GANPAT UNIVERSITY

FACULTY OF PHARMACY

TEACHING AND EXAMINATION SCHEME

Program	Master of Pharmacy (M.Pharm)	Branch	Pharmaceutics	Semester	1	Version	2.0.0.0
Effective from	2018-19	Effective for batches admitted onwards	2018-19				

S. N	Subject Code	Subject Name	Theory / Practical/ Seminar	Teaching Scheme		Examination Scheme			
				Credit	Hours Per Week	Marks			Total Marks
						CE	SE	ES	
1	MAT101T	Modern Pharmaceutical Analytical Techniques	Theory	4	4	10	15	75	100
2	MPH102T	Drug Delivery System	Theory	4	4	10	15	75	100
3	MPH103T	Modern Pharmaceutics	Theory	4	4	10	15	75	100
4	MPH104T	Regulatory Affair	Theory	4	4	10	15	75	100
5	MPH105P	Pharmaceutics Practical I	Practical	6	12	20	30	100	150
6	MEL106S	Seminar	Seminar	4	8	-	-	100	100
			Total	26	36	60	90	500	650

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FACULTY OF PHARMACY										
Program	Master of Pharmacy		Branch/Spec.	Pharmaceutics						
Semester	I		Version	2.0.0.0						
Effective from Academic Year		2018-19	Effective for the batches Admitted onwards					June 2018		
Subject code	MAT101T	Subject Name	Modern Pharmaceutical Analytical Techniques							
Teaching scheme		Examination scheme								
Credit	4		CE	SE	ES	Total		SE	ES	
Hours	4	Marks	10	15	75	100	Duration	1 hr.	3 hr.	

Pre-requisites

Nil

Scope and Objectives:

This subject deals with various advanced analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are UV, Fluorimeter, NMR, Mass spectrometer, IR, HPLC, GC etc.

Learning Outcome:

- Student shall be able to understand the theoretical and practical skills of the instruments.
- Student shall be able to do analysis of various drugs in single and combination dosage forms.
- Student shall be able to design and develop analytical skills.

Syllabus- Theory

Unit	Content	Hrs
1	UV-Visible spectroscopy: Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV/Visible Spectroscopy	08
2	Spetrofluorimetry: Theory of Fluorescence, Factors affecting fluorescence, Quenchers, Instrumentation and Applications of fluorescence spectrophotometer	06
3	Flame emission spectroscopy and Atomic absorption spectroscopy: Principle, Instrumentation, Interferences and Applications	08
4	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	05
5	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	07
6	Mass Spectroscopy: Principle, Theory, Instrumentation, 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	05
7	Chromatography: Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution and applications of the following: a) Paper chromatography b) Thin Layer chromatography c) Ion exchange chromatography d) Column chromatography e) Gas chromatography f) High Performance Liquid chromatography	10
8	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.	07
9	Thermal Analysis: Polