Nirma University

Institute of Pharmacy

Programme: **Master of Pharmacy in Pharmaceutics**

NIRMA UNIVERSITY

Institute of Pharmacy

(M. Pharm.: Pharmaceutics)

(Semester - I)

L	T	P	C
4			4

Course Code	**MPH101T**
Course Title	**Modern Pharmaceutical Analytical Techniques**

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.

Objectives:

After completion of course student is able to know,

1. Chemicals and Excipients.
2. The analysis of various drugs in single and combination dosage forms.
3. Theoretical and practical skills of the instruments

Course Learning Outcomes (CLO):

At the end of the course, students will be able to -

1. Recall the fundamental concepts of different spectroscopic techniques.
2. Understand the basics of immunological assays.
3. Recognize the fundamentals, instrumentation and applications of various chromatographic methods
4. Discuss the instrumentation and application of various spectroscopic techniques
5. Describe various electrophoretic techniques

Syllabus: **Teaching hours: 60 Hours**

UNIT I 11 Hours

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- **UV-Visible spectroscopy:**

Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV-Visible spectroscopy.

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.

Spectroflourimetry:Theory of Fluorescence, Factors affecting fluorescence, Quenchers, Instrumentation and Applications of fluorescence spectrophotometer.Flame emission spectroscopy and Atomic absorption spectroscopy:Principle, Instrumentation, Interferences and Applications.

UNIT II 11 Hours

- 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 13C NMR. Applications of NMR spectroscopy.

UNIT III 11 Hours

- 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, Meta stable 10ns, Isotopic peaks and Applications of Mass spectroscopy.

UNIT IV 11 Hours

- Chromatography:

Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution and applications of the following:

- Paper Chromatoraphy
- Thin Layer chromatography
- Ion exchange chromatography
- Column chromatography
- Gas chromatography
- High Performance Liquid chromatography
- Affinity chromatography

UNITV 16 Hours

- Electrophoresis:
  Principle, Instrumentation , Working conditions, factors affecting separation and applications the following:

  - Paper electrophoresis
  - Gel electrophoresis
  - Capillary electrophoresis
  - Zone electrophoresis
  - Moving boundary electrophoresis
  - Iso electric focusing

  X ray Crystallography:

  Production of X rays, Different X ray diffraction methods, Bragg's law, Rotating cryst technique, X ray powder technique, Types of crystals and applications of X-ray diffraction.

- Immunological assays:
  RIA (Radio immune assay), ELISA, Bioluminescence assays.

Suggested ReadingsA: (Latest edition)

1. Silverstein, R. M., Webster, F. X., Kiemle, D. J., & Bryce, D. L. Spectrometric Identification of Organic Compounds. Johnwiley & sons.
2. Skoog, D. A. H., James, F., & Nieman, T. A. Principles of Instrumental Analysis. Eastern press.
3. Hobart, W. H., Merritt LL, Dean John. A., Instrumental Methods of Analysis. CBS publishers.
4. Beckett, A. H., & Stenlake, J. B. (Eds.). Practical Pharmaceutical Chemistry: Part II Fourth Edition (Vol. 2). A&C Black.
5. Kemp, W. Organic Spectroscopy. ELBS.
6. Shethi, P. D. Quantitative Analysis of Drugs m Pharmaceutical Formulations. CBS Publishers.
7. Munson, J. W. Phannaceutical Analysis: Modern Methods (Vol. 11). CRC Press.

L= Lecture, T= Tutorial, P= Practical, C= Credit

A this is not an exhaustive list

(M. Pharm.: Pharmaceutics)

(Semester - I)

L	T	P	C
4	-		4

Course Code	MPH 102T
Course Title	Drug Delivery Systems

Scope:

This course is designed to impart knowledge on the area of advances in novel drug delivery systems.

Objectives:

Upon completion of the course, student should be able to understand

1. The various approaches for development of novel drug delivery systems.
2. The criteria for selection of drugs and polymers for the development of delivering systems
3. The formulation and evaluation of Novel drug delivery systems.

Course Learning Outcomes (CLO):

At the end of the course, students will be able to -

1. Understand the concepts and approaches of sustained/controlled and novel drug delivery systems.
2. Demonstrate techniques for formulation development of novel drug delivery
3. Discuss various approaches for site specific drug delivery systems.
4. Describe types of drug targeting and its applications.
5. Evaluate novel oral, topical and parenteral drug delivery systems.

Syllabus: Teaching hours: 60 Hours

UNIT-I 10 Hours

- Sustained Release (SR) and Controlled Release (CR) formulation: Introduction & basic concepts, advantages/ disadvantages, factors influencing, Physicochemical & biological approaches for SR/CR formulation, Mechanism of Drug Delivery from SR/CR formulation. Polymers: int roduction , definition, classification, properties and application Dosage Forms for Personalized Medicine: Introduction, Definition, Pharmacogenetics, Categories of Patients for Personalized Medicines: Customized drug delivery systems, Bioelectronic Medicines, 3D printing of pharmaceuticals, Telepharmacy.

UNIT-II 10 Hours

- Rate Controlled Drug Delivery Systems:
  Principles & Fundamentals, Types, Activation; Modulated Drug Delivery Systems; Mechanically activated, PH activated , Enzyme activated, and Osmotic activated Drug Delivery Systems Feedback regulated Drug Delivery Systems; Principles & Fundamentals.

UNIT-III 10 Hours

- Gastro-Retentive Drug Delivery Systems:
  Principle, concepts advantages and disadvantages, Modulation of GI transit time approaches to extend GI transit. Buccal Drug Delivery Systems: Principle of muco-adhesion, advantages and disadvantages, Mechanism of drug permeation, Methods of formulation and its evaluations.

UNIT-IV 16 Hours

- Occular Drug Delivery Systems:
  Barriers of drug permeation, Methods to overcome barriers.

- Trans Dermal Drug Delivery Systems:
  Structure of skin and barriers, Penetration enhancers, Transdermal Drug Delivery Systems, Formulation and evaluation

UNIT-V 14 Hours

- Protein and Peptide Delivery:
  Barriers for protein delivery. Formulation and Evaluation of delivery systems of proteins and other macromolecules.

- Vaccine delivery systems:
  Vaccines, uptake of antigens, single shot vaccines, mucosal and transdermal delivery of vaccmes.

Suggested Readings": (Latest Edition)

1. Chien, Y W. Novel Drug Delivery Systems, New York: Marcel Dekker, Inc.
2. Robinson, J. R., Lee V. H. L. Controlled Drug Delivery Systems, New York: Marcel Dekker, Inc.
3. Edith Mathiowitz, Encyclopedia of controlled delivery, New York: Wiley Interscience Publication, John Wiley and Sons, Inc.
4. Jain, N.K. Controlled and Novel Drug Delivery, New Delhi: CBS Publishers & Distributors.
5. Vyas, S. **P.** and Khar, R. K. Controlled Drug Delivery - concepts and advances, New Delhi: Vallabh Prakashan.

JOURNALS

1. Indian Journal of Pharmaceutical Sciences (IPA)
2. Indian drugs (IDMA)
3. Journal of controlled release (Elsevier Sciences) desirable
4. Drug Development and Industrial Pharmacy (Marcel & Decker) desirable

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(M. Pharm.: Pharmaceutics)

(Semester - I)

L	T	P	C
4	-		4

Course Code	**MPH 103T**
Course Title	**Modern Pharmaceutics**

Scope:

Course designed to impart advanced knowledge and skills required to learn various aspects and concepts at pharmaceutical industries

Objectives:

Upon completion of the course, student should be able to understand

1. The elements of preformulation studies.
2. The Active Pharmaceutical Ingredients and Generic drug Product development
3. Industrial Management and GMP Considerations.
4. Optimization Techniques & Pilot Plant Scale Up Techniques
5. Stability Testing, sterilization process & packaging of dosage forms.

Course Leaming Outcomes (CLO):

At the end of the course, students will be able to -

1. Identify key preformulation parameters for various dosage forms
2. Recognize the importance of optimization techniques and its selection
3. Explain types, protocol and process of validation
4. Correlate GMP with pharmaceutical production including pilot scale up
5. Estimate diffusion and dissolution parameters for drug release
6. Prepare stability, sterilization and packaging protocol of various dosage forms

Syllabus **Teaching hours: 60 Hours**

UNIT I **10 Hours**

- Preformation Concepts: Drug Excipient interactions - different methods, kinetics of stability, Stability testing. Theories of dispersion and pharmaceutical Dispersion (Emulsion and Suspension, SMEDDS) preparation and stability, Large and small volume parental - physiological and formulation consideration, Manufacturing and evaluation.

UNIT II 10 Hours

- Optimization techniques in Pharmaceutical Formulation: Concept and parameters of optimization, Optimization techniques in pharmaceutical formulation and processing. Statistical design, Response surface method, Contour designs, Factorial designs and application in formulation.

UNIT III 10 Hours

- Validation: Introduction to Pharmaceutical Validation, Scope & merits of Validation, Validation and calibration of Master plan, ICH & WHO guidelines for calibration and validation of equipments, Validation of specific dosage form, Types of validation. Government regulation, Manufacturing Process Model, URS, DQ, IQ, OQ & PQ of facilities

UNIT IV 10 Hours

- cGMP & Industrial Management: Objectives and policies of current good manufacturing practices, layout of buildings, services, equipments and their maintenance Production management: Production organization, materials management, handling and transportation, inventory management and control, production and planning control, Sales forecasting, budget and cost control, industrial and personal relationship. Concept of Total Quality Management

UNIT V 20 Hours

- Compression and compaction: Physics of tablet compression, compression, consolidation, effect of friction, distribution of forces, compaction profiles. Solubility enhancement techniques.
- Study of consolidation parameters: Diffusion parameters, Dissolution parameters and Pharmacokinetic parameters, Heckal plats, Similarity factors - f2 and fl, Higuchi and peppas plot, Linearity Concept of significance, Standard deviation , chi square test , student T-test, Anova test.

