M. Pharm (MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES)			
Sub Code:	23PMPT10		
University Examinations	Theory = 75	CIA = 25	

Scope	This subject deals with various advanced analytical instrumental techniques for identification, characterization, and quantification of drugs. Instruments dealt are NMR, Mass spectrometer, IR, HPLC, GC etc.
Objective	After completion of course student is able to know Chemicals and Excipients. The analysis of various drugs in single and combination dosage forms. Theoretical and practical skills of the instruments.

Unit	1	a. UV-Visible spectroscopy: Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, choice of solvents and solvent effect and Applications of UV Visible spectroscopy. b. IR spectroscopy: Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier Transform IR Spectrometer, Factors affecting vibrational frequencies and Applications of IR spectroscopy c. Spectro flourimetry: Theory of Fluorescence, Factors affecting fluorescence, Quenchers, Instrumentation and Applications of fluorescence spectrophotometer. d. Flame emission spectroscopy and atomic absorption spectroscopy: Principle, Instrumentation, Interferences and Applications.
Unit	2	NMR spectroscopy: Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and 13CNMR. Applications of NMR spectroscopy
Unit	3	Mass Spectroscopy: Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules, Metastable ions, Isotopic peaks, and Applications of Mass spectroscopy
Unit	4	Chromatography: Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution and applications of the following: a) Paper chromatography b) Thin Layer chromatography c) Ion exchange chromatography d) Column chromatography e) Gas chromatography f) High Performance Liquid chromatography g) g) Affinity chromatography
Unit	5	a. Electrophoresis: Principle, Instrumentation, working conditions, factors affecting separation and applications of the following: a) Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresis

		d) Zone electrophoresis e) Moving boundary electrophoresis f) Isoelectric focusing b. Xray Crystallography: Production of X-rays, Different Xray diffraction methods, Bragg 's law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of Xray diffraction.
Unit	6	Immunological assays: RIA(Radioimmunoassay), ELISA, Bioluminescence assays.

Books Recommended

1.SpectrometricIdentificationofOrganiccompounds-Robert M Silverstein, Sixth edition, John Wiley &Sons,2004.

2.Principlesof Instrumental Analysis-Doglas A Skoog, F. James Holler, Timothy A. Nieman,5th edition, Eastern press, Bangalore,1998.

3.Instrumentalmethodsofanalysis–Willards,7th edition, CBS publishers.
4.PracticalPharmaceuticalChemistry–Beckett and Stenlake, Vol II,4th edition, CBS Publishers, NewDelhi,1997.

5.OrganicSpectroscopy-WilliamKemp,3rd edition, ELBS,1991.
6.QuantitativeAnalysisofDrugsinPharmaceuticalformulation-PDSethi,3rd Edition, CBS Publishers, NewDelhi,1997.

7. Pharmaceutical Analysis-Modern methods–PartB-JW Munson, Volume 11, Marcel Dekker Series.

M. Pharm (Principles of Formulation Development)			
Sub Code:	23PMPT11		
University Examinations	Theory = 75	IA = 25	

Scope	This subject deals with basic principles in the development of dosage forms.
Objective	After completion of course student can select excipients, polymers in the development of dosage form for a given API. He can analyze the mechanisms involved in the release of drug, factors affecting stability of the product etc.

Unit	1	Pre-formulation studies: properties of drugs: solubility, size, pKa, log P, Polymorphism, Solvates, Hydrates, Crystal habit, salts, prodrug, stability Characterization and evaluation of drug and excipients : properties, interactions, compatibility
Unit	2	Excipients and Vehicle Selection; Types and Criteria Newer pharmaceutical excipients-diluents, stabilizers, preservatives, surfactants, solubilizers, super disintegrants, organoleptic additives
Unit	3	Polymers- a) introduction, classification, basic principles of polymerization, characterization and evaluation b) Biodegradable and non-biodegradable polymers and their pharmaceutical applications

Unit	4	Evaluation of drug release: Understanding the kinetics and mechanisms of drug release- Diffusion-models, theories, diffusion testing Dissolution-theories, models, dissolution testing, role of dissolution testing in bio-waivers.
Unit	5	Theories of Dispersion, stability of disperse systems
Unit	6	Concepts of Tableting: compaction and compression Stability testing and ICH guidelines

Books Recommended:

1. Rowe RC, Sheskey PJ, Quinn ME, Association AP. Handbook of Pharmaceutical Excipients. Sixth ed: Pharmaceutical Press; 2009.
2. Langer R, Chasin M. Biodegradable polymers as drug delivery systems. Marcel Dekker, New York; 1990.
3. Joseph RR, Vincent HL. Controlled drug delivery: Fundamentals and applications: Marcel Dekker, New York; 1988.
4. David E B, Paul Findlay W. Pharmaceutical Excipients: Characterization by IR, Rahman, and NMR Spectroscopy. 1st ed: CRC Press; 1999.
5. Fred Billmeyer W. Textbook of polymer science: Wiley; 1984.
6. Banker GS, Siepmann J, Rhodes C. Modern pharmaceutics: CRC Press; 2002.
7. Robinson JR. Sustained and controlled release drug delivery systems: Marcel Dekker, New York; 1978.
8. Rathbone MJ, Hadgraft J, Roberts MS, Lane ME. Modified-Release Drug Delivery Technology. second ed2008.
9. Mathiowitz E. Encyclopedia of controlled drug delivery: Wiley-Interscience; 1999.
10. Tarcha PJ. Polymers for Controlled Drug Delivery. First ed: CRC Press; 1990.
11. Huynh-Ba K. Handbook of stability testing in pharmaceutical development: regulations, methodologies, and best practices: Springer Science & Business Media; 2008.
12. Gowariker VR, Viswanathan NV, Sreedhar J. Polymer Science: Wiley Eastern; 1986.
13. Tess RW, Poehlein GW. Applied Polymer Science: American Chemical Society.; 1985.
14. Carstensen JT, Rhodes CT. Drug Stability: Principles and Practices. 3rd ed: Informa Healthcare; 2000.
15. Current ICH guidelines: *www.ich.org.*

M. Pharm (SPECIALIZED DRUG DELIVERY SYSTEMS)			
Sub Code:	23PMPT12		
University Examinations	Theory = 75	IA = 25	

Scope	This subject deals with novel or specialised drug delivery system for API.
Objective	After completion of course student can prepare new specialised drug delivery systems for APIs.

Unit	1	Sustained and Controlled Drug Delivery systems: Need, Requirements, Approaches for Design and Development, Characterization and Evaluation
Unit	2	Oral Novel Drug Delivery systems: Buccal, Gastric, enteric, colonic, rectal drug delivery systems

Unit	3	Transdermal drug delivery systems Ocular drug delivery systems
Unit	4	Vaginal drug delivery systems Uterine drug delivery systems
Unit	5	Nasal drug delivery systems Pulmonary drug delivery system: Metered dose inhalers, Dry powder inhalers and inhalation techniques and devices.
Unit	6	Triggered drug delivery systems: trigger mechanisms, External and Internal triggers Design aspects: Bio-activated systems, Externally activated systems

Books Recommended:

1. Novel Drug Delivery Systems, Y.W.Chien, Marcel Dekker, New York.
2. Edith Mathiowitz Ed. Encyclopedia of controlled drug delivery, John Wiley and Sons NY. 1999.
3. Controlled Release Dosage Form Design, Kim. C., CRC Press, Boca Raton, Florida, USA.
4. Bioadhesive Drug Delivery Systems, E. Mathiowitz, Vol 98, Marcel Dekker, NY.
5. Nasal Systemic Drug Delivery, Y. W. Chien and K.S.E. Su, Vol 39, Marcel Dekker, NY.
6. Drug Delivery Devices, Vol 32, P Tyle, Marcel Dekker, NY.
7. Drug Targeting, Strategies, Principles and applications, Francies G.E., Delgado Cristina, Humana Press, New Jersey, 2000.
8. Drug Targeting, Organ Specific Strategies (E. R. Monnhod, H. Kubiny, H. Timmerman), Molana Grietie, Dirk K.F. Meijer, Willey-VCH verley GmbH, 2001.
9. Targeted & controlled drug delivery (Novel Carrier Sysytem), S.P.Vyas & R.K.Khar, CBC Publisher & Distributors, New Delhi.
10. Advance in Controled & Novel Drug Delivery, N.K.Jain, CBC Publisher & Distributors, New Delhi.
11. Controlled Drug Delivery, J. R. Robinson and V. H. Lee, Marcel Dekker, Inc., New York.

