creation of ANDA process, Hatch Waxman Act, patent term restoration, criteria for patent term extension, various types of Hatch Waxman Exclusivities, the concept of therapeutic equivalence, ANDA review process.
8. **Paragraph IV certification ANDAs:** different ANDA Patent certification options, Medicare Modernization Act, implications of this act on 30 months stay period and 180-day exclusivity, triggering and forfeiture of 180-day exclusivity, shared exclusivity
9. **ANDA with suitability petition:** case studies of drug products considered appropriate for filing under suitability petition.

Books and References Recommended:

1. FDA Regulatory Affairs *A Guide for Prescription Drugs, Medical Devices, and Biologics*, Douglas J. Pisano and David S. Mantus, Informa Healthcare, 2nd Edition, 2008.
2. *Guidebook For Drug Regulatory Submissions*, Sandy Weinberg, Wiley, 2009.
3. *Multiregional Clinical Trials for Simultaneous Global New Drug Development*, Joshua Chen and Hui Quan, CRC Press, 2016.
4. *New Drug Approval Process*, Richard A. Guarino, Informa Healthcare, 5th Edition, 2009.
5. *Pharmaceutical Pre-Approval Inspections, A Guide To Regulatory Success*, Martin D. Hynes III, Informa Healthcare, 2nd Edition, 2008.
6. *The FDA and Worldwide Current Good Manufacturing Practices and Quality System Requirements Guidebook for Finished Pharmaceuticals*, José Rodríguez-Pérez, ASQ Quality Press, 2014.
7. *The Pharmaceutical Regulatory Process*, Ira R. Berry and Robert P. Martin, Informa Healthcare, 2nd Edition, 2008.
8. www.ema.europa.eu and www.fda.gov

Course outcomes:

After the successful completion of the course, students should be able to:

- i. Explain the process of drug discovery, development and generic product development
- ii. Explain the requirement of various regulatory agencies for approval of a new drug product across the globe.
- iii. Develop basic understanding of generating clinical trial protocols
- iv. Understand the concept of pharmacovigilance and its significance
- v. Demonstrate the process for the registration of Indian drug product in overseas market
- vi. Explain the filing of IND and NDA for a new chemical entity.
- vii. Demonstrate the importance of Chemistry, manufacturing, and control (CMC) information in NDA
- viii. Explain how hybrid NDA differs from NDA and when it can be filed for approval
- ix. Explain the importance of the Hatch Waxman Act for approval of ANDA
- x. Differentiate between the paragraph I, II, III & IV ANDA filing

GE-520

Fundamentals of Intellectual Property (IP) and Technology Management (1 credit)

- 1. Intellectual property:** Concepts and fundamentals; Concepts regarding intellectual property (IP), intellectual property protection (IPP) and intellectual property rights (IPR); Economic importance, mechanisms for the protection of intellectual property-patents, copyrights, trademark; Factors affecting the choice of IP protection; Penalties for violation; Role of IP in the 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 Organization), WIPO (World Intellectual Property Organization) 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 genetic 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 attorneys' technical aspects, criteria for selection, addresses, fee, rights and responsibilities of a patentee; Practical aspects regarding maintaining of a PATENT FILE; Patent infringement- meaning, scope, litigation, case studies and examples; Patenting by research students, lecturers and scientists-University / organizational rules in India and abroad; Thesis research paper publication, credit sharing by workers, financial incentives; Useful information sources for patents related information-internet sites, brochures, periodicals, CD ROMs; Significance of copyright protection for researchers; Indian Copyright Law and digital technologies-Berne convention, WIPO copyright treaty (WCT), WIPO performance and Phonogram Treaty (WPPT); Protection for computer data bases, multimedia works; Trademarks 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 infringements.
- 4. Technology development / transfer /commercialization 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-commercialization and commercialization-practical aspects and problems; Significance of transfer of technology (TOT), bottlenecks; Managing technology transfer-guidelines for research students, scientists and related personal; TOT agencies in India-APCTD, NRDC, TIFAC, BCIL, TBSE/SIDBI; TOT related documentation-confidentiality agreements, licensing, MOUs, legal issues; Compulsory licensing excess to medicine issues; DOHA declaration, POST WTO product patent regime from 2005; Challenges for Indian pharmaceutical industry in the context of globalization 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 benefits of modern biotechnology; Voluntary adoption of pollution control strategies.