Suggested Readings: (Latest Edition)

1. Leon Lachmann, & Herbert, A.L. The Theory and Practice of Industrial Pharmacy. New Delhi: CBS Publishers & Distributors Pvt. Ltd.
2. Lieberman, H.A., Leon, Lachmann, Schwartz, J.B. Pharmaceutical dosage forms: Tablets Vol.1-3, New York: Marcel Dekker
3. Lieberman, H.A., Leon, Lachmann, Schwartz, J. B. Pharmaceutical Dosage forms: Disperse systems, Vol, 1-2, New York: Marcel Dekker
4. Lieberman, H.A., Leon, Lachmann, Schwartz, J.B. Pharmaceutical Dosage forms: Parenteral medications Vol. 1-2, New York: Marcel Dekker
5. Gilbert, S.B. and Rhodes, C.T. Modem Pharmaceutics, New York: Marcel Dekker
6. Remington, J. P., & Gennaro, A. R. Remington: The Science and Practice of Pharmacy. Lippincott Williams.
7. Bean, H.S. and Beckett, A.H. Advances in Pharmaceutical Sciences, London: Academic Press
8. Sinko, Martyns Physical Pharmacy and Pharmaceutical Sciences, Lippincott Williams and Walkins.
9. Bentley, A.O., & Rawlins, E.A. Bentley's Text Book of Pharmaceutics. USA: Elsevier Health Sciences.
10. Sidney, **H.** W. Good manufacturing practices for Pharmaceuticals: A plan for total quality control, New York: Marcel Dekker.
11. Organization of Pharmaceutical producers of lndia. Quality Assurance Guide.

12. Kohli, D.P.S. and Shah, D.H. Drug formulation manual, New Delhi: Eastern publishers
13. Sharma, P.P. How to practice GMPs, Agra: Vandhana Publications.
14. Berry, F.R. and Nash, R.A. Pharmaceutical Process Validation, Marcel Dekker
15. Wells, J. J. Pharmaceutical Preformulations, Ellis Horwood Limited
16. Evans J.R., Anderson Sweeney and Williams. Applied production and operations management, south-Western.
17. Swarbrick, J. Encyclopaedia of Pharmaceutical technology, Vol 1-111, CRC press.

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(M. Pharm.: Pharmaceutics)

(Semester - I)

L	T	P	C
4	-		4

Course Code	**MPH 104T**
Course Title	**Regulatory Affairs**

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

Objectives:

Upon completion of the course, it is expected that the students will be able to understand

1. The Concepts of innovator and generic drugs, drug development process
2. The Regulatory guidance's and guidelines for filing and approval process
3. Preparation of Dossiers and their submission to regulatory agencies in different countries
4. Post approval regulatory requirements for actives and drug products
5. Submission of global documents in CTD/ eCTD formats
6. Clinical trials requirements for approvals for conducting clinical trials
7. Pharmacovigilence and process of monitoring in clinical trials.

Course Learning Outcomes (CLO):

At the end of the course, students will be able to -

1. Understand the drug approval processes for various regulatory agencies
2. Explain various types of documentation in pharmaceutical Industries
3. Understand preparation of Dossiers and their submission including post approval requirements for different countries
4. Describe global submission of IND, NDA and ANDA.
5. Review the requirements for approvals for conducting clinical trials
6. Interpret various regulations for clinical trials and pharmacovigilance

Syllabus: Teaching hours: 60 Hours

UNIT I 12 Hours

- Documentation in pharmaceutical industry: Master formula record, DMF (Drug Master File), distribution records. Generic drugs product development Introduction, Hatch-Waxman act and amendments , CFR (CODE OF FEDERAL REGULATION), drug

product performance, in-vitro, ANDA regulatory approval process, NDA approval process, BE and drug product assessment, in - vivo, scale up process approval changes, post marketing surveillance, outsourcing BA and BE to CRO.

UNIT II 12 Hours

- Regulatory requirement for product approval: API, biologics, novel, therapies obtaining NDA, ANDA for generic drugs ways and means of US registration for foreign drugs

UNIT III 12 Hours

- Regulatory requirements of various countries: CMC, post approval regulatory affairs. Regulation for combination products and medical devices CTD and ECTD format, industry and FDA liaison. ICH - Guidelines of ICH-Q,S E,M. Regulatory requirements of EU, MHRA, TGA and ROW countries.

UNIT IV 12 Hours

- Non clinical drug development: Global submission of IND, NDA, ANDA. Investigation medicinal products dossier, dossier (IMPD) and investigator brochure (IB)

UNIT V 12 Hours

- Clinical trials: Developing clinical trial protocols. Institutional review board / independent ethics committee Formulation and working procedures informed Consent process and procedures. HIPAA-new, requirement to clinical study process, pharmacovigilance safety monitoring in clinical trials.

Suggested Readings": (Latest Edition)

1. Leon Shargel and IsaderKaufer, Generic Drug Product Development, Solid Oral Dosage forms, Marcel Dekker series.
2. Berry, I. R. and Robert, P. M. The Pharmaceutical Regulatory Process, Drugs and the Pharmaceutical Sciences, Informa Health care Publishers.
3. Richard, A. G., New Drug Approval Process: Accelerating Global Registrations, Drugs and the Pharmaceutical Sciences, Informa Healthcare
4. Sandy Weinberg. Guidebook for drug regulatory submissions, Wiley & Sons.Inc.
5. Douglas J. P., David Mantus. FDA regulatory affairs: a guide for prescription drugs, medical devices, and biologics Informa Healthcare
6. Fay A. R. and Rodney K. A. Clinical Trials and Human Research: A Practical Guide to Regulatory Compliance, John Wiley & Sons.
7. www.ich.org/
8. www.fda.gov/
9. europa.eu/index_en.htm
10. https://www.tga.gov.au/tga-basics

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(M. Pharm.: Pharmaceutics)

(Semester - I)

L	T	P	C
		12	6

Course Code	MPH 105P
Course Title	Pharmaceutics Practical I

PRACTICALS **180 Hours**

1. Analysis of pharmacopoeia} compounds and their formulations by UV Vis spectrophotometer
2. Simultaneous estimation of multi component containing formulations by UV spectrophotometry
3. Experiments based on HPLC
4. Experiments based on Gas Chromatography
5. Estimation ofriboflavin/quinine sulphate by fluorimetry
6. Estimation of sodium/potassiumby flame photometry
7. To perform In-vitro dissolution profile of CR/ SR marketed formulation
8. Formulation and evaluation of sustained release matrix tablets
9. Formulation and evaluation osmotically controlled DDS
10. Preparation and evaluation of Floating DDS- hydro dynamically balanced DDS
11. Formulation and evaluation ofMucoadhesive tablets.
12. Formulation and evaluation of transdermal patches.
13. To carry out prefonnulation studies of tablets.
14. To study the effect of compressional force on tablets disintegration time.
15. To study Micromeritic properties of powders and granulation.
16. To study the effect of particle size on dissolution of a tablet.
17. To study the effect of binders on dissolution of a tablet.
18. To plot Heckal plot, Higuchi and peppas plot and determine similarity factors.

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(M.Pharm. - Pharmaceutics)

(Semester - I)

L	T	p	C
		7	4

Course Code	MPH106S
Course Title	Seminar /Assignment-I

Nirma University

Institute of Pharmacy

M. Pharm. Semester – I

COURSE NAME: ADVANCED INSTRUMENTAL METHODS [3PH106]

Learning outcomes:

After successful completion of the course, student will be able to:

- Understand the fundamentals of spectroscopy and chromatographic techniques.
- Use spectroscopy for the quantitative and qualitative analysis of drugs.
- Predict the structure of unknown compounds.

Theory (Detailed Syllabus)	**L**	**P**	**C**
	3	**3**	**5**

Applications and recent trends in the modem methodology used for the analysis of drugs and their metabolites of the following techniques

A) Spectroscopic Techniques

UV-Visible spectrophotometry: Theory of electronic spectroscopy, absorption by organic molecules, choice of solvent and solvent effect, applications of UV-Visible spectroscopy, Woodward - Fischer rules for calculating absorption maximum, photometric titrations and its applications

Infra-red spectrophotometry: Absorption in the infrared region, factors influencing molecular vibrations, Canculation of vibrational frequencies, applications, interpretation of infra red spectra, FTIR- Theory, Instrumentation, Attenuated Total reflectance spectroscopy (ATR)

Nuclear Magnetic Resonance Spectroscopy: Basic principles, theory of PMR spectroscopy, Instrumentation, applications, Chemical shift, spin-spin coupling, factors affecting chemical shift and spin coupling, ^{13}C NMR spectroscopy, interpretation of NMR spectra, 2D NMR spectroscopy Mass spectroscopy : Basic principles, ion formation and types, Fragmentation rules, recognition of molecular ion peak, Tandem mass spectroscopy, MALDI, FAB, SIMS, Structure elucidation of pharmaceutical compounds using different spectroscopic Techniques like UV-Visible, IR, NMR, MASS etc..

B) Separation Techniques

Classification of chromatographic methods based upon mechanism of separation, mode of separation, ion pair chromatography and applications

1. High Pressure Liquid Chromatography: RP-HPLC, chiral, Hydrophobic interaction, Size exclusion, Ion exchange, Affinity chromatography, ion chromatography
2. Gas chromatography: column operation, derivatization methods
3. Hyphenated techniques: LC-MS, LC-MS/MS, GC-MS, tandam mass spectroscopy
4. HPTLC
5. Super Critical Fluid Chromatography: Basic Principles, Instrumentation

Practical

1 Analysis of drugs and raw materials using official pharmacopoeia! methods based on modern instrumental techniques.

2 Testing of related substances and foreign substances in raw materials as per LP.

3 Assay for the raw materials, calculated either on anhydrous or hydrous basis as per LP.
4 Interpretation of UV, IR, NMR and Mass spectra and its use in structure elucidation.

Books Recommended

1. R. M. Silversterin, G. C. Bassler and T. C. Morrihl, Spectrometric Identification of Organic Compounds, 6th edn, John Wiley, New York, 1998.
2. P. S. Kalsi, Spectroscopy of Organic Compounds, New Age Publication, 2002.
3. D. A. Skoog, E. J. Holler and T. A. Nieman, Principles oflnstrumental Analysis , Harcourt Asia Pte Ltd, 2001.
4. S. Lindsay, High Performance Liquid Chromatography, Analytical Chemistry by Open Leaming (ACOL), Wiley, 1987.