M. Pharm (REGULATORY REQUIREMENTS FOR PHARMACEUTICALS)			
Sub Code:	23PMPT13		
University Examinations	Theory = 75	IA = 25	

Scope	Course designed to impart advanced knowledge and skills required to learn the concept of generic drug and their development, various regulatory filings in different countries, different phases of clinical trials and submitting regulatory documents: filing process of IND, NDA and ANDA. To know the approval process of. To know the chemistry, manufacturing controls and their regulatory importance. To learn the documentation requirements for To learn the importance
Objective	Upon completion of the course, it is expected that the students will be able to understand The Concepts of innovator and generic drugs, drug development process. The Regulatory guidance's and guidelines for filing and approval process. Preparation of Dossiers and their submission to regulatory agencies in different countries.

	Post approval regulatory requirements for actives and drug products. Submission of global documents in CTD/e CTD formats. Clinicaltrialsrequirementsforapprovalsforconductingclinicaltrials. Pharmacovigilance and process of monitoring in clinical trials.

Unit	1	Different regulatory guidelines: USA, EU countries, India and others Drug regulatory authorities in India— Introduction, Organization and General guidelines
Unit	2	Regulation and registration of Drugs, Medical devices, Cosmetics, Biologics & Biotechnological products in India ICH guidelines for Quality
Unit	3	Regulations concerning manufacturing practices (cGMP), laboratory practices (GLP), clinical practices (GCP), ISO 9000 series
Unit	4	New drug Application (NDA) and abbreviated new drug application (ANDA): contents and format, guidelines for filing NDA, New Drug Approval, exclusivities, Biowaver requirements in ANDA, Para I, II and III and IV approvals, 505 (b) 2 application and 505(j) application, Orange Book.
Unit	5	Regulatory documents (Dossier, Drug Master file (DMF), Common technical document (CTD/e CTD), NDA and ANDA, BLA etc.), their importance. Chemistry, Pharmacy, Manufacturing: Pharmaceutical Development, Packing material, active ingredients, excipients, controlled tests on the finished products, stability data, analytical method validation, bio-pharmaceutics
Unit	6	Preclinical pharmacology and toxicology: single dose, repeat dose, reproductive toxicity, mutagenicity, Oncogenicity/carcinogenicity, animal pharmacokinetics and toxicokinetics Clinical pharmacology and pharmacodynamics, pharmacokinetics in man, Ethnic, genetic and environmental factors. Clinical trials - general aspects of design and interpretation, statistical analysis of clinical data.

Books Recommended:

1. S. H. Willig, M.M.Tuckerman and W.S.Hitchings, ―Good Manufacturing Practices for Pharmaceuticals‖, Drugs and Pharm. Sci. Series, Vol. 16, Marcel Dekker Inc., N.Y.
2. Anthony c. Cartwright & Brain R. Matthews ―International Pharmaceutical Product Registration, Aspects of Quality, Safety and Efficacy‖- Taylor & Francis
3. Richard A. Guarino (Ed.) New Drug Approval Process, Marcel Dekker, Inc. New1P York.
4. www.mohfw.nic.in
5. www.usfda.gov
6. www.mhra.gov.uk
7. FDA regulatory Affairs, edited by D. J. Pisano and D. Mantus, CRS Press, Boca Rocan,Florida.
8. Drugs and Cosmetics Act, 1940 and its rules, published by Ministry of health and family welfare, Government of India
9. www.ich.org

