C. U. SHAH UNIVERSITY
Wadhwan City

FACULTY OF: Pharmaceutical Sciences

DEPARTMENT OF: Pharmaceutics

SEMESTER: I

CODE: MPH 101T

NAME: Modern Pharmaceutical Analytical Techniques

Teaching & Evaluation Scheme:-

Subject Code	Name of the Subject	Teaching Scheme (Hours)				Credits	Evaluation Scheme								Total
							Theory				Practical				
		Th	Tu	Pr	Total		Internal Exam		End Semester Exam		Internal Exam		End Semester Exam		Total
							Marks	Hrs	Marks	Hrs	Marks	Hrs	Marks	Hrs	
MPH101T	Modern Pharmaceutical Analytical Techniques	4	0	0	4	4	15	1	75	3	--	--	--	--	100
							10 (CM)	--							

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,

- Chemicals and Excipients
- The analysis of various drugs in single and combination dosage forms
- Theoretical and practical skills of the instruments

COURSE OUTLINE:-

Sr. No.	Course Content	Hours
1	a) UV-Visible spectroscopy: Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV- Visible spectroscopy. b) IR spectroscopy: Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier - Transform IR Spectrometer, Factors affecting vibrational frequencies and Applications of IR spectroscopy c) Spectroflourimetry: Theory of Fluorescence, Factors affecting fluorescence, Quenchers, Instrumentation and Applications of fluorescence spectrophotometer. d) Flame emission spectroscopy and Atomic absorption spectroscopy: Principle, Instrumentation, Interferences and Applications.	11
2	NMR spectroscopy: Quantum numbers and their role in NMR,Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift,	11

	Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and 13C NMR. Applications of NMR spectroscopy.	
3	Mass Spectroscopy: Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules, Meta stable ions, Isotopic peaks and Applications of Mass spectroscopy.	11
4	Chromatography: Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution and applications of the following: Paper chromatography b) Thin Layer chromatography c) Ion exchange chromatography d) Column chromatography e) Gas chromatography f) High Performance Liquid chromatography g) Affinity chromatography	11
5	a. Electrophoresis: Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following: a) Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresis d) Zone electrophoresis e) Moving boundary electrophoresis f) Iso electric focusing b. 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.	11
6	Immunological assays: RIA (Radio immuno assay), ELISA, Bioluminescence assays.	5
	Total	60

REFERENCES:

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.
4. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi, 1997.
5. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis- Modern methods – Part B - J W Munson, Volume 11, Marcel Dekker Series

C. U. SHAH UNIVERSITY
Wadhwan City

FACULTY OF: Pharmaceutical Sciences

DEPARTMENT OF: Pharmaceutics

SEMESTER: I

CODE: MPH 102T

NAME: Drug Delivery Systems

Teaching & Evaluation Scheme:-

Subject Code	Name of the Subject	Teaching Scheme (Hours)				Credits	Evaluation Scheme								Total
							Theory				Practical				
		Th	Tu	Pr	Total		Internal Exam		End Semester Exam		Internal Exam		End Semester Exam		
							Marks	Hrs	Marks	Hrs	Marks	Hrs	Marks	Hrs	
MPH102T	Drug Delivery Systems	4	0	0	4	4	15	1	75	3	--	--	--	--	100
							10 (CM)	--							

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

OBJECTIVE:
Upon completion of the course, student shall be able to understand.
- The various approaches for development of novel drug delivery systems.
- The criteria for selection of drugs and polymers for the development of delivering system
- The formulation and evaluation of Novel drug delivery systems

COURSE OUTLINE:

Sr. No	COURSE CONTENTS	Hours
01	Sustained Release (SR) and Controlled Release (CR) formulations: 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.	10 Hrs
02	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.	10 Hrs