Books and References Recommended:

1. Fundamentals of Patenting and Licensing for Scientists and Engineers, Matthew Y Ma, World Scientific Publishing Co. Pte. Ltd. 2nd Edition, 2015.
2. Fundamentals of Intellectual Property Rights: For Students, Industrialist and Patent Lawyers, 1st Edition, 2017, by Ramakrishna B and Anil Kumar
3. Intellectual Property Rights, Bioethics, Biosafety and Entrepreneurship in Biotechnology, I K International Publishing House Pvt. Ltd; 1st edition, 2020, Sibi G.
4. Intellectual Property: The Law of Trademarks, Copyrights, Patents, and Trade Secrets, 4th Edition, Cengage Learning Publisher, 2013, Bouchoux DE
5. Intellectual Property Rights in Agricultural Biotechnology (Biotechnology in Agriculture Series), 2nd Edition, CABI Publishing, 2003, Frederic H. Erbisch and Karim Maredia
6. Pharmaceutical Process Scale-Up, Second Edition (Drugs and the Pharmaceutical Sciences), 2nd edition, CRS press, 2005, Michael Levin (Editor)

Course outcomes:

After the successful completion of the course, students should be able to:

- i. Define patenting and its requirements
- ii. Express various types of patent applications
- iii. Explain different types of patent filing like PCT or country-specific
- iv. Explain the rule for patenting including novelty, obviousness, prior art
- v. Describe patent life and extension of patent validity
- vi. Analyze Trade-related aspects of intellectual property rights
- vii. Explain the aspects related to technology development, transfer and commercialization
- viii. Express the ethics and values in Intellectual Property

Semester-II

PE-620

Controlled Drug Delivery (2 credits)

1. **Influence of drug properties and routes of drug administration on the design of sustained and controlled release systems:** Scientific rationale for designing controlled drug delivery, Physico-chemical properties and biological factors influencing the design and performance of sustained/controlled release products
2. **Polymeric materials in controlled drug delivery:** Polymer classification, physical and chemical characterization techniques for biomaterials, Polymers for controlled drug release, stimuli sensitive polymers. Biodegradable polymers, Biodegradation of polymers, Co-polymers, and block co-polymers in drug delivery.
3. **Biopharmaceutic and pharmacokinetic aspects of Controlled Drug Delivery Systems:** Strategies and design, factors affecting controlled release drug delivery system (CRDDS), 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.
4. **Peroral controlled drug release delivery:** Design and fabrication of oral systems, dissolution-controlled release, diffusion and dissolution-controlled release, Ion-exchange resins, pH-independent formulations, osmotically controlled release, altered density formulations, Case studies
5. **Parenteral controlled drug delivery:** Major routes of parenteral administration; selection, design and development, biopharmaceutics of sustained/controlled release parenteral drugs products, the polymer used in the design of controlled parenteral drug delivery systems, Sterilization of pharmaceuticals: Technology
6. **Transdermal/skin drug delivery system:** Principles of skin permeation, factors affecting transdermal/skin drug delivery, skin permeation promoters, Mechanical skin permeation enhancers viz. Iontophoresis, sonophoresis and electroporation, Chemical skin permeation enhancers, the pharmacokinetics of skin permeation, design, development, and evaluation of various types of transdermal drug delivery systems, an overview of microneedles in transdermal drug delivery.
7. **Implantable Therapeutics Systems** - Historical background; Advantages, disadvantages, and applications; Types of implantable therapeutic systems including self-regulated and implantable pump systems; non-biodegradable and biodegradable polymers used for implantable systems.

8. **Proteins/peptides drug delivery systems:** Barriers to peptide and protein delivery, pharmacokinetics, different routes of delivery, site-specific protein/peptide drug delivery such as macromolecular drug carriers, hybrid protein delivery systems, practical considerations.
9. **Controlled release formulations for alternate routes of administration:** Consideration for controlled release in pulmonary/nasal, controlled ocular (Ocuser systems), buccal, rectal, and vaginal drug delivery.
10. **Regulatory approval pathways involved in controlled release formulations:** New Drug Application and abbreviated new drug applications.
11. **Role of controlled release in veterinary, Nutraceuticals, and Agro-based formulations:** Background and present scenario, formulation considerations, significant hurdles and, future prospects.

Books and References Recommended:

1. Controlled Drug Delivery *Fundamentals and Applications*, Joseph R. Robinson, Vincent H. L. Lee, Marcel Dekker, 2nd Edition, 1987.
2. Controlled Drug Delivery Systems *Towards New Frontiers in Patient Care*, Filippo Rossi, Giuseppe Perale, Maurizio Masi, Springer, 2016.
3. Controlled Drug Delivery Volume I Basic Concepts, Stephen D. Bruck, CRC Press, 2019.
4. Controlled Drug Delivery Volume II Clinical Applications, Stephen D. Bruck, CRC Press, 2019.
5. Design of Controlled Release Drug Delivery Systems, Xiaoling Li, Bhaskara R. Jasti, McGraw-Hill, 2006.
6. Encyclopedia of Pharmaceutical Technology, James Swarbrick, Volume 2, Informa Healthcare, 3rd Edition. 2007.
7. Fundamentals and Applications of Controlled Release Drug Delivery, Juergen Siepmann, Ronald A. Siegel, Michael J. Rathbone, Springer, 2012.
8. Oral Controlled Release Formulation Design and Drug Delivery *Theory To Practice*, Hong Wen, Kinam Park, Wiley, 2010.
9. Tekade RK (Editor), *Dosage Form Design Considerations*, Volume -I, Publisher: ELSEVIER, ISBN: 978-0-12-814423-7, Place of Publication: USA
10. Tekade RK (Editor), *Dosage Form Design Parameters*, Volume – II, Publisher: ELSEVIER, ISBN: 9780128144213, Place of Publication: USA
11. Tekade RK (Editor), *Basic Fundamentals of Drug Delivery*, Publisher: ELSEVIER, ISBN: 78-0-12-817909-3, Place of Publication: USA
12. Tekade RK (Editor), *Drug Delivery Systems*, Publisher: ELSEVIER, ISBN: 978-0128144879, Place of Publication: USA

Course outcomes:

After the successful completion of the course, students should be able to:

- i. Demonstrate various kinds of Physico-chemical properties to be considered in designing the controlled release drug delivery system (CRDDS),
- ii. Explain various types of oral CRDDS releasing the drug through a different mechanism
- iii. Analyze when to design the parenteral CRDDS
- iv. Define various factors to be considered while designing parenteral CRDDS.
- v. Explain the principles and techniques used in the design of controlled release drug delivery systems
- vi. Deduce the criteria for the selection of drugs and polymers in the development of CRDDS
- vii. Link various biopharmaceutics and pharmacokinetic parameters with the selection of CRDDS to optimize the therapeutic response
- viii. Write the approaches for the development of controlled drug delivery systems and their evaluation
- ix. Explain the formulation and characterization of transdermal and implantable drug delivery systems
- x. Describe the importance of transdermal drug delivery and methods to develop the same
- xi. Explain the labile nature of proteins/peptides impacting their oral bioavailability and dosage form designing

PE-630

Pharmaceutical Product Development - I (1 Credit)

1. **Development of dosage forms:** Four-stage development including preformulation, prototype development, scale-up studies, and commercialization.
2. **Design of materials and product specifications:** Creation and optimization of material and product specifications. In-process, product release, and regulatory specifications.
3. **Quality by design (QbD):** Fundamentals of pharmaceutical quality by design, identification of critical quality attributes, essential attributes of the material, critical parameters in the process, and quality risk

management.

4. **Methods of optimization** – OVAT and Design of experiments (DOE). Experimental designs, screening designs, factorial designs, composite designs, mixture designs, response surface methodology. Applications of systematic optimization techniques.
5. **Process analytical technology (PAT)** and other control strategies for QbD.
6. Process and Equipment validation in formulation development: Regulatory basis of validation; advantages; validation planning and organization; Equipment and process validation, Type of the validation; Prerequisites for successful validation
7. **Documentation protocols:** Forms and maintenance of records in the product development department, including clinical batches.
8. **Case studies or regulatory guidelines** related to the above topics shall be discussed after each topic.