M. Pharm (PHARMACEUTICAL TECHNOLOGY PRACTICAL I)			
Sub Code:	23PMPT1P		
University Examinations	Theory = 100	IA = 50	

1. Analysis of pharmacopoeial compounds and their formulations by UV-Vis spectrophotometer
2. Simultaneous estimation of multicomponent containing formulations by UV spectrophotometry
3.Experiments based on HPLC
4.Experiments based on Gas Chromatography
5.Estimation of riboflavin/quinine sulphate by fluorimetry
6.Estimation of sodium/potassium by flame photometry
7. Preformulation studies of given drugs: Determination of solubility, size, pKa, log P, Polymorphism, Solvates, Hydrates, Crystal habit, flow behavior, compression behavior and stability
8. To prepare, Characterize and Evaluate Sustained and Controlled Drug Delivery systems
9. To prepare, Characterize and Evaluate Buccal Drug Delivery systems
10. To prepare, Characterize and Evaluate Enteric Drug Delivery systems
11. To prepare, Characterize and Evaluate Colon Drug Delivery systems
12. To prepare, Characterize and Evaluate Rectal drug delivery systems
13. To prepare, Characterize and Evaluate Transdermal drug delivery systems
14. To prepare, Characterize and Evaluate Ocular drug delivery systems
15. To prepare, Characterize and Evaluate Vaginal drug delivery systems
16. To prepare, Characterize and Evaluate Nasal drug delivery systems
17. Determination of Molecular weight of polymers by various techniques – e.g. viscometry
18. Preparation and characterization of polymers by various methods
19.Study and evaluation of biodegradability of a biodegradable polymer
20. Study the effect of factors affecting diffusion
21. Study the effect of factors affecting dissolution
22. Understand the kinetics and mechanisms of drug release from dissolution profiles.
23. Study the factors affecting stability of drugs
24. Conduct stability studies as per ICH guidelines and predict shelf life

M. Pharm (Carriers for Drug Delivery)			
Sub Code:	23PMPT20		
University Examinations	Theory = 75	IA = 25	

Scope	This course is designed to impart knowledge on the area of advances in novel drug delivery systems.
Objective	Upon completion of the course student shall be able to understand. The various approaches for development of novel drug delivery systems. The criteria for selection of drugs and polymers for the development of NDDS. The formulation and evaluation of novel drug delivery systems.

Unit	1	**Microparticles**: Microspheres and Microcapsules, microencapsulation techniques. Characterization and Evaluation Kinetics and mechanisms of drug release
Unit	2	Colloidal dispersions -multiple emulsions, microemulsions, SMEDDs, nanoemulsions SNEDDs
Unit	3	**Vesicular systems**: Formulation, manufacturing, evaluation and applications of: a) Liposomes, Stealth liposomes, Niosomes. **b) Other vesicular systems**: Erythrosomes, Pharmacosomes, Ultradeformable vesicles, Ethosomes, aquasomes, Polymersomes etc.
Unit	4	**Nanocarriers**- Formulation, manufacturing, evaluation and applications of: **a)** polymeric nanoparticles, **b)** solid lipid nanoparticles, nanostructured lipid carriers, lipid drug conjugates
Unit	5	**Nanosuspensions, nanocrystals**: theories of nanosizing, Formulation aspects, top down and bottom-up techniques for manufacturing, and evaluation.
Unit	6	**Other nanocarriers** - Dendrimers, MSNs, CNTs, QD, metal nanoparticles etc.

Books Recommended:

1. Deasy PB. Microencapsulation and Related Drug Processes: Books on Demand; 1996.
2. Lachman L, Lieberman HA, Kanig JL. The Theory and Practice of Industrial Pharmacy: Varghese Publishing House; 1986.
3. Edith Mathiowitz Ed. Encyclopedia of controlled drug delivery, John Wiley and Sons NY. 1999.
4. Benita S. Microencapsulation: Methods and Industrial Applications, Second Edition: CRC Press; 2005.
5. Lieberman HA, Rieger MM, Banker GS. Pharmaceutical Dosage Forms- Disperse Systems: Marcel Dekker, New York; 1998.
6. Kreuter J. Colloidal drug delivery systems: Marcel Dekker Inc; New York; 1994.
7. Murthy RSR. Vesicular & Particulate Drug Delivery Systems: Career Publications; 2010.
8. Jain NK. Controlled and novel drug delivery. First ed: CBS Publisher; 2010.
9. Chien YW, Cabana BE, Mares SE. Novel Drug Delivery Systems: Fundamentals, Developmental Concepts, Biomedical Assessments: Marcel Dekker, 1982.

