Nirma University

Institute of Pharmacy

Teaching & Examination Scheme of (M. Pharm. - Pharmaceutics)

Semester I

Sr. No.	Course Code	Course Title	Teaching Scheme				Examination Scheme				
			L	LPW/PW	T	C	Duration		Component Weightage		
							SEE	LPW/PW	CE	LPW/PW	SEE
1	MPH101T	Modern Pharmaceutical Analytical Techniques	4	-	-	4	3.0	-	0.60	-	0.40
2	MPH102T	Drug Delivery Systems	4	-	-	4	3.0	-	0.60	-	0.40
3	MPH103T	Modern Pharmaceutics	4	-	-	4	3.0	-	0.60	-	0.40
4	MPH104T	Regulatory Affairs	4	-	-	4	3.0	-	0.60	-	0.40
5	MPH105P	Pharmaceutics Practical I	-	12	-	6	-	6.0	-	1.00	-
6	MPH106S	Seminar / Assignment	-	7	-	4	-	-	-	1.00	-
		Total	16	19	-	26					
			35								

L: Lectures, P/T: Practicals/Tutorial, C: Credits
LPW/PW: Laboratory / Project Work
SEE: Semester End Examination
CE: Continuous Evaluation

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

- 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 ions, 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

UNIT V 16 Hours

- Electrophoresis:
  Principle, Instrumentation, Working conditions, factors affecting separation and applications of 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 crystal technique, X ray powder technique, Types of crystals and applications of X-ray diffraction.

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

Suggested Readings^: (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 in Pharmaceutical Formulations. CBS Publishers.
7. Munson, J. W. Pharmaceutical Analysis: Modern Methods (Vol. 11). CRC Press.

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

^ 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: introduction, 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 vaccines.

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 Learning 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 f1, 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. Modern 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 India. 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 I – III, 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 pharmacopoeial 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 of riboflavin/quinine sulphate by fluorimetry
6. Estimation of sodium/potassium by 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 of Mucoadhesive tablets.
12. Formulation and evaluation of transdermal patches.
13. To carry out preformulation 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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