03	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.	10 Hrs
04	Occular Drug Delivery Systems: Barriers of drug permeation, Methods to overcome barriers.	06 Hrs
05	Transdermal Drug Delivery Systems: Structure of skin and barriers, Penetration enhancers, Transdermal Drug Delivery Systems, Formulation and evaluation.	10 Hrs
06	Protein and Peptide Delivery: Barriers for protein delivery. Formulation and Evaluation of delivery systems of proteins and other macromolecules.	08 Hrs
07	Vaccine delivery systems: Vaccines, uptake of antigens, single shot vaccines, mucosal and transdermal delivery of vaccines.	06 Hrs
	Total	60

REFERENCES:

1. Y W. Chien, Novel Drug Delivery Systems, 2nd edition, revised and expanded, Marcel Dekker, Inc., New York, 1992.

2. Robinson, J. R., Lee V. H. L, Controlled Drug Delivery Systems, Marcel Dekker,Inc., New York, 1992.

3. Encyclopedia of controlled delivery, Editor- Edith Mathiowitz, Published by WileyInterscience Publication, John Wiley and Sons, Inc, New York! Chichester/Weinheim

4. N.K. Jain, Controlled and Novel Drug Delivery, CBS Publishers & Distributors, New Delhi, First edition 1997 (reprint in 2001).

5. S.P.Vyas and R.K.Khar, Controlled Drug Delivery - concepts and advances, Vallabh Prakashan, New Delhi, First edition 2002

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

C. U. SHAH UNIVERSITY
Wadhwan City

FACULTY OF: Pharmaceutical Sciences

DEPARTMENT OF: Pharmaceutics

SEMESTER: I

CODE: MPH 103T

NAME: Modern Pharmaceutics

Teaching & Evaluation Scheme:-

Subject Code	Name of the Subject	Teaching Scheme (Hours)				Credits	Evaluation Scheme								Total
							Theory				Practical				
		Th	Tu	Pr	Total		Internal Exam		End Semester Exam		Internal Exam		End Semester Exam		
							Marks	Hrs	Marks	Hrs	Marks	Hrs	Marks	Hrs	
MPH103T	Modern Pharmaceutics	4	0	0	4	4	15 / 10 (CM)	1 / --	75	3	--	--	--	--	100

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 shall be able to understand
- The elements of preformulation studies.
- The Active Pharmaceutical Ingredients and Generic drug Product development
- Industrial Management and GMP Considerations.
- Optimization Techniques & Pilot Plant Scale Up Techniques
- Stability Testing, sterilization process & packaging of dosage forms

COURSE OUTLINE:

Sr. No	COURSE CONTENTS	Hours
01	a. 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.	10
	b. 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	10
02	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 & P.Q. of facilities	10

03	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.	10
04	Compression and compaction: Physics of tablet compression, compression, consolidation, effect of friction, distribution of forces, compaction profiles. Solubility.	10
05	Study of consolidation parameters; Diffusion parameters, Dissolution parameters and Pharmacokinetic parameters, Heckel plots, Similarity factors – f2 and f1, Higuchi and Peppas plot, Linearity Concept of significance, Standard deviation , Chi square test, students T-test , ANOVA test.	10
Total		60

REFERENCES:

1. Theory and Practice of Industrial Pharmacy By Lachmann and Libermann
2. Pharmaceutical dosage forms: Tablets Vol. 1-3 by Leon Lachmann.
3. Pharmaceutical Dosage forms: Disperse systems, Vol, 1-2; By Leon Lachmann.
4. Pharmaceutical Dosage forms: Parenteral medications Vol. 1-2; By Leon Lachmann.
5. Modern Pharmaceutics; By Gillbert and S. Banker.
6. Remington's Pharmaceutical Sciences.
7. Advances in Pharmaceutical Sciences Vol. 1-5; By H.S. Bean & A.H. Beckett.
8. Physical Pharmacy; By Alfred martin
9. Bentley's Textbook of Pharmaceutics – by Rawlins.
10. Good manufacturing practices for Pharmaceuticals: A plan for total quality control, Second edition; By Sidney H. Willig.
11. Quality Assurance Guide; By Organization of Pharmaceutical producers of India.
12. Drug formulation manual; By D.P.S. Kohli and D.H.Shah. Eastern publishers, New Delhi.
13. How to practice GMPs; By P.P.Sharma. Vandhana Publications, Agra.
14. Pharmaceutical Process Validation; By Fra. R. Berry and Robert A. Nash.
15. Pharmaceutical Preformulations; By J.J. Wells.
16. Applied production and operations management; By Evans, Anderson, Sweeney and Williams.
17. Encyclopaedia of Pharmaceutical technology, Vol I – III.