Books and References Recommended:

1. Ansel's Pharmaceutical Dosage Forms and Drug Delivery Systems, Loyd V. Allen and Howard C. Ansel, Wolters Kluwer Health, 10th Edition, 2014.
2. Aulton's Pharmaceutics *The Design and Manufacture of Medicines*, Michael E. Aulton and Kevin M. G. Taylor, Elsevier, 5th Edition, 2018.
3. Bentley's Textbook of Pharmaceutics An Adaptation, Sanjay K. Jain and Vandana Soni, Elsevier, 2012.
4. Developing Solid Oral Dosage Forms *Pharmaceutical Theory & Practice*, Yihong Qiu et. al, Academic Press, 2nd Edition, 2017.
5. Encyclopedia of Pharmaceutical Technology, James Swarbrick, Volume 1-6, Informa Healthcare, 3rd Edition, 2007.
6. Modern Pharmaceutics Volume 1 & 2, Alexander T. Florence, Juergen Siepmann, Informa Healthcare, 5th Edition, 2009.
7. Parenteral Medications, Sandeep Nema, John D. Ludwig, Informa Healthcare, CRC Press, 4th Edition, 2019.
8. Pharmaceutical Dosage Forms and Drug Delivery, Ram I. Mahato and Ajit S. Narang, CRC Press, 3rd Edition, 2018.
9. Pharmaceutical Formulation *The Science and Technology of Dosage Forms*, Geoffrey D. Tovey, Royal Society of Chemistry, 2018.
10. Pharmaceutical Quality By Design *A Practical Approach*, Walkiria S. Schlindwein and Mark Gibson, Wiley, 2018.
11. Pharmaceutics *Basic Principles And Application To Pharmacy Practice*, Alekha K. Dash, Somnath Singh, Justin Tolman, Academic Press (Elsevier), 2014.

Course outcomes:

After the successful completion of the course, students should be able to:

- i. Demonstrate the life cycle of dosage forms and analyse critical bottlenecks in each cycle.
- ii. Explain the stages involved in the drug product development life cycle like preformulation, prototype development, scale-up, and commercialization.
- iii. Describe the process of development of product specifications and the role of different team members.
- iv. Apply optimization methods and quality building methods in dosage form design.
- v. Explain the difference between in-process, release, and stability specification for the drug product.
- vi. Identify and understanding the critical material attributes (CMA), critical process parameters (CPP), and critical quality attributes (CQA) and quality risk management (QRM).
- vii. Explain the development of the pharmaceutical product by quality-by-design (QbD)
- viii. Apply various optimization techniques like the design of experiment (DoE), factorial design, and response surface methodology in optimization of drug product development.
- ix. Demonstrate the importance of PAT in drug product manufacturing.
- x. Explain the importance of process validation and regulatory requirement for process validation.
- xi. Express the role of documentation protocols and their maintenance.

PE-640

Pharmaceutical Product development-II (1 Credit)

- 1. Formulation additives:** Study of different types of additives, e.g., antioxidants and preservatives, coloring and flavoring 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. Implications of the quantitative selection of each excipient in product development.
- 2. Improved tablet production:** Advances in materials, material handling, granulation equipment, and granulation technologies; process automation. Physics of Compression & Compaction, tablet compression tooling; Processing problems in tablet and troubleshooting.
- 3. Tablet coating:** Advances in equipment for coating, sugar coating, film coating, advanced coating technologies, particle coating, Wurster processes, centrifugal powder coating, compression coating, functional film coating, spray drying, aqueous-phase separation, coacervation, nonaqueous-phase separation interfacial polymerization, sustained-release product designing through the coating, novel polymeric coating materials. Aqueous-based film coating, solvent-free coating, coating defects.
- 4. Specialized tablets:** Recent advances in tablet technology and automation in manufacturing process Formulation and evaluation of effervescent, orodispersible/ mouth dissolving tablets, chewable tablets, Multilayered tablets, Matrix tablets.
- 5. Liquid and poly-disperse systems:** Suspensions: theoretical considerations, flocculated and deflocculated suspensions, excipients utilized, evaluation of suspension stability. Emulsions: descriptive theories of emulsification, formulation aspects, stability evaluation, advances in emulsion technology-multiple, micro, and nanoemulsions.
- 6. Inhalation Products:** Nebulizers, Inhalers – Metered Dose Inhalers (MDI) and Dry Powder Inhalers (DPIs): Formulation and evaluation aspects, types of excipients/propellants, devices used, and stability aspects.
- 7. Herbal Formulation Development:** Importance of herbal formulations, Challenges, Formulation considerations, testing of herbal formulations, Stability considerations and future prospects

Books and References Recommended:

1. Ansel's Pharmaceutical Dosage Forms and Drug Delivery Systems, Loyd V. Allen and Howard C. Ansel, Wolters Kluwer Health, 10th Edition, 2014.
2. Aulton's Pharmaceutics *The Design and Manufacture of Medicines*, Michael E. Aulton and Kevin M. G. Taylor, Elsevier, 5th Edition, 2018.
3. Bentley's Textbook of Pharmaceutics An Adaptation, Sanjay K. Jain and Vandana Soni, Elsevier, 2012.
4. Developing Solid Oral Dosage Forms *Pharmaceutical Theory & Practice*, Yihong Qiu et al., Academic Press, 2nd Edition, 2017.
5. Encyclopedia of Pharmaceutical Technology, James Swarbrick, Volume 1-6, Informa Healthcare, 3rd Edition, 2007.
6. Handbook of Pharmaceutical Excipients, Sheskey Paul J, Cook Walter G, Cable Colin G, Pharmaceutical Press, 8th Edition, 2017.
7. Modern Pharmaceutics Volume 1 & 2, Alexander T. Florence, Juergen Siepmann, Informa Healthcare, 5th Edition, 2009.
8. Parenteral Medications, Sandeep Nema, John D. Ludwig, Informa Healthcare, CRC Press, 4th Edition, 2019.
9. Pharmaceutical Dosage Forms and Drug Delivery, Ram I. Mahato and Ajit S. Narang, CRC Press, 3rd Edition, 2018.
10. Pharmaceutical Dosage Forms: Tablets, Volume 1-3, Larry L. Augsburger and Stephen W. Hoag, Informa Healthcare, 3rd Edition, 2008.
11. Pharmaceutical Formulation *The Science and Technology of Dosage Forms*, Geoffrey D. Tovey, Royal Society of Chemistry, 2018.
12. Pharmaceutics *Basic Principles And Application To Pharmacy Practice*, Alekha K. Dash, Somnath Singh, Justin Tolman, Academic Press (Elsevier), 2014.

Course outcomes:

After the successful completion of the course, students should be able to:

- i. Evaluate the properties of formulation additives and select the fitting additive for different formulations.
- ii. Understand critical parameters for the development of tablet products, inhalation products.
- iii. Understand basic principles of colloidal science
- iv. Able to formulate and evaluate different dispersed system products.
- v. Identify the manufacturing and formulation reasons behind product failures.
- vi. Identify methodology for improved tablet production
- vii. Demonstrate different types of coating like film coating, sugar coating, sustained release coating, Wurster coating for taste masking of pellets, and to impart sustained-release property.
- viii. Develop suspension dosage form and be able to differentiate between flocculated and deflocculated suspension
- ix. Demonstrate the factors affecting the stability of suspension dosage form.
- x. Write the theory of emulsification
- xi. Demonstrate stability issues in emulsion dosage forms like creaming, flocculation, and coalescence.
- xii. Explain the development of Metered Dose Inhalers (MDI) and Dry Powder Inhalers (DPIs).
- xiii. Explain the development of herbal based drug formulation

PE-650

Targeted Drug Delivery Systems (2 Credits)

1. **Fundamentals of targeted drug delivery:** Drug Development from Concept to Market, Limitation of Conventional Drug Delivery Systems available in the market, Characteristics of Ideal Drug Delivery Systems, Need of targeted drug delivery, Challenges, and obstacles to targeted drug delivery
2. **Molecular pharmaceuticals:** Molecular Biology and Drug Delivery, Molecular basis of drug Absorption & transport, ligand-receptor interaction, Types of drug targeting, Levels of drug targeting, Physicochemical and physiological basis of targeting, EPR effects, receptor-mediated endocytosis. Pharmacokinetics and Biopharmaceutics considerations, Role of RES uptake, Macrophage uptake, drug efflux
3. **Recent developments in targeted drug delivery:** Novel platforms for targeted drug delivery, multifunctional approach in targeted drug delivery, Carriers for the active transport of drugs (With special emphasis on p-glycoprotein & design of pgp inhibitors)
4. **Chemical drug delivery systems:** Prodrug concept for drug design, drug targeting, and antibody directed enzyme prodrug therapy (ADEPT), soft drug design, Lipid-drug/ polymer-drug conjugate.
5. **Vesicular and Colloidal drug delivery systems:** Preparation and characterization, biopharmaceutical considerations, evaluation, and applications in drug delivery of the following delivery vectors:
 - a) Liposomes, transfersomes, ethosomes, Niosomes, Layersomes, Bilosomes, Emulsomes, Virosomes, Cubosomes, Aquasomes, Pharmacosomes
 - b) Solid lipid nanoparticles and nanostructured lipid carriers
 - c) Polymeric nanoparticles –PLGA, chitosan, albumin, gelatin, alginate, etc.
 - d) Dendrimers
 - e) Polymeric micelles
 - f) Carbon nanotubes
 - g) Metallic nanoparticles
6. **Cellular carrier systems:** Resealed Erythrocytes, Exosomes, Mesenchymal stem cells
7. **Stimuli-responsive drug delivery systems:** Magnetically, thermal and pH-assisted drug delivery systems, Photothermal-, photodynamic, magnetically- modulated drug delivery systems
8. **Targeted brain delivery:** Overview of the brain, various barriers for brain delivery, specific targets for brain delivery, concept, Nasal to brain delivery, types and key elements: Ideal carrier systems for brain delivery and approach with case studies depicting utility in various brain diseases.
9. **Targeted Tumor Delivery:** Structural features of tumor vasculature, levels of tumor targeting, tumor ligands for targeted drug delivery, biopharmaceutical characteristics of delivery systems for tumor-specific delivery.
10. Gene, oligonucleotide, RNAi (siRNA/miRNA) delivery systems
11. Overview of the colon, liver, macrophage, mitochondrial, and M cells targeting.
12. **Problem-based Learning, Case studies, and workshops:** Innovative formulation approaches for the treatment of Cancer, Diabetes, Neurodegenerative disorder. Discussion on clinical trial and patent status of various Novel Drug Delivery Systems.

Books and References Recommended:

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
4. Drug Delivery and Targeting *For Pharmacists and Pharmaceutical Scientists*, Anya M.Hillery, Andrew W.Lloyd, James Swarbrick, Taylor & Francis, 2001.
5. Drug Targeting Organ-Specific Strategies, Grietje Molema and Dirk K. F. Meijer, WILEY-VCH, 2001.
6. Drug Targeting Technology *Physical • Chemical • Biological Methods*, Hans Schreier, Marcel Dekker, 2001.
7. Interfacial Phenomena In Drug Delivery And Targeting, Graham Buckton, CRC Press, 1995.
8. Nanoarchitectonics for Smart Delivery and Drug Targeting, Alina Maria Holban and Alexandru Mihai Grumezescu, William Andrew (Elsevier), 2016.
9. Targeted Drug Delivery, Methods and Protocols, Rachael W. Sirianni, Humana Press, 2018.
10. Targeted Drug Delivery: Concepts and Design, Padma V. Devarajan and Sanyog Jain, Springer, 2015.
11. Targeted Intracellular Drug Delivery by Receptor Mediated Endocytosis, Padma V. Devarajan, Prajakta Dandekar and Anisha A. D'Souza, , Springer (AAPS), 2019.
12. Therapeutic Monoclonal Antibodies: From Bench to Clinic, Zhiqiang An, Wiley, 2009.
13. Tekade RK (Editor), Basic Fundamentals of Drug Delivery, Publisher: ELSEVIER, ISBN: 78-0-12-817909-3, Place of Publication: USA
14. Tekade RK (Editor), Biomaterials and Bio-Nanotechnology, Publisher: ELSEVIER, ISBN: 978-0-12-814427-5, Place of Publication: USA
15. Tekade RK (Editor), Drug Delivery Systems, Publisher: ELSEVIER, ISBN: 978-0128144879, Place of Publication: USA

Course outcomes:

After the successful completion of the course, students should be able to:

- i. Demonstrate the fundamentals of targeted drug delivery like levels of targeting, use of EPR effect in cancer drug targeting.
- ii. Explain the principles and techniques used in the design of targeted release drug delivery systems
- iii. Learn the criteria for selection of drugs polymers and conjugation strategies for the development of targeted drug delivery systems
- iv. Learn various approaches for the development of targeted drug delivery systems.
- v. Plan evaluation of targeted drug delivery systems
- vi. Describe the aspects of the design and performance of drug dosage forms concerning their molecular properties
- vii. Explain the molecular and cellular basis of drug uptake of targeted drug carriers.
- viii. Explain the recent advances in Gene, oligonucleotide, RNAi (siRNA/miRNA) delivery systems
- ix. Explain the approaches that can be used for colon, liver, macrophage, mitochondrial and M cells targeting
- x. Explain the use of cellular carrier systems in drug targeting.