M. Pharm (ADVANCED BIOPHARMACEUTICS AND PHARMACOKINETICS)			
Sub Code:	23PMPT21		
University Examinations	Theory = 75	IA = 25	

Scope	This course is designed to impart knowledge and skills necessary for dose calculations, dose adjustments and to apply biopharmaceutics theories in practical problem solving. Basic theoretical discussions of the principles of biopharmaceuticsandpharmacokineticsareprovidedtohelpthestudents' to clarify the concepts.
Objective	Upon completion of this course, it is expected that students will be able understand, The basic concepts in biopharmaceutics and pharmacokinetics. The use raw data and derive the pharmacokinetic models and parameters the best describe the process of drug absorption, distribution, metabolism and elimination. The critical evaluation of biopharmaceutic studies involving drug product equivalency. The design and evaluation of dosage regimens of the drugs using pharmacokinetic and biopharmaceutic parameters. The potential clinical pharmacokinetic problems and application of basics of pharmacokinetic.

Unit	1	Drug Absorption from the Gastrointestinal Tract: Gastrointestinal tract, Mechanism of drug absorption, Factors affecting drug absorption, pH–partition theory of drug absorption, Formulation and physicochemical factors: Dissolution rate, Dissolution process, Noyes–Whitney equation and drug dissolution, Factors affecting the dissolution rate. Gastrointestinal absorption: role of the dosage form: Solution (elixir, syrup and solution), Suspension, Capsule, Tablet. Dissolution methods, Formulation and processing factors, Correlation of in vivo data with in vitro dissolution data. Transport model: Permeability-Solubility-Charge State and the pH Partition Hypothesis, Properties of the Gastrointestinal Tract (GIT), pH Microclimate Intracellular pH Environment, Tight-Junction Complex.
Unit	2	Biopharmaceutic considerations in drug product design and In Vitro Drug Product Performance: Introduction, biopharmaceutic factors affecting drug bioavailability, rate-limiting steps in drug absorption, physicochemical nature of the drug formulation factors affecting drug product performance, in vitro: dissolution and drug release testing, compendial methods of dissolution, alternative methods of dissolution testing, meeting dissolution requirements, problems of variable control in dissolution testing performance of drug products. In vitro–in vivo correlation, dissolution profile comparisons, drug product stability, considerations in the design of a drug product.
Unit	3	Pharmacokinetics: Basic considerations, pharmacokinetic models, compartment modelling: one compartment model- IV bolus, IV infusion, extra-vascular. Multi compartment model: two compartment - model in brief.

Unit	4	Non-linear pharmacokinetics: causes of non-linearity, Michaelis – Menten equation, estimation of Kmax and Vmax. Drug interactions: introduction, the effect of protein binding interactions, the effect of tissue-binding interactions, cytochrome p450-based drug interactions, drug interactions linked to transporters.
Unit	5	Drug Product Performance, In Vivo: Bioavailability and Bioequivalence: drug product performance, purpose of bioavailability studies, relative and absolute availability. Methods for assessing bioavailability, bioequivalence studies, design and evaluation of bioequivalence studies, study designs, cross over study designs, evaluation of the data, bioequivalence example, study submission and drug review process. Biopharmaceutics classification system, methods. Permeability: In-vitro, in-situ and In-vivo methods. generic biologics (biosimilar drug products), clinical significance of bioequivalence studies, special concerns in bioavailability and bioequivalence studies, generic substitution.
Unit	6	Application of Pharmacokinetics: Modified-Release Drug Products, Targeted Drug Delivery Systems and Biotechnological Products. Introduction to Pharmacokinetics and pharmacodynamic, drug interactions. Pharmacokinetics and pharmacodynamics of biotechnology drugs. Introduction, Proteins and peptides, Monoclonal antibodies, Oligonucleotides, Vaccines (immunotherapy), Gene therapies

References

1. Biopharmaceutics and Clinical Pharmacokinetics by Milo Gibaldi, Philadelphia, Lea and Febiger
2. Biopharmaceutics and Pharmacokinetics, A. Treatise, D .M. Brahmankar and Sunil B. Jaiswal., VallabPrakashan, Pitampura, Delhi
3. Applied Biopharmaceutics and Pharmacokinetics by Shargel. Land YuABC, Connecticut Appleton Century Crofts,
4. Textbook of Biopharmaceutics and Pharmacokinetics, Dr. Shobha Rani R. Hiremath, Prism Book
5. Pharmacokinetics by Milo Gibaldi and D. Perrier, Marcel Dekker Inc.,New York
6. Current Concepts in Pharmaceutical Sciences: Biopharmaceutics,Swarbrick. J, Leaand Febiger, Philadelphia,
7. Clinical Pharmacokinetics, Concepts and Applications by MalcolmRowland and Thom~ N. Tozer, Lea and Febiger, Philadelphia
8. Dissolution, Bioavailability and Bioequivalence, Abdou. H.M, Mack Publishing Company, Pennsylvania
9. Biopharmaceutics and Clinical Pharmacokinetics, An Introduction, by Robert. E. Notari, Marcel Dekker Inc, NewYork and Basel
10. Biopharmaceutics and Relevant Pharmacokinetics by John. G Wagner and M.Pemarowski, Drug Intelligence Publications, Hamilton, Illinois
11. Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James. G. Boylan, Marcel Dekker Inc, New York, 1996.
12. Basic Pharmacokinetics, Sunil S Jambhekar and Philip J Breen, Pharmaceutical Press, RPS Publishing
13. Absorption and Drug Development- Solubility, Permeability, and Charge State, Alex Avdeef, John Wiley & Sons, Inc.