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FACULTY OF: Pharmaceutical Sciences

DEPARTMENT OF: Pharmaceutics

SEMESTER: I

CODE: MPH 104T

NAME: Regulatory Affairs

Teaching & Evaluation Scheme:-

Subject Code	Name of the Subject	Teaching Scheme (Hours)				Credits	Evaluation Scheme								Total
							Theory				Practical				
		Th	Tu	Pr	Total		Internal Exam		End Semester Exam		Internal Exam		End Semester Exam		
							Marks	Hrs	Marks	Hrs	Marks	Hrs	Marks	Hrs	
MPH104T	Regulatory Affairs	4	0	0	4	4	15	1	75	3	--	--	--	--	100
							10 (CM)	--							

SCOPE:

Course designed to impart advanced knowledge and skills required to learn the concept of generic drug and their development, various regulatory filings in different countries, different phases of clinical trials and submitting regulatory documents: filing process of IND, NDA and ANDA

- To know the approval process of
- To know the chemistry, manufacturing controls and their regulatory importance
- To learn the documentation requirements for
- To learn the importance and

OBJECTIVES:

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

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

COURSE OUTLINE:

Sr. No	COURSE CONTENTS	Hours
01	• 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-	12

	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.	
	• Regulatory requirement for product approval: API, biologics, novel, therapies obtaining NDA, ANDA for generic drugs ways and means of US registration for foreign drugs	12
02	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.	12
03	Non clinical drug development: Global submission of IND, NDA, ANDA. Investigation of medicinal products dossier, dossier (IMPD) and investigator brochure (IB).	12
04	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.	12
	Total	60

REFERENCES

1. Generic Drug Product Development, Solid Oral Dosage forms, Leon Shargel and IsaderKaufer,Marcel Dekker series, Vol.143
2. The Pharmaceutical Regulatory Process, Second Edition Edited by Ira R. Berry and Robert P.Martin, Drugs and the Pharmaceutical Sciences, Vol.185, Informa Health care Publishers.
3. New Drug Approval Process: Accelerating Global Registrations by Richard a Guarino, MD, 5th edition, Drugs and the Pharmaceutical Sciences, Vol.190.
4. Guidebook for drug regulatory submissions / Sandy Weinberg. By John Wiley & Sons.Inc.
5. FDA regulatory affairs: a guide for prescription drugs, medical devices, and biologics/edited By Douglas J. Pisano, David Mantus.
6. Clinical Trials and Human Research: A Practical Guide to Regulatory Compliance By Fay A.Rozovsky and Rodney K. Adams
7. www.ich.org/
8. www.fda.gov/
9. europa.eu/index_en.htm
10. https://www.tga.gov.au/tga-basics

C. U. SHAH UNIVERSITY
Wadhwan City

FACULTY OF: Pharmaceutical Sciences

DEPARTMENT OF: Pharmaceutics

SEMESTER: I

CODE: MPH 105P

NAME: Pharmaceutics Practical – I

Teaching & Evaluation Scheme:-

Subject Code	Name of the Subject	Teaching Scheme (Hours)				Credits	Evaluation Scheme								Total
		Th	Tu	Pr	Total		Theory				Practical				
							Internal Exam		End Semester Exam		Internal Exam		End Semester Exam		
							Marks	Hrs	Marks	Hrs	Marks	Hrs	Marks	Hrs	
MPH105P	Pharmaceutics Practical - I	--	--	12	12	6	--	--	--	--	30	6	100	6	150
											20 (CM)	--			

PRACTICALS:

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 Muco adhesive 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.