Sethi, P.D., High performance thin layer chromatography: Quantitative analysis of pharmaceutical formulations, 1996.

Nirma University
Institute of Pharmacy

M. Pharm. [Pharmaceutical Technology & Bio-pharmaceutics]
Semester-I

COURSE NAME: ADVANCES IN PHARMACEUTICAL TECHNOLOGY [3PT102]

Learning Outcomes:

After successful completion of course, students will be able to:

- Demonstrate practical skills and expertise for specialized pharmaceutical processes and techniques by advances in technologies and formulation development of solid and liquid dosage forms.
- Apply their in-depth knowledge in the field of design and perfonnance of pharmaceutical dosage forms.
- Evaluate therapeutic management of diseases based on knowledge of drug development & characterization.
- Develop formulation using suitable packaging technology.

Theory (Detailed Syllabus)

L	P	C
3	6	6

1) Introduction to modified release drug delivery system

Concepts of Absorption, Distribution, Metabolism and Excretion in the modified release drug delivery systems. Novel physical, chemical and biological approaches for sustained and controlled drug delivery, factors influencing the design and performance of controlled release dosage form.

2) Specialized Pharmaceutical Process & Techniques

Freeze Drying (Lyophillization), Spray Processing, Fluidized Bed Processing, Extrusion and Spheronization, Super Critical Fluid Processing, Spherical Crystallization, Vacuum Drying, Nanonization. Advances in technologies for formulation development of solid , non-sterile and sterile liquid.

3) Current Pharmaceutical Excipients and Carriers

Brief overview, classification and applications of currently used pharmaceutical excipients and carriers. Study of physicochemical properties, mechanism and applications of pharmaceutical polymers like vinyl, cellulose ethers, polyesters, silicones, polysaccharides and miscellaneous.

4) Advances in Pharmaceutical Packaging

Materials for packaging of pharmaceuticals, types of packaging components and their evaluation, Regulatory aspects related to packaging, Stability aspects and product - package interaction, Innovations in packaging technology.

5) Drug approval process

Brief overview of INDA, NDA and ANDA: General requirements, Investigational brochure and clinical study protocols, including concept of Paragraph I to IV.

Practicals

1. Practical relating to modified release drug delivery.
2. Practicals related to development of multifunctional excipients (co-processed excipients).
3. Practicals relating to types of Packaging components and their evaluations.

Books Recommended

1. Phannaceutical Preformulation by J. T. Carstensen, Marcel Dekker, New York
2. Drug stability, principles and practices, by J. T. Carstensen, Marcel Dekker, New York
3. Handbook of Pharmaceutical Excipients, Raymond Rowe, Paul Sheskey and Paul Welle, Pharmaceutical Press, London.
4. Modem Pharmaceutics by Gilbert S. Banker and Christopher T. Rodhes, Marcel Dekker, New York
5. Sustained Controlled drug and delivery by Joseph R. Robinson, Marcel Dekker, New York
6. Freeze drying - Lyophilization of pharmaceutical and biological products, by Louis Rey and Joan C. May lnforma healthcare, New York
7. Hand book of Pharmaceuitcal Granulation Technology, Dilip Parikh, T&F
8. Polymeric drug delivery systems, by Glen S. Kwon, Taylor and Francis
9. Pharmaceutical Preformulation and Formulation: A Practical Guide from Candidate Drug Selection to Commercial Dosage Form Ed by Mark Gibson, Informa Healthcare, UK
10. Handbook of Preformulation: Chemical, Biological and Botanical Drugs by Sarfaraz K.Niazi, Informa Healthcare, UK
11. Pharmaceutical Packaging technolo gy, D. D. Dean, Taylor and francis, UK
12. Pharmaceutical Packaging technolo gy, U. **K.** Jain, Pharmmed press, India
13. Packaging of Pharmaceuticals and Healthcare Products, H. Lockhart and F. A. Paine, Blackie A&P, London.
14. Phannaceutical Packaging Handbook, E. J. Bauer, Infonna Healthcare, UK
15. Quality Control of Packaging Materials in the Phannaceutical Industry, Kenneth Harbour, lnforma Healthcare, UK
16. Excipient Development for Pharmaceutical, Biotechnology and Drug Delivery Technology by Ashok Katdare, Informa Healthcare, UK.
17. Pharmaceutical Photostability and Stabilization Technology Ed by Joseph T. Piechocki and Karl Thoma, Informa Healthcare, UK.
18. Photostability of Drugs and Drug Formulations Ed by Hjorth Tonnesen, Taylor and francis, UK

M. Pharm. [Pharmaceutical Technology & Bio-pharmaceutics]
Semester-I

COURSE NAME: FORMULATION, DEVELOPMENT AND OPTIMIZATION (3PT103)

Learning Outcomes:

After successful completion of course, students will be able to:

- Identify the critical parameters for dissolution and diffusion studies of various dosage forms.
- Demonstrate the knowledge of the regulatory requirements (i.e. stability and dissolution studies).
- Perform the preformulation and stability study with understanding its significance.
- Apply various optimization techniques such as factorial design, composite design, simplex lattice design and composite mixtures in various dosage forms using various research problems.

Theory (Detailed Syllabus)

L	P	C
3	*3*	*5*

1. **Pharmaceutical Preformulation**
   Perspective & Concepts, Preformulation methodology : Selection of Drug candidate and type of formulation, Physical, Chemical and Pharmaceutical Factors influencing formulation of drugs, Analytical Methods for characterization of Drug & Excipients, Drug- Excipient compatibility study
2. **Principles of Kinetics and Stability Testing**
   Basic concepts & Objectives, order ofreaction, Physical, Chemical and Pharmaceutical Factors influencing stability studies, Chemical and Physical stability testing methodologies, Photostability study, Significance of Accelerated stability study, Shelf life and Expiry dating, Indian and International Guidelines for stability testing, Stability of packaging material
3. **Drug release study**
   - Dissolution study
     Introduction and im portance, factors affecting dissolution , biopharmaceutical classification system (BCS) : its significance on dissolution study and application **in** dosage form development , selection of dissolution medium and conditions, comparison of dissolution profile by model independent (similarity and dissimilarity factor) and dependent method, SUPAC guidelines for the dosage forms.
   - Diffusion study
     Significance, factors affecting diffusion, mechanism, methods, apparatus used in diffusion study, overview of diffusion study of various dosage form and statistical analysis.

4. **Optimization techniques for pharmaceutical formulation**
   Introduction and applications, types of variables , selection of variables, full and fractional factorial designs, composite designs, simplex lattice, mixture designs and sequential optimization, Artificial Neural Network (ANN).

5. **Specialized Formulations**
   Brief studies on Reconstituted suspensions, Rapidly disintegrating tablets, films, beads, Microemulsion, Microencapsulations , In-situ gelling system, Self-emulsifying drug delivery systems (SEDDS), Capsules from non animal source, Metered Dose Inhalers (MDI) and Dry Powder Inhalers (DPI).

Practicals

1. Preformulation studies of various drugs and dosage forms.
2. Accelerated stability studies of drug and its formulations.
3. Practicals related to calculation of Shelflife and overages.
4. Practicals relating to specialized formulations.
5. In vitro dissolution studies of drugs and dosage forms.
6. Practicals relating to statistical optimization of dosage forms.

Books Recommended

1. Phannaceutical Dosage Forms: Tablets Vol. 1, Vol. 2 and Vol. 3, Lieberman, Leon Lachman and Joseph B. Schwartz, Marcel Dekker , New York.
2. Encyclopedia of Pharmaceutical Technology Vol. 1, Vol. 2 and Vol. 3, by James Swarbrick and James C. Boylan by Banker, Gilbert S. Rhodes, Christopher T., Marcel Dekker, New York.
3. Sustained and controlled drug and delivery by Joseph R. Robinson, Marcel Dekker, New York.
4. Pharmaceutical Statistics by Sanford Bolton, Marcel Dekker, New York.
5. Pharmaceutical Dissolution Testing by Banakar, Marcel Dekker, New York.
6. Drug formulations, Manual, by D. P. S. Kohli, D. H. Shah, Eastern publishers, New Delhi, India
7. New drug approval process, by Richard A. Guarino, Marcel Dekker, NY
8. Modified release drug delivery technology , Volume 1 & 2, by Michael J. Rathbone, Michael S. Roberts, lnforma Healthcare, UK
9. Pharmaceutical Inhalation Aerosol Technology, by Anthony J. Hic key, Marcel and Dekker, NY
10. Pharmaceutical Dissolution Testing by Jennifer Dressman and Johannes Kramer, Taylor & Francis , UK
11. New Drug Approval Process: Accelerating Global Registrations Ed by Richard A. Guarin o, Marcel Dekker, NY
12. Pharmaceutical Experimental Design by Gareth A. Lewis , Didier Mathieu and Roger PhanTan-Luu, Marcel and Dekker, NY

M. Pharm. Semester - I

COURSE NAME: COMMUNICATION SKILLS FOR PHARMACISTS [3PH108]

Learning Outcomes:

After successful completion of the course student will be able to :

- Use appropriate vocabulary for fluent and confident oral communication
- Recognize and understand important aspects of non-verbal communication
- Demonstrate communication capacities in speaking, writing, listening and narrating in English
- Prepare curriculum vitae and job application

Tutorial (Detailed Syllabus)

L T C

2 2

Practice Assignments based on the following topics will be conducted

1. **Non-verbal communication**
   Meaning and process of pharmaceutical communication kinesics, types of communication, psychological and social aspects of communication, barriers to effective communication.
2. **Oral communication (verbal communication)**
   Effective presentation skills, group discussion dynamics, personal interview techniques, seminar presentation, media choice for oral presentation, active listening through recorded speech. correct pronunciation, group discussion. delivering the speech or presentation, traditional text based oral presentation. visual element of texts, tables, figures, charts, etc.
3. **Written communication**
   Technical - writing and discussion, technical instructions, writing research papers, paragraph development, curriculum vitae and job application.
4. **Mechanics of language and vocabulary building**
5. **Listening skills**
   Types of listening, barriers to effective listening, tips to improve listening skills.