PE-670

Models for Testing of Drug Delivery Systems (1 Credit)

1. **In vitro Testing of Drug Delivery Systems:** Drug Loading and Entrapment efficiency, Particle Size Distribution, surface charge analysis, and its importance, *in vitro* drug release profiling,
2. **Ex vivo testing of Drug Delivery System:** *In vitro* assessment of cellular compatibility, Assay methods: Agar diffusion, Elution, *In vivo* assessment of tissue compatibility, Pyrogenicity, Research leads for designing drug delivery systems with improved biocompatibility, *In vitro* cell culture techniques for evaluation of drug permeation from DDS including isolation maintenance of cell lines, culturing monolayers, Transportation and bio interaction Properties across biological systems, Interaction with body components, blood compatibility, tissue compatibility, carcinogenicity, and mutagenicity testing. Ocular and cutaneous irritation, Acute, sub-acute, and chronic toxicity testing – Biochemical basis of toxicity, Bioassays, *In vitro/ex vivo* models for evaluation of Drug absorption *In vitro* cytotoxicity evaluation using cell cultures and techniques such as MTT assay, Dye uptake, etc.

3. **Pharmacological and toxicological testing Methods:** Fates of interactions of materials with the human body; Inflammation, Immune response, Systemic toxicity and hypersensitivity, Blood coagulation, Carcinogenesis, Infection, Blood-biomaterial interactions, Testing hemocompatibility, Design of toxicological studies, Toxicity by routes – Parental, oral, percutaneous and inhalation, Biodistribution profiling, Target organ toxicity exemplified by hepatotoxicity and cutaneous (dermal) toxicity.
4. **Problem-based Learning, Case studies, and workshops:** Focused discussion on formulation testing in the disease model

Books and References Recommended:

1. Drug Discovery and Evaluation Pharmacological Assays, Hans Gerhard Vogel, Springer-Verlag Berlin Heidelberg, 3rd Edition, 2008.
2. Absorbable and Biodegradable Polymers, Shalaby W. Shalaby and Karen J.L. Burg, CRC Press, 2005.
3. Aulton's Pharmaceutics *The Design and Manufacture of Medicines*, Michael E. Aulton and Kevin M. G. Taylor, Elsevier, 5th Edition, 2018.
4. Drug Stability *Principles and Practices*, Jens T. Carstensen and C. T. Rhodes, Marcel Dekker, 3rd Edition, 2000.
5. Encyclopedia of Pharmaceutical Technology Volume 1-6, James Swarbrick, Informa Healthcare, 3rd Edition, 2007.
6. Handbook of Pharmaceutical Excipients, Sheskey Paul J, Cook Walter G, Cable Colin G, Pharmaceutical Press, 8th Edition, 2017.
7. Lachman Liebermans The Theory And Practice Of Industrial Pharmacy, Roop K Khar, SP Vyas, Farhan J Ahmad and Gaurav K Jain, CBS Publication, 4th Edition, 2020.
8. Martin's Physical Pharmacy and Pharmaceutical Sciences, Patrick J. Sinko, Yashveer Singh, Wolters Kluwer - Lippincott Williams & Wilkins (LWW), 6th Edition, 2011.
9. Modern Pharmaceutics Volume 1 & 2, Alexander T. Florence, Juergen Siepmann, Informa Healthcare, 5th Edition, 2009.
10. Pharmaceutical Dissolution Testing, Jennifer J. Dressman and Johannes Krämer, CRC Press, 2005.
11. Pharmaceutical Dosage Forms: *Disperse Systems Volume 3*, Herbert Lieberman, CRC Press, 2nd Edition, 2019.
12. Remington *The Science and Practice of Pharmacy, Adeboye Adejare*, Academic Press, 23rd Edition, 2020.

Course outcomes:

After the successful completion of the course, students should be able to:

- i. Determine the drug entrapment and drug loading in drug delivery system
- ii. Demonstrate and apply different tests for the evaluation of drug delivery systems.
- iii. Able to select and apply the most appropriate test for the product.
- iv. Explain various parameters that are used to govern the quality control of colloidal carrier systems.
- v. Correlate and exploit test results
- vi. Explain various in-vitro test that can be used to demonstrate the blood compatibility, cytotoxicity of colloidal carriers
- vii. Explain the model that can be used to measure the permeability of drug molecules.
- viii. Explain the interactions of materials with the human body; Inflammation, Immune response, Systemic toxicity, and hypersensitivity, Blood coagulation
- ix. Explain the toxicity by routes such as parental, oral, percutaneous, and inhalation, biodistribution profiling, and target organ toxicity.

PE-660

Solid State Pharmaceutics (1 credit)

- 1. Levels of solid-state properties:** Molecular/particle/bulk level properties, the interdependence of various levels on each other, the role of different levels during pharmaceutical development and process development
- 2. Molecular-level:** Crystalline form, definition, the 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 software. Computational solid-state pharmaceutics and molecular dynamics.
- 3. Polymorphism:** Definition, the significance of polymorphism in drug product performance, packing / conformational polymorphism, thermodynamics of polymorphs, enantiotropy / monotropy, the concept of the transition temperature, Burger, and Ramberger rule. Regulatory concerns related to polymorphism, introduction to the latest regulatory position on polymorphism.
- 4. Crystallization process:** Basics of crystallization process applied in drug research, Molecular aggregation events in crystallization, energetic of crystallization, enthalpy entropy balance, types of nucleation, Ostwald's step rule, experimental protocols for polymorph screening, crystal design strategies; Co-crystals: Introduction, the formation of co-crystals and its applications in drug delivery
- 5. Amorphous state:** Definition, Role of amorphous state in drug delivery, long-range order versus short-range order, the disorder in the amorphous state, the concept of glass transition temperature (T_g), the thermodynamic necessity for T_g, entropy crisis.
- 6. Role of amorphous state in drug delivery:** Particulate level properties and its implications on product performance and processing, Solubility advantage, spring parachute effect during solubility studies, physical instability of the amorphous form, techniques for stabilization of amorphous form, amorphous solid solutions/dispersions.
- 7. Particulate level properties:** Crystal habit, generation of different crystal habits, implications of crystal habit on product performance, and processing.
- 8. Bulk level:** Bulk density, compressibility, flow properties, cohesivity, electrostatics, aggregation, agglomeration, role in formulation development, and processing.
- 9. Testing of solid-state purity.**
- 10. Solid-state in light of nanocrystals.**

Books and References Recommended:

1. Advanced Pharmaceutical Solids, Jens T. Carstensen, Marcel Dekker, 2001.
2. Advanced Pharmaceutics *Physicochemical Principles*, Cherng-ju Kim, CRC Press, 2004.
3. Bentley's Textbook of Pharmaceutics An Adaptation, Sanjay K. Jain and Vandana Soni, Elsevier, 2012.
4. Crystal Engineering: A textbook, Edited by G. R. Desiraju, J. J. Vittal and A. Ramanan
5. Handbook of Preformulation *Chemical, Biological, and Botanical Drugs*, Sarfaraz K. Niazi, CRC Press, 2nd Edition, 2019.
6. Integrated Pharmaceutics *Applied Preformulation, Product Design, and Regulatory Science*, Antoine Al-achi, Mali Ram Gupta, William Craig Stagner, Wiley, 2013.
7. Pharmaceutics *Basic Principles And Application To Pharmacy Practice*, Alekha K. Dash, Somnath Singh, Justin Tolman, Academic Press (Elsevier), 2014.
8. Physicochemical Principles of Pharmacy, Alexander T Florence and David Attwood, Pharmaceutical Press, 4th Edition, 2006.
9. Polymorphism in Pharmaceutical Solids Edited by Harry Brittain
10. Polymorphism in Pharmaceutical Solids, Harry G. Brittain, Informa Healthcare, 2nd Edition, 2009.
11. Solid State Characterization of Pharmaceuticals Edited by Angeline and Mark Zarkzewski
12. Solid State Characterization of Pharmaceuticals, Richard A. Storey and Ingvar Ymen, Wiley, 2011.

Course outcomes:

After the successful completion of the course, students should be able to:

- i. Differentiate different solid states of drug compounds using different analytical techniques.
- ii. Identify drug candidates and formulation challenges that can be overcome by solid-state manipulation.
- iii. Explain different methods of preparation of drugs with different solid-state properties.

- iv. Describe the role of polymers in stabilizing the amorphous state.
- v. Demonstrate various techniques that can be used to evaluate crystalline/amorphous nature of drug substance
- vi. Explain the significance of polymorphism in drug product performance
- vii. Demonstrate the difference between crystalline and amorphous drug substances
- viii. Explain the factors to be considered in the selection of most appropriate polymorph in dosage form development
- ix. Explain the solubility advantage and physical instability of the amorphous form.
- x. Demonstrate the techniques that can be used for stabilization of amorphous form
- xi. Explain the effect of crystallinity and amorphous nature of drug substance on its bulk property