M. Pharm (ADVANCES IN PHARMACEUTICAL TECHNOLOGY)			
Sub Code:	23PMPT22		
University Examinations	Theory = 75	IA = 25	

Scope	This course is designed to get knowledge about technologies adopted in Pharmaceutical Industry
Objective	Upon successful completion student will have knowledge on various important processes that are adopted in industry.

Unit	1	**Pharmaceutical factory location:** Site selection, layout and planning. **Design layout of manufacturing unit:** Consideration for design of large scale manufacturing unit including intricate design criteria and equipment required for units to manufacture of sterile and nonsterile products with special reference to different dosage forms, solids, liquids, semisolids, sterile.
Unit	2	**Utility services**, Service facilities, HVAC and personnel facilities. **Production Management** a) Production Planning and inventory control, Fundamentals of production, economic policy, manufacturing economics, production capacities, production lines and job balancing. b) Pharmaceutical process flow and work study. Pilot plant, scale up technique.
Unit	3	Fundamentals of Formulation and Process Development: Analytical process development a. Manufacturing process development (solid, semisolid, liquid). b. Manufacturing process development for sterile dosage forms and nanobiotechnology products
Unit	4	Pharmaceutical Development: Approaches for pharmaceutical development. a. Quality by Design (QBD) approach, ICH Q8 (R2), general considerations and structure, Quality Target Product Profile (QTPP), Critical Quality Attributes (CQAs), Critical Process Parameters (CPPs), Critical Material Attributes (CMAs), Selection of variables, Risk Assessment for the processes, Risk assessment tools (Fish-bone—Ishikawa diagram), b. Experimental designs, Design Space, Real Time Release Testing (RTRT), Process Analytical Technology (PAT), Control strategies
Unit	5	Quality risk management (QRM): General principles, Quality Risk Management Process; a. Risk control, communication and review, Risk management methods and tools (failure b. Mode effects analysis (FMEA), Failure mode, effects and criticality analysis (FMECA), Fault tree analysis (FTA), Hazard Analysis and Critical Control Points (HACCP), Hazard Operability Analysis (HAZOP), Preliminary Hazard Analysis (PHA), Risk Ranking and Filtering, Use of statistical tools.

		c. QRM applications to integrated quality management, regulatory operations, development, facilities, equipment and utilities, materials management, production, laboratory control and stability studies and packaging and labelling, case studies
Unit	6	**ICH guidelines** concerning Product and process development

Books Recommended:

1. H.A. Liebermen & L. Lachman, ―Pharmaceutical Dosage Forms: Tablets‖, Vols. I to III, Marcel Dekker Inc N.Y.

2. K.E.Avis, ―Pharmaceutical Dosage Forms : Parental Medication‖, Vol. I, Marcel Dekker Inc., N.Y.

3. S. Turco and R.E.King, ―Sterile Dosage Forms‖, 2nd edition

4. Pharmaceutical Production Facilities: Design and Applications (Pharmaceutical Science Series) second edition, CRC press -1998.

5. Basic principles of marketing and management

6. Staton, Etzel and Walker-fundaments of marketing.

7. Philip kotler – marketing management

8. Philip kotler and Armstrong- principles of marketing

9. http://en.wikipedia.org

10. B.T.Loftus & R.A.Nash, ―Pharmaceutical Process Validation‖, Drugs and Pharm Sci. Series, Vol. 23, Maarcel Dekker Inc., N.Y.