Books Recommended

1. Tindall W.N, Beardsley R.S., Kimberlin C.L., Communication Skills in Pharmacy Practice: A Practical Guide for Students and Practiti oners, Lippincott Williams & Wilkins.
2. J. R. Matthews and R.W. Matthews, Successful Scientific Writin g, Cambridge University Press Sin gapore.
3. R. A. Day, How to write and publish a scientific paper, Cambridge University Press Singapore.
4. A. J. Rutherford , Basic Communication Skills for Technology, Pearson.
5. R.C. Sharma and K. Mohan Business Correspondence and Report Writing Tata McGraw

M. Pharm. Semester - I

COURSE NAME: SUBJECT SEMINAR [3PT104]

L T C

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NIRMA UNIVERSITY

Institute of Pharmacy

(M. Pharm.: Pharmaceutics)

(Semester - II)

L	T	P	C
4	-		4

Course Code	**MPH201T**
Course Title	**Molecular Pharmaceutics (Nano Tech & Targeted DDS)**

Scope:

This course is designed to impart knowledge on the area of advances in novel drug delivery systems.

Objectives:

1. The various approaches for development of novel drug delivery systems.
2. The criteria for selection of drugs and polymers for the development of NTDS
3. The fonnulation and evaluation of novel drug delivery systems.

Course Learning Outcomes (CLO):

At the end of the course, students will be able to -

1. Understand the conceP.tS of targeted and gene based drug delivery systems.
2. Compare various approaches for development of targeted drug delivery systems.
3. Explain types, manufacturing techniques and applications of microparticulate, nanoparticulate and vesicular drug delivery systems.
4. []iscuss various approaches for pulmonary drug delivery systems.
5. Analyze various nano and targeted drug delivery systems.

Syllabus: Teaching Hours: 60 Hours

UNIT I 12 Hours

- Targeted Drug Delivery Systems:

Concepts, Events and biological process involved in drug targeting . Tumor targeting and Brain specific delivery.

UNIT II 12 Hours

- Targeting Methods:

  Introduction preparation and evaluation. Nano Particles & Liposomes: Types, preparation and evaluation.

UNIT III 12 Hours

- Micro Capsules / Micro Spheres:

  Types, preparation and evaluation, Monoclonal Antibodies; preparation and application, preparation and application of Niosomes, Aquasomes, Phytosomes, Electrosomes.

UNIT IV 12 Hours

- Pulmonary Drug Delivery Systems :

  Aerosols, propellents, Containers Types, preparation and evaluation, Intra Nasal Route Delivery systems; Types, preparation and evaluation.

UNITY 12 Hours

- Nucleic acid based therapeutic delivery system:

  Gene therapy, introduction (ex-vivo & in-vivo gene therapy). Potential target diseases for gene therapy (inherited disorder and cancer). Gene expression systems (viral and nonviral gene transfer). Liposomal gene delivery systems. Biodistribution and Pharmacokinetics. Knowledge of therapeutic antisense molecules and aptamers as drugs of future.

Suggested Readings A: (Latest edition)

1. Y W. Chien, Novel Drug Delivery Systems, 2nd edition, revised and expanded, Marcel Dekker, Inc., New York, 1992.
2. S.P.Vyas and R.K.Khar, Controlled Drug Delivery - concepts and advances, Vallabh Prakashan, New Delhi, First edition 2002.
3. N.K. Jain, Controlled and Novel Drug Delivery, CBS Publishers & Distributors, New Delhi, First edition 1997 (reprint in 2001).

L= Lecture, T= Tutorial, P= Practical, C= Credit

A this is not an exhaustive list

(M. Pharm.: Pharmaceutics)

(Semester - II)

L	T	P	C
4			4

Course Code	**MPH202T**
Course Title	**Advanced Biopharmaceutics & Pharmacokinetics**

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 biopharmaceutics and pharmacokinetics are provided to help the students' to clarify the concepts.

Objectives:

After completion of course student is able to know,

1. The basic concepts in biopharmaceutics and pharmacokinetics.
2. The use raw data and derive the pharmacokinetic models and parameters the best describe the process of drug absorption, distribution, metabolism and elimination.
3. The critical evaluation of biopharmaceutic studies involving drug product equivalency.
4. The design and evaluation of dosage regimens of the drugs using pharmacokinetic and biopharmaceutic parameters.
5. The potential clinical pharmacokinetic problems and application of basics of pharmacokinetic

Course Learning Outcomes (CLO):

At the end of the course, students will be able to -

1. Understand concept of drug absorption in human.
2. Correlate drug dissolution with pharmacokinetics.
3. Derive the pharmacokinetic parameters alongwith its interpretation.
4. Estimate pharmacokinetics parameters with its application.
5. Explain development of BA-BE protocol as per various regulations.
6. Apply concepts of pharmacokinetics in clinical situations.

Syllabus: Teaching Hours: 60 Hours

UNIT I 12 Hours

- Drug Absorption From The Gastrointestinal Tract:

Gastrointestinal tract, Mechanism of drug absorption, Factors affecting passive drug absorption, pH- partition theory of drug absorption. Factors affecting drug absorption: 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) as a dosage form ,Suspension as a dosage form, Capsule as a dosage form, Tablet as a dosage form, 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 II 12 Hours

- Biopharmaceutic Considerations m 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 III 12 Hours

- Pharmacokinetics:

Basic considerations, Phannacokinetic models, Compartment modeling: One compartment model-IV bolus, IV infusion, Extravascular. Multi Compartment model: Two compartment - model in brief, Non Linear Pharmacokinetics: Cause of non-linearity, Michaelis - Menten equation, Estimation K_{max} and V_{max}. 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 IV 12 Hours

- 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, Crossover Study Designs, Evaluation of the Data, Bioequivalence Example, Study Submission and Drug Review Process. Biopharmaceutics Classification System, Generic Biologics (Biosimilar Drug Products), Clinical Significance of Bioequivalence Studies, Special Concerns in Bioavailability and Bioequivalence Studies, Generic Substitution.

UNITY 12 Hours

- Application of Pharmacokinetics:

Modified-Release Drug Products, Targeted Drug Delivery Systems and Biotechnological Products. Pharmacokinetic and pharmacodynamic, drug interactions. Pharmacokinetics and pharmacodynamics of biotechnology drugs. Introduction, Proteins and peptides, Monoclonal antibodies, Oligonucleotides, Vaccines (immunotherapy), Gene therapies.

Suggested Readings": (Latest edition)

1. Gibaldi Milo. Biopharmaceutics and Clinical Pharmacokinetics, Philadelphia, Lea and Febiger.

2. Brahmankar D. M., Jaiswal S. B. Biopharmaceutics and Pharmacokinetics: A Treatise, Delhi, Vallabh Prakashan.

3. Shargel, Applied Biophannaceutics and Pharmacokinetics, Connecticut Appleton Century Crofts.

4. Rani S., Hiremath, R. Textbook of Biopharmaceutics and Pharmacokinetics, Prism Book

5. Gibaldi M., Perrier D. Pharmacokinetics, New York, Marcel Dekker Inc.

6. Swarbrick. J, Current Concepts in Pharmaceutical Sciences: Biopharmaceutics. Philadelphia, Leaand Febiger.

7. Rowland M., Tozer T. Clinical Pharmacokinetics, Concepts and Applications Philadelphia, Leaand Febiger.

8. Abdou H. M Dissolution, Bioavailability and Bioequivalence, Pennsylvania, Mack Publishing Company.

9. Notari **R.** E. Biopharmaceutics and Clinical Pharmacokinetics, An Introduction, New York, Marcel Dekker Inc,

10. Wagner J. G., Pemarowski M. Biopharmaceutics and Relevant Pharmacokinetics, Hamilton, Illinois, Drug Intelligence Publications.

11. Swarbrick J., Boylan J. G. Encyclopedia of Pharmaceutical Technology, New York, Marcel Dekker Inc,

12. Jambhekar S.S., Breen P J. Basic Pharmacokinetics, pharmaceutical press, RPS Publishing.

13. Avdeef A. Absorption and Drug Development- Solubility, Permeability, and Charge State. John Wiley & Sons, Inc

L= Lecture, T= Tutorial, P= Practical, C= Credit

" this is not an exhaustive list

(Semester - II)

L	T	P	C
4			4

Course Code	**MPH203T**
Course Title	**Computer Aided Drug Delivery System**

Scope:

This course 1s designed to impart knowledge and skills necessary for computer Applications in pharmaceutical research and development who want to understand the application of computers across the entire drug research and development process. Basic theoretical discussions of the principles of more integrated and coherent use of computerized information (informatics) in the drug development process are provided to help the students to clarify the concepts.

Objectives:

After completion of course student is able to know,

1. History of Computers in Pharmaceutical Research and Development
2. Computational Modeling of Drug Disposition
3. Computers **in** Preclinical Development
4. Optimization Techniques **in** Pharmaceutical Formulation
5. Computers **in** Market Analysis
6. Computers **in** Clinical Development
7. Artificial Intelligence (AI) and Robotics
8. Computational fluid dynamics (CFD)

Course Learning Outcomes (CLO):

At the end of the course, students will be able to -

I. Recall applications of computers in pharmaceutical research and development

2. Understand QbD guidelines with its implications.

3. Relate with Artificial intelligence (AI), Robotics and Computational fluid dynamics

4. Discuss significance of computational modeling of drug disposition

5. Apply optimization techniques in pharmaceutical formulation

6. Internet computer generated market analysis and clinical development data.

Syllabus: **Teaching Hours: 60 Hours**

UNIT I **12 Hours**

- **Computers in Pharmaceutical Research and Development:**

  A General Overview: History of Computers in Pharmaceutical Research and Development. Statistical modeling in Pharmaceutical research and development: Descriptive versus Mechanistic Modeling, Statistical Parameter ,Estimation, Confidence Regions, Nonlinearity at the Optimum, Sensitivity Analysis, Optimal Design, Population Modeling

- **Quality-by-Design In Pharmaceutical Development:**

  Introduction, ICH Q8 guideline, Regulatory and industry views on QbD, Scientifically based QbD - examples of application

UNIT II **12 Hours**

- **Computational Modeling Of Drug Disposition:**

  Introduction ,Modeling Techniques: Drug Absorption, Solubility, Intestinal Permeation, Drug Distribution ,Drug Excretion, Active Transport; P-gp, BCRP, Nucleoside Transporters, hPEPTl, ASBT, OCT,OATP, BBB-Choline Transporter.

UNIT III **12 Hours**

- **Computer-aided formulation development:**
  Concept of optimization, Optimization parameters, Factorial design, Optimization technology & Screening design. Computers in Pharmaceutical Formulat ion: Development of pharmaceutical emulsions, microemulsion drug carriers Legal Protection of Innovative Uses of Computers in R&D, The Ethics of Computing in Pharmaceutical Research, Computers in Market analysis

UNIT IV **12 Hours**

- **Computer-aided biopharmaceutical characterization:**
  Gastrointestinal absorption simulation Introduction, Theoretical background, Model construction, Parameter sensitivity analysis, Virtual trial, Fed vs. fasted state, In vitro dissolution and *in vitro-in vivo* correlation, Biowaiver considerations
- **Computer Simulations in Pharmacokinetics and Pharmacodynamics:**
  Introduction, Computer Simulation: Whole Organism, Isolated Tissues, Organs, Cell, Proteins and Genes.
- **Computers in Clinical Development:**
  Clinical Data Collection and Management, Regulation of Computer Systems

UNITV **12 Hours**

- **Artificial Intelligence (Al), Robotics and Computational fluid dynamics:**
  General overview, Pharmaceutical Automation, Pharmaceutical applications, Advantages and

Disadvantages. Current Challenges and Future Directions.

REFERENCES: (Latest edition)

1. Ekins, S. Computer Applications in Pharmaceutical Research and Development. John Wiley & Sons. (2006)
2. Djuris, J. Computer-Aided Applications in Pharmaceutical Technology. First Edition. Woodhead Publishing.
3. Swarbrick, J. Boylan, J.G. Encyclopedia of Pharmaceutical Technology. (Volume 20) New York, Marcel Dekker Inc.

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(M. Pharm.: Pharmaceutics)

(Semester - II)

L	T	P	C
4	-		4

Course Code	**MPH204T**
Course Title	**Cosmetics and Cosmeceuticals**

Scope:

This course is designed to impart knowledge and skills necessary for the fundamental need for cosmetic and cosmeceutical products.

Objectives:

Upon completion of the course, the students shall be able to understand

1. Key ingredients used in cosmetics and cosmeceuticals.
2. Key building blocks for various formulations.
3. Current technologies in the market
4. Various key ingredients and basic science to develop cosmetics and cosmeceuticals
5. Scientific knowledge to develop cosmetics and cosmeceuticals with desired Safety, stability, and efficacy.

Course Learning Outcomes (CLO):

At the end of the course, students will be able to -

1. Understand regulatory requirements of cosmeceuticals.
2. Discuss safety, stability, and efficacy aspects of cosmetic products
3. Identify key ingredients used in cosmetics and cosmeceuticals.
4. Explain current technologies in the market for cosmetic manufacturing
5. Design, develop and evaluate cosmetic products including herbals

Syllabus: **Teaching Hours: 60 Hours**

UNIT I **12 Hours**

- **Cosmetics - Regulatory:**
  Definition of cosmetic products as per Indian regulation. Indian regulatory requirements for labeling of cosmetics Regulatory provisions relating to import of cosmetics, Misbranded and spurious cosmetics. Regulatory provisions relating to manufacture of cosmetics - Conditions for obtaining license, prohibition of manufacture and sale of certain cosmetics, loan license, offences and penalties.

UNIT II **12 Hours**

- **Cosmetics - Biological aspects:**
  Structure of skin relating to problems like dry skin, acne, pigmentation, prickly heat, wrinkles and body odor. Structure of hair and hair growth cycle. Common problems associated with oral cavity. Cleansing and care needs for face, eye lids, lips, hands, feet, nail, scalp, neck, body and under-arm.

UNIT III **12 Hours**

- **Formulation Building blocks:**
  Building blocks for different product formulations of cosmetics/cosmeceuticals. Surfactants - Classification and application. Emollients, rheological additives: classification and application. Antimicrobial used as preservatives, their merits and demerits. Factors affecting microbial preservative efficacy. Building blocks for formulation of a moisturizing cream, vanishing cream, cold cream, shampoo and toothpaste. Soaps and syndet bars.
  Perfumes: Classification of perfumes. Perfume ingredients listed as allergens in EU regulation.
  Controversial ingredients: Parabens, formaldehyde liberators, dioxane.

UNIT IV **12 Hours**

- **Design of cosmeceutical products:**
  Sun protection, sunscreens classification and regulatory aspects. Addressing dry skin, acne, sun-protection, pigmentation, prickly heat, wrinkles, body odor, dandruff, dental cavities, bleeding gums, mouth odor and sensitive teeth through cosmeceutical formulations.

UNIT V **12 Hours**

- **Herbal Cosmetics:**
  Herbal ingredients used in Hair care, skin care and oral care. Review of guidelines for herbal cosmetics by private bodies like cosmos with respect to preservatives, emollients, foaming agents, emulsifiers and rheology modifiers. Challenges in formulating herbal cosmetics.

Suggested Readings": (Latest Edition)

I. Rieger, M. (2009). *Harry's Cosmeticology: 8th edition 2 volume Set.*
2. Saraf, S., & Saraf, S. (2008). Cosmetics a practical manual. Hyderabad: PharmaMed Press.
3. Butler, **H.** (2000). *Poucher's perfumes, cosmetics, and soaps* (10th ed.). Dordrecht: Kluwer Academic.
4. Williams, D. F., & Schmitt, W. **H.** (1992). *Chemistry and Technology of the Cosmetics and Toiletries Industry.* Dordrecht: Springer Netherlands.
5. Bare!, A. 0 ., Paye, M., & Maibach, H. I. (2001). *Handbook of cosmetic science and technology.* New York: Marcel Dekker.
6. *1997 CTFA membership directory.* (1997). Washington: CTFA.
7. *Khar, R.* K. (2006). *Cosmetic Technology.* Delhi Birla Publications.
8. *Sharma, P.P.* (2005). *Cosmetic Formulations Manufacturing and Quality Control.* Delhi Vandana Publication

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(M. Pharm.: Pharmaceutics)

(Semester - II)

L	T	P	C
		12	6

Course Code	**MPH205P**
Course Title	**Pharmaceutics Practical** II

PRACTICALS **180 Hours**

1. To study the effect of temperature change , non solvent addition, incompatible polymer addition in microcapsules preparation
2. Preparation and evaluation of Alginate beads
3. Formulation and evaluation of gelatin /albumin microspheres
4. Formulation and evaluation of liposomes/niosomes
5. Formulation and evaluation of spherules
6. Improvement of dissolution characteristics of slightly soluble drug by Solid dispersion technique.
7. Comparison of dissolution of two different marketed products /brands
8. Protein binding studies of a highly protein bound drug & poorly protein bound drug
9. Bioavailability studies of Paracetamol in animals.
10. Pharmacokinetic and IVIVC data analysis by WinnolineR software
11. In vitro cell studies for permeability and metabolism
12. DoE Using Design Expert® Software
13. Formulation data analysis Using Design Expert® Software
14. Quality-by-Design in Pharmaceutical Development
15. Computer Simulations in Pharmacokinetics and Pharmacodynamics
16. Computational Modeling Of Drug Disposition
17. To develop Clinical Data Collection manual
18. To carry out Sensitivity Analysis, and Population Modeling.
19. Development and evaluation of Creams
20. Development and evaluation of Shampoo and Toothpaste base
21. To incorporate herbal and chemical actives to develop products
22. To address Dry skin, acne, blemish, Wrinkles, bleeding gums and dandruff

L= Lecture, T= Tutorial, P= Practical, C= Credit

(M.Pharm. - Pharmaceutics)

(Semester –I I)

L	T	p	C
		7	4

Course Code	**MPH206S**
Course Title	**Seminar /Assignment-II**

COURSE NAME : APPROACHES TO PHARMACEUTICAL RESEARCH [3PH201]

Learning Outcomes:

After successful completion of the course student will be able to :

- Understand the research process, research design and various aspects related to pharmaceutical research.
- Recall the brilliant discoveries done in past from some of the top pharmaceutical industries through case studies.
- Identify the various governmental and non-governmental funding agencies with their basic criterion for getting research grants.
- Apply the concepts of bio-statistics and its role in the pharmaceutical research.

Theory (Detailed Syllabus)

L	T	C
2	2	4

I. Research
   - Aim objective & purpose and need for Research,
   - Types of Research
   - Selecting a problem and preparing a research proposal,
   - Methods, Design and Tools used in research
   - Literature Survey, Printing & Secondary Sources of Information
   - E-Resources
   - Documentation - How, techniques, importance and uses of computers
   - The research Report/Paper writing/thesis writing and Scientific Writing
   - Patent Search and Reading of Patents

II. Presentation of Experimental Data

III. Ethics in Research & Publication

IV. Procurement of Research Grants from various agencies, International Agencies, Government bodies and Private bodies.

V. Industry - Institute Interaction & Interaction with Research Organization. Case studies of development of pharmaceuticals from Lab sources to the market.

VI. Biostatistics:
Probability theory and distributions, sampling distributions and the central limit theorem. Population parameters and their sample estimates; descriptive statistics for central tendency and dispersion; hypothesis testing and confidence intervals for means, variances, and proportions; the chi-square statistic; categorical data analysis; linear correlation and regression model; analysis of variance; and nonparametric methods, application in pharmaceutical research

Tutorial

1. Case studies of the above topics mentioned in the theory section.
2. Assignments based on the above syllabus. 3. Writing applications to agencies for Research Grants.

Books Recommended

1. Research In education : John V. Best, James V. Kahn
2. Presentation Skills- Michael Halton- Indian Society for Institute Education
3. A practical Introduction to copyright- Gravin Mcfarlane
4. Thesis Projects in science and Engineering _ Richard M. Davis
5. Scientists in legal System- Ann Labor Science
6. Thesis and Assignment Writing- Jonathan Anderson

M. Pharm. [Pharmaceutical Technology & Bio-pharmaceutics]
Semester - II

COURSE NAME: GMP AND PHARMACEUTICAL PROCESS VALIDATION [3PT202]

Learning Outcomes:

After successful completion of course, students will be able to:

- Understand the Good Manufacturing Practices/Quality Assurance System of a Pharmaceutical Industry in obtaining effective & safe formulation.
- Apply core elements of GMP as well as new drug application filing in a real world workplace setting.
- Analyze the regulatory requirements of various countries.
- Prepare various documents as per GMP.

Theory (Detailed Syllabus)

L	P	C
3	6	6

1) Good Manufacturing Practices

1. GMP in manufacturing, processing and packaging of drugs
11. GMP practices in finished products, organization, personnel, buildings and facilities, equipments, production and packaging
m. Brief introduction of GLP
iv. Third party GMP certification

2) Pharmaceutical Process Validation for :

1. Pharmaceutical ingredients
11. Solid dosage forms
m. Sterilization processes and sterile products
1v. Computer system validation
v. Analytical Method validation

Change controls and SUPAC guidelines for IR, MR and SS dosage forms

3) Preparation of qualitative and quantitative departmental layouts with equipments required for different dosage forms- solids, liquids, semisolids and sterile formulations.

4) Detailed study of the equipments required in the manufacture of different dosage forms as per Schedule-M

5) Preparations of documents like batch manufacturing record and batch packaging record.

6) Preparation of standard operative procedures for equipments, manufacturing and processing steps

7) **Pharmaceutical process scale-up**

Scale-up for tablets, parenterals, non-parenteral liquids and semi-solids

8) Preparation of documents for new drug application and export registration procedures. Brief study of general requirements of health regulatory agencies like MCA, TGA, ANVISA, FDA, MHLW-PMDA (Japan), MHRA, EMEA, CDSCO, etc.

Practicals

1. GMP protocols for manufacturing and packaging of pharmaceuticals.
2. Validation procedures for pharmaceutical processes, equipments and dosage forms.
3. Flow charts for manufacturing dosage forms like tablet, capsule, parenterals etc.
4. SOP preparation for manufacturing process and equipments.
5. Scale up procedures for pharmaceutical dosage forms.
6. Designing factory layout requirements as per Schedule-M for pharmaceutical manufacturing.
7. Application of guidelines as per SUPAC for IR/MR/SS dosage forms. 8. Preparation of dossiers for foreign registration

Books Recommended

1. Encyclopedia of Phannaceutical Technology, Vol 1-3, by Swarbrick, James, Marcel Dekker, New York.
2. Pharmaceutical Process Validation, by Nash A., Robert, Wachter H., Alfred, Marcel Dekker, New York.
3. Pharmaceutical Process Scale Up, by Levin M, Marcel Dekker, New York
4. Good Manufacturing of Pharmaceuticals, by Willig **H.,** Sidney, Marcel Dekker, New York
5. Validation of Pharmaceutical Processes, Carleton **J.,** Frederick, Agalloco **P.,** James, Marcel Dekker, New York
6. Quality Assurance of Pharmaceuticals: A Compendium of Guidelines and Related Materials : GMP and Inspection, WHO, Geneva
7. How to Practice in GMPs: A Guide to Implement GMPs by P. P. Sharma
8. How to Practice GMP's : A Guide to cGMP Compliance with PAT and HACCP by P. P.Sharma
9. Good Design Practices for GMP Pharmaceutical Facilities edited by Andrew A.Signor and Terry Jacobs, Taylor & Francis
10. Pharmaceutical Master Validation Plan: The Ultimate Guide to FDA, GMP and GLP by Syed Imtiaz Haider, St. Lucie Press
11. . Guidelines on cGMP and Quality at Pharmaceutical Products by S. Iyer, Career Publications

MPharm. [Pharmaceutical Technology & Bio-pharmaceutics]
Semester - II

COURSE NAME: ADVANCES IN BIOPHARMACEUTICS AND PHARMACOKINETICS [3PT203]

Learning Outcomes:

After successful completion of course, students will be able to:

- Understand the regulatory guidelines for BA-BE studies.
- Determine pharmacokinetic parameters using different methods and softwares.
- Apply phannacokinetic and biopharmaceutical parameters in designing the drug delivery.
- Analyze therapeutic efficacy of dosage form based on PK-PD parameters.
- Design the BA-BE study protocols for various dosage forms.

Theory (Detailed Syllabus)

L	P	C
3	*3*	*5*

1) Biopharmaceutics

Brief overview on Absorption, Distribution, Metabolism and Excretion (ADME) process of drug in body and its importance in design of drug delivery systems.

2) Pharmacokinetics

- Types of Pharmacokinetic Models, Methods to determine various pharmacokinetic parameters from plasma-concentration time data and Urinary excretion data for single and Multi-Compartmental Model, Non-compartmental Model and Physiological Model.
- Non-linear Pharmacokinetics and Chrono-pharmacokinetics
- Clinical Pharmacokinetics : Dosage Regimen, Dosage Calculation in Modified release systems, Dose adjustment for pediatric - geriatric patients, Dose adjustment in renal & hepatic failure, Pharmacokinetic Drug Interactions.
- Application of Computer software for pharmacokinetic study.

3) Bioavailability - Bioequivalence Studies

Methods for determination, Federal Requirements, Study Designs and Statistical concepts, Protocols as per Regulatory guidelines of CDSCO and FDA, Therapeutic indexing of drugs.

4) IVIVC and BCS

Levels ofln-vivo In-vitro Correlation (IVIVC), Biopharmaceutical Classification System (BCS), concept of Biowaiver, Methods for bioavailability predilections from drug release study.

Practicals

1. Calculations related to Fundamentals of zero-order and first-order pharmacokinetics
2. Determination of various pharmacokinetics parameters from Plasma concentration time data for One compartment and Multi compartment model for intravenous and extra venous administrations.
3. Determinations of Pharmacokinetics parameters from Urinary Excretion Data
4. Calculations related to Non-Linear Pharmacokinetics
5. Dose Adjustment calculations in clinical pharmacokinetics
6. Demonstration of various pharmacokinetic softwares.
7. In-vivo pharmacokineic study on animal.

Books Recommended

1. Biopharmaceutics and Clinical Phannacy - An Introduction by Notari, E., Robert, Marcel Dekker, New York.
2. Pharmacokinetic and Clinical Calculation by Khan A., Mansor, Reddy K., Indra, Technomic Publishing Comapany Inc., Pennsylvania, USA.
3. Clinical Pharmacokinetics - Concepts and Application by Rowland M., Tozer N., Thomas, B. I. Waverly Pvt. Ltd., New Delhi.
4. Applied Biopharmaceutics and Pharmacokinetics, by Shargel L., Mc-Graw Hill, New York.
5. Pharmacokinetics for the pharmaceutical scientist by Wagner G., John, Technomic Publishing Comapany Inc., Pennsylvania, USA .
6. . Simulation for the designing clinical trials by Kimki C., Hui, Duffull B., Stephen, Marcel Dekker, New York.
7. Biopharmaceutics and Pharmacokinetics A Treatise, by Brahmankar MD, Jaiswal B S, Vallabh Prakashan, Delhi
8. Clinical Pharmacokinetics Handbook by Larry A.Bauer, McGraw-Hill Medical, New York
9. Biopharmaceutics and Pharmacok:inetics by Venkateswarlu V., PharmaMed Press
10. Introduction to Biopharmaceutics and Pharmacok:inetics by Tipnis, Career Publications
11. Pharmacokinetics, by M. Gibaldi and D. Perrier, Marcel Dekker, New York
12. Clinical Pharmacokinetics by Soraya Dhillon and Andrzej Kostrzewski, Pharmaceutical Press, UK
13. Concepts in Clinical Pharmacokinetics by Joseph T.DiPiro, William J.Spruill, Robert A.Blouin, Jane M.Pruemer and William E.Wade, ASHP, USA
14. Basic Pharmacokinetics by Sunil S. Jambhekar and Philip J. Breen, Pharmaceutical Press, UK
15. Computational Phannacokinetics by Anders Kallen, Chapman & Hall
16. Biopharmaceutics and Pharmacokinetics by P. L. Madan, Jaypee Brothers Medical Publication, India
17. Pharmacokinetics : Regulatory-Industrial-Academic Perspectives by Peter G. Welling and Francis L. S. Tse, Marcel Dekker, New York
18. Handbook of Basic Pharmacokinetics by Wolfgang A.Ritchell and Gregory L.Keam s, American Pharmaceutical Association, USA
19. Pharmacokinetics for the Pharmaceutical Scientist by John G. Wagner, Technomic Publishing.
20. Pharmacokinetics in Drug Development: Regulatory and Development Paradigms. by Peter L. Bonate and Danny R. Howard, AAPS Press, USA
21. Pharmaceutical Product Development: In Vitro - In Vivo Correlation by Dukshina Murthy Chilkuri, Gangadhar Sunkara and David Young, Informa Healthcare, UK

Website Recommended

1) http://www.fda.gov /
2) http://www.cder.org/
3) http://cdsco .nic .in/

NIRMA UNIVERSITY

Institute of Pharmacy

(M. Pharm)

(Semester - 111)

L	T	P	C
4	-		4

Course Code	**MRM301T**
Course Title	**Research Methodology & Biostatistics**

Course Learning Outcomes (CLO):

At the end of the course, students will be able to -

1. List various types of research and significance of review of literature
2. Describe the parametric and non- parametric tests related to biostatistics
3. Discuss various types of medical research
4. Explain CPCSEA guidelines for laboratory animal facility
5. Express the role of declaration of Helsinki

Syllabus: **Teaching hours: 60 Hours**

UNIT I **15 Hours**

General Research Methodology: Research, objective, protocol design, requirements, practical difficulties, review of literature, study design, types of studies, strategies to eliminate errors/bias, controls, randomization, crossover design, placebo, blinding and related labelling techniques, conduct, monitoring, analysis and interpretation, reporting and record keeping, Scientific writing.

UNIT II **20 Hours**

Biostatistics: Definition, application, sample size, importance of sample size, factors influencing sample size, dropouts, statistical tests of significance, type of significance tests, parametric tests (students "t" test, ANOVA, Correlation coefficient, regression), non-parametric tests (wilcoxan rank tests, analysis of variance, correlation, chi square test), null hypothesis, P values, degree of freedom, interpretation of P values, application based case studies.

UNIT III **10 Hours**

Medical Research: History, values m medical ethics, autonomy, beneficence, non-

maleficence, double effect, conflicts between autonomy and beneficence /non-maleficence, euthanasia, informed consent, confidentiality, criticisms of orthodox medical ethics, importance of communication, control resolution, guidelines, ethics committees, cultural concerns, truth telling, online business practices, conflicts of interest, referral, vendor relationships, treatment of family members, sexual relationships, fatality.

UNIT IV **05 Hours**

CPCSEA guidelines for laboratory animal facility: Goals, veterinary care, quarantine, surveillance, diagnosis, treatment and control of disease, personal hygiene, location of animal facilities to laboratories, anesthesia, euthanasia, physical facilities, environment, animal husbandry, record keeping, SOPs, personnel and training, transport of lab animals, Import of animals.

UNITV **10 Hours**

General Guidelines of clinical research, ICH E9 guidelines, Declaration of Helsinki: History, introduction, basic principles for all medical research, and additional principles for medical research combined with medical care.

Suggested ReadingsA: (Latest Edition)

1. Best, J.W., Kahn, J.V., *Research In Education.* New Delhi, Prentice Hall oflndia Pvt. Ltd.
2. Halton, M., *Presentation Skills.* Indian Society for Institute Education
3. Mcfarlane, G., *A Practical Introduction to Copyright.* McGraw Hill
4. Davis, R.M., *Thesis Projects in Science and Engineering.* St. Martin's Press.
5. Anderson, J., *Thesis and Assignment Writing.* John Wiley & Sons.

L= Lecture, T= Tutorial, P= Practical, C= Credit

A this is not an exhaustive list

(M. Pharm - Pharmaceutics)

(Semester - III)

L	T	P	C
1			1

Course Code	MPH302T
Course Title	Journal Club – I

(M. Pharm - Pharmaceutics)

(Semester - III)

L	T	P	C
2			2

Course Code	MPH303T
Course Title	Discussion / Presentation (Proposal Presentation)

(M. Pharm - Pharmaceutics)

(Semester - III)

L	T	P	C
		28	14

Course Code	MPH304P
Course Title	Research Work

(M. Pharm - Pharmaceutics)

(Semester - IV)

L	T	P	C
1			1

Course Code	MPH401T
Course Title	Journal Club – II

(M. Pharm - Pharmaceutics)

(Semester - IV)

L	T	P	C
		31	16

Course Code	MPH402P
Course Title	Research Work and Colloquium

(M. Pharm - Pharmaceutics)

(Semester - IV)

L	T	P	C
3			3

Course Code	MPH403T
Course Title	Discussion / Final Presentation

M. Pharm. [Pharmaceutical Technology & Bio-pharmaceutics]
Semester - III

COURSE NAME: ADVANCES IN NOVEL DRUG DELIVERY SYSTEMS [3PT302]
(Self-Study Course)

Learning Outcomes:

After successful completion of course, students will be able to:

- Identify the critical factors and excipients for formulation development.
- Use the knowledge in developing suitable drug delivery.
- Evaluate novel formulations as per requirements.
- Manage the processes and parameters in the formulation development in pharmaceutical industry.

Theory (Detailed Syllabus)

L P C

\- 4

Basic concepts, Anatomy physiology, factors, formulation strategies, evaluation and latest developments of the following novel drug delivery systems:

1) Oral drug delivery system including strips, diskettes and film products
2) Gastro-retentive drug delivery system
3) Colon drug delivery system
A) Transdermal & its specialized drug delivery system
5) Ocular drug delivery system
6) Parenteral drug delivery system
'(J) Microspheres, Niosomes Liposomes, Resealed erythrocytes
8) Nanoparticulate drug delivery systems
) Mucosal, Pulmonary & Nasal drug delivery system
O} Targeted drug delivery system including targeting to CNS and tumor cells
11) Protein & Peptide drug delivery system 12) Intelligent drug delivery systems 13) Biotechnology based pharmaceuticals

Books Recommended

1. Encyclopedia of Controlled Drug Delivery, Vol. I & II, by Edith Mathiowitz, Wiley lnterscience
2. Handbook of Pharmaceutical Controlled Release Technology, by Wise, Marcel Dekker, New York
3. Modified Release Drug Delivery Vol l & 2, by Rathbone, Hadgraft, Roberts, Lane, Informa Healthcare, UK
4. Design of Controlled Release Drug Delivery System, by Xiaoling Li, B.R.Jasti, Mc-graw Hill
5. Treatise on Controlled Drug Delivery, by Agis Kydonieus, Marcel Dekker, NY
6. Drug Targeting Techniques, by Hans Schreier, Marcel Dekker, New York
7. Ophthalmic Drug Delivery System, Ashim Mitra, Marcel Dekker, New York
8. Transdermal Drug Delivery, R.H.Guy, J.Hadgraft, Marcel Dekker, New York
9. Electrically Assisted Transdermal & Topical Drug Delivery, A.K.Banga, T&F
10. Polymeric Drug Delivery System, G.S.Kwon, Marcel Dekker, New York
11. Nanoparticulate Technology for Drug Delivery, R.B.Gupta, U.B.Kompell, T&F
12. Vesicular & Particulate Drug Delivery System, RSR Murthy, Career Publication
13. Handbook of Particulate Drug Delivery, Vol I & 2, by Ravikumar, American Scientific Publication.
14. Nanoparticulate Drug Delivery System, Thassu, Deleers, Pathak, Informa Healthcare, UK
15. Liposome Technologies, Vol I, II, III, Gregoriadis, Informa Healthcare, UK
16. Liposomes, Vol. I & 2, Volkmar weissing, Humana Press
17. Microencapsulaion, by Simon Benita, Tylor & Francis
18. Colloids in Drug Delivery, by Monzer Fanun, CRC Press, UK
19. Carrier Based Drug Delivery, Sonke svenson, American Chemical Society, USA
20. Drug Delivery of Oral Cavity, by Ghosh, Pfister, Tylor & Francis
21. Oral Colon Specific Drug Delivery, by David Friend, CRC Press
22. Bioadhesive Drug Delivery System, by Mathiowitz, Chickering, Lehr, MD
23. lntraocular Drug Delivery, by Jaffe, Ashton, Pearson, Tylor & Francis
24. Targeted Delivery of Small & macromolecular Drugs, by Narang & Mahato, CRC
25. Delivery Techniques for Biophannaceuticals, by L.Jorgensen, H.M.Nielsen, Wiley lnterscience.
26. Oral Drug Delivery of Macromolecular Drug, by Andreas Bernkop-schnurch, Spinger

M.Pharm. [Pharmaceutics) SEMESTER- III

COURSE NAME: MAJOR PROJECT PART – I [3PT303]

L	P	C
		16

M.Pharm. [Pharmaceutics) SEMESTER- IV

COURSE NAME: MAJOR PROJECT PART – II [3PT401]

L	P	C
		20

COURSE NAME: BIO-AVAILABILITY & BIOEQUIV ALENCE TESTING
Course Code: 3EP2T23

Learning Outcomes:

After successful completion of course, students will be able to:

- Understand the concept and significance of Bioavailability and Bioequivalence study in various dosage forms.
- Apply statistical concepts and methodology in BA-BE study design.
  Correlate the regulatory requirements and procedures for BA-BE studies.

Theory (Detailed Syllabus)

L	P	C
2	–	2

1) Bioavailability:
   Absorption of drugs and dosage forms, factors influencing bioavailability, evaluation of bioavailability of drugs and dosage forms.
2) Bioequivalance:
   Absolute, relative, using IV & urinary data, for modified release dosage forms.
3) Bioavailability studu rotocol, Study designs for new and approved drugs
4) Statistical concepts used in estimation of bioavailability and bioequivalance stud ies.
5) n vivo in vitro correlation models in determining bioavailability
6) Regulatory agencies and procedures for Bioavailability & Bioequivalance testing

Books Recommended

1. Applied Biopharmaceutics and Pharmacokinetics, by Shargel L., Mc-Graw Hill, New York.
2. Clinical Phannacokinetics - Concepts and Application by Rowland M., Tozer N., Thomas, B. I. Waverly Pvt. Ltd., New Delhi.
3. Pharmacokinetic and Clinical Calculation by Khan A., Mansor, Reddy K., Indra, Technomic Publishing Comapany Inc., Pennsylvania, USA.
4. Simulation for the designing clinical trials by Kimki C., Hui, Duffull B., Stephen, Marcel Dekker, New York.
5. Biopharmaceutics and Pharmacokinetics by P. L. Madan, Jaypee Brothers Medical Publication, India
6. Clinical Pharmacokinetics Handbook by Larry A.Bauer, McGraw-Hill, New York

Nirma University
Institute of Pharmac
Syllabus of M.Pharm Electives offered:

COURSE NAME: CLINICAL TRIALS AND PHARMACOVIGILANCE
Course Code: 3EP2P36

Learning Outcomes:
After successful completion of course, students will be able to:

- Design and conduct the various phases of clinical trials.
- Evaluate, monitor , prevent and manage the adverse drug reactions
- Develop the pharmacovigilance programmes.

Theory (Detailed Syllabus)	**L**	**P**	**C**
	2		**2**

1) Introduction to clinical trials
2) Research design and conduct of clinical trials
   a) Role of pharmacist in clinical trial.
   b) Various phases of clinical trials
   c) Planning and execution of clinical trials
   d) Guidelines of good clinical research practice and ethical requirements
   e) Monitoring and auditing of clinical trials
3) Pharmacovigilance
   - Scope, definition and aim
   - Adverse Drug Reactions (ADRs): Classification, mechanism, predisposing factors,causality assessment
   - Reporting, evaluation, monitoring, preventing and management of ADRs
   - Role of pharmacists in management of ADR
   - Counterfeit medicines

Books Recommended

1. Fundamental of Clinical Trials. Lawrence M. Friedman, Curt D. Furberg and David L. DeMets. Springer verlag, New York , Inc.
2. Clinical Trials, A Practical Approach. Stuart J. Pocock. John Wiley & Sons, Ltd.
3. Clinical Trials, A Methodologic Perspective. Steven Piantadosi. John Wiley & Sons, Inc, NZ.
4. Clinical Trials in oncology, Stephanie Green, Jacqueline Benedetti, John Crowley, Chapman & Hall/CRC, London.

Nirma University
Institute of Pharmac
Syllabus of M.Pharm Electives offered:

COURSE NAME: QUALITY BY DESIGN FOR PHARMACEUTICALS
Course Code: 3EP2T52

Learning outcomes:

After successful completion of the course, student will be able to

- Understand the concept of quality by design and its applications in pharmaceutical research
- Apply quality by design for optimization of dosage forms, method development, drug discovery and clinical trials
- Analyze data generated using factorial design, composite design, simplex lattice design etc.
- Evaluate experimental design data using softwares and statistical tools.
- Create methodology to develop cost effective robust formulation/method as per regulatory requirements .

Theory (Detailed Syllabus)

L	P	C
3		3

1. **Introduction**
   History of existing formulation development methodology, Basic concepts & objectives of quality by design (QbD) approaches. Importance with special emphasis on safety, effectiveness and quality from the perspective of patients requirements.
2. **Fundamentals of QbD**
   Defining target product profile, target product quality profile and critical quality attributes, risk assessment, fishbone diagram, Design space and control strategies.
3. **QbD for formulation of dosage forms**
   Implementation of QbD at formulation development and manufacturing liquid, semisolid, solid and sterile formulations.
4. **Design of Ex_l!eriment(DOE)and Process analytical tool PAT**
   Introduction, types, scope and applications, brief overview of screening designs, response surface methodology etc., concepts and application of PAT
5. **An overview of pharmaceutical development guidelines like Q8, Q9, QlO and other regulatory guidelines related to QbD.**

Total Lectures: 45

Books Recommended :

1. Pharmaceutical Statistics by Sanford Bolton, 2nd Edition, 2008, Marcel Dekker Inc., New York, USA.
2. New Drug Approval Process: Accelerating Global Registrations by Richard A. Guarino , 2005, Marcel Dekker, New York, USA.
3. Pharmaceutical Experimental Design by Gareth A. Lewis, Didier Mathieu and Roger Phan-Tan-Luu,, 2005, Marcel and Dekker, New York, USA.
4. http://www.fda.gov/ Quality by design for ANDAs: An example for imm ediate/modified release dosage forms.

COURSE NAME: MASS SPECTROMETRY COUPLED TO SEPARATION TECHNIQUES IN PHARMACEUTICAL
COURSE CODE: 3EP2A33

Learning Outcomes

Upon completion of the course, the student will be able to

- Interpret the fragmentation patterns expected to arise in the mass spectrum. **ENT 10**
- Determine the molecular structure using mass spectrum of a **S 21**
- Design and develop LC-MS analytical method for drugs and formulations. **S 17**
- Understand the applications of MS in drug metabolism, peptide- and protein analysis, pharmacokinetics, environmental analysis and other related disciplines. **EMP 1**

Theory (Detailed Syllabus)

L	P	C
2	-	2

1. Introduction to basic concepts of mass spectrometry (MS).
2. Introduction to tandem mass spectrometry (MS-MS).
3. Ionisation techniques: electrospray ionisation, atmospheric pressure chemical ionisation, electron impact, photo-ionization and matrix-assisted laser description ionization.
4. Mass analyzers (quadropoles - single/triple, ion traps, TOFs).
5. Quantitative analysis using MS (MS-MS).
6. Structure elucidation by means of MS (MS-MS and MS^0).
7. Chromatographic aspects regarding MS.
8. Development of LC-MS methods.
9. Application of MS in drug metabolism, peptide- and protein analysis, pharmacokinetics, environmental analysis and other related disciplines.

Books Recommended

1. P. S. Kalsi, Spectroscopy of Organic Compounds, New Age Publication, 2002.
2. D. A. Skoog, E. J. Holler and T. A. Nieman, Principles of Instrumental Analysis, Harcourt Asia Pte Ltd, 2001.
3. S. Lindsay, High Performance Liquid Chromatography, Analytical Chemistry by Open Leaming (ACOL), Wiley, 1987.

COURSE NAME: MODERN CONCEPTS IN PHARMACOLOGY
Course Code : 3EP2L14

Learning Outcomes:

After successful completion of course, students will be able to:

- Explain pathophysiology and clinical manifestations of disorders pertaining to autonomic nervous system, central nervous system, renal and cardiovascular systems, cancer and inflammatory disorders
- Apply their knowledge for clinical management of the above disorders.

Theory (Detailed Syllabus)

L	P	C
3	-	3

- Drug actions influencing the autonomic nervous system
- Drugs acting on the Central nervous system
    a. Neurotransmission in CNS
    b. Psychopharmacological agents
    c. Anti-epileptic agents
    d. Anti-parkinsonian agents
    e. Opioid analgesics
- Drugs acting on Renal and cardiovascular system
    a. Diuretics
    b. Anti-hypertensives
    c. Anti-anginal and drugs used in acute coronary syndrome
    d. Cardiotonics
    e. Anti-arrhythmics
    f. Drug used in Hyper lipoproteinemias
- Anti- asthmatics and anti-inflammatory drugs
- Anti-neoplastic agents

Books Recommended

1. Goodman Gilman A., Rall T.W., Nies A.I.S. and Taylor, P. Goodman and Gilman's The pharmacological Basis of therapeutics, Mc Graw Hill, Pergamon Press.
2. Rang, H.P. and Dale, M.M. Pharmacology, Churchil Livingstone
3. Katzung, B.G. Basic and Clinical Pharmacology, McGraw Hill, New York.
4. Ghosh, M.N. Fundamentals of experimental pharmacology, Scientific Book agency, Kolkata
5. Macleod, L.J. Pharmacological experiments on isolated preparations, Elsevier Health Sciences.

COURSE NAME: APPLIED INDUSTRIAL PHARMACOLOGY
COURSE CODE: 3EP2L26

Learning Outcomes:

After successful completion of course, students will be able to:

- Design protocols for new drug developments as per national and international regulatory guidelines.
- Apply the principles of clinical pharmacokinetics for management of the diseases.

Theory (Detailed Syllabus)

L	P	C
2	-	2

1) Clinical Pharmacology, Clinical Pharmacokinetics, Therapeutic drug monitoring: Concepts and Applications
2) Pre-clinical Testing strategy vis a vis envisaged clinical studies
3) Design and organization of Phase-I to Phase-IV clinical studies. GCP, ICH and WHO guidelines.
4) General principles of toxicology and pre-clinical toxicity studies in accordance with Schedule Y and ICH guidelines etc.
5) Regulatory Protocol & Guidelines

Books Recommended

1. Dhillon S., Kostrzewski, A., Clinical Pharmacokinetics, Pharmaceutical Press, London.
2. Dipiro, J., Spruill, W., Wade, W., Blouin, R., Pruemer, J., Concepts in clinical pharmacokinetics, American society of health-system pharmacists, Inc.
3. Burton, M., Shaw, L., Schentag, J., Evans, W., Applied pharmacokinetics & pharmacodynamics, Lippincott Williams & Wilkins, Philadelphia
4. Kimki C., Hui, Duffull B., Stephen, Simulation for the designing clinical trials by Marcel Dekker Inc., New York.
5. Tom Walley, Alan Haycox and Angela Boland, Pharmacoeconomics, Elsevier.
6. Bootman JL, Townsend RJ, McGhan WF, Principles of Pharmacoeconomics, Harvey Whitney Books Company, Cincinnati, OH
7. Bryan Ballantyne, Timothy marrs, Paul Turner. General & Applied Toxicology by Stockton press

COURSE NAME: REGULATORY GUIDELINES & INTELLECTUAL PROPERTY RIGHTS
COURSE CODE: 3EP2H19

Learning Outcomes

Upon completion of the course, the student will be able to

- Understand the regulatory guidelines at national as well as world wide.
- Prepare documents necessary for import, Export, manufacturing and distribution of drugs.
- Express guidelines required to carry out Toxicity studies carcinogenicity & teratogenicity studies.
- Discuss IPR issues, patent filing in India and foreign countries.

Theory (Detailed Syllabus)

L	P	C
3	-	3

1. Regulatory Guidelines

- Pharmaceutical Legislation
- Regulatory Bodies of different countries
- Indian Regulatory Authorities
- Regulatory guidelines of India, ICH guidelines
  Guidelines for Import, Export, Manufacturing and distribution of drugs
- Brief study of various Regulatory Guidelines of other countries mainly USA and Europe. Variation filing for changes as per regulatory guidelines
- Basics of Clinical trials and Clinical Research, Features of Clinical Trials, Good Clinical Practices, Bioavailability studies, Clinical trials Regulatory affairs.
- Guidelines required to carry out Toxicity studies carcinogenicity & teratogenicity studies.
- Pharmacovigilance
- ADR reporting.
- Orphan drug indications.

2. Intellectual Property Rights:

- Intellectual Property Rights, TRIPS and GATT agreement, Patent, Copyright and Trademarks, Exclusive Marketing Rights
- Patent system in India: Types of patent, patent rights, claims, patent infringement, forms & filings
- Patent applications in foreign countries

Books Recommended

1. Regulation of Medical Procucts edited by J P Griffin and J O'Grady, BMJ Books Publications, 2003
2. International IT Regulations and compliance Quality standards in the pharmaceutical and regulated Industries, Siri H. Segalsatd. A John Wiley and Sons. Ltd, Publication.
3. Official websites related to various guidelines.
4. Drug & Cosmetic Act, 1940, Controller of Publications, India.
5. Encyclopaedia of clinical pharmacy, Edited by Joseph T. Dipiro, Marcel Dekker.
6. IPR Handbook for Pharma Students and researchers, Parikshit Bansal, Pharma Book Syndicate.
7. The law of patents with special focus on pharmaceuticals in India, Feroz-Ali Khader.