11. S. Bolton, ―Pharamaceutical Statistics : Practical & Clinical Applications‖, Drugs and Pharm. Sci. Series, Vol. 25, Marcel Dekker Inc., N.Y.

12. G.S.Banker & C.T.Rhodes, ―Modern Pharmaceutics‖, Drugs and Pharm. Sci. Series, Vol. 7, Marcel Dekker Inc., N.Y.

13. United States of Pharmacopeia

14. Code of Federal Register 21

15. ICH guidelines: www.ich.org

16. Specification of Drug Substances and Products, 1st Edition Development and Validation of Analytical Methods

17. Process Analytical Technology: Spectroscopic Tools and Implementation Strategies for the Chemical and Pharmaceutical Industries, 2nd Edition Katherine A. Bakeev (Editor)

18. Quality By Design Putting Theory Into Practice Edited and Authored by: Siegfried Schmitt.

19. John Sharp, Quality in the Manufacture of Medicines and other Healthcare Products

20. http://www.pharmaqbd.com/qbd_guidance.

M. Pharm (NOVEL FORMULATION APPROACHES)			
Sub Code:	23PMPT23		
University Examinations	Theory = 75	IA = 25	

Scope	This course is designed to impart knowledge on the area of advances in novel drug delivery systems.
Objective	Upon completion of the course student shall be able to understand. The various approaches for development of novel drug delivery systems especially targeting. The criteria for selection of drugs and polymers for the development of NDDS. The formulation and evaluation of novel drug delivery systems.

Unit	1	Targeted Drug Delivery Systems-Need for drug targeting, active and passive targeting, approaches for targeting
Unit	2	Targeting strategies for Cancer- Pathophysiology of cancer, site specific chemotherapy to lung, liver, CNS, uterus and other organs using various delivery systems.
Unit	3	Vaccine delivery systems: - Uptake of antigens, single shot vaccines, immune response, oral, mucosal, nasal, transdermal and injectable vaccines. Formulation, stability issues
Unit	4	Gene delivery- Potential target diseases for gene therapy, gene delivery systems Proteins and peptide delivery-barriers for protein and peptide delivery, formulation and evaluation of delivery systems of proteins and other macromolecules
Unit	5	Cosmeceuticals-Advances in cosmeceuticals such as skincare, hair care, dental products such as mouthwash, toothpaste etc including herbal cosmetics.
Unit	6	Approaches for improving solubility, bioavailability, flow properties etc.: Co-crystals, Inclusion complexes, liquid-solid compacts, solid dispersions,

Books recommended

1. Targeted & controlled drug delivery (Novel Carrier Sysytem), S.P.Vyas & R.K.Khar, CBC Publisher & Distributors, New Delhi.
2. Harry‘s cosmeticology, 8th edition.
3. Cosmetics-formulation, manufacture and quality control, 4th edition
4. Alain Rolland & sean M Sullivan, Pharmaceutical gene delivery systems, Drugs and pharmaceutical sciences, vol. 131, Marcel Dekker series.
5. Edith Mathiowitz, Encyclopedia of controlled drug delivery, John Wiley &sons, Inc.
6. Hans Schreier, Drug targeting technology, Drugs and pharmaceutical sciences, volume 115, Marcel dekker series.
7. Kreuter J. Colloidal drug delivery systems: Marcel Dekker Inc; New York; 1994.
8. Murthy RSR. Vesicular & Particulate Drug Delivery Systems: Career Publications; 2010.

M. Pharm (PHARMACEUTICAL TECHNOLOGY PRACTICAL II)			
Sub Code:	23PMPT2P		
University Examinations	Theory = 100	IA = 50	

1. Preparation and evaluation of
i) Microspheres and Microcapsules using various methods
ii) Multiple emulsions, microemulsions, SMEDDs, nanoemulsions SNEDDs
iii) Liposomes, niosomes by different methods
iv) Polymeric nanoparticles
v) Solid lipid nanoparticles**,** nanostructured lipid carriers, lipid drug conjugates
vi) Nanosuspensions, nanocrystals

2. Study of biopharmaceutic and pharmacokinetic parameters-transdermal diffusion, plasma protein binding, hepatic metabolism, drug interactions

3. Formulation of cosmeticeuticals- skin and hair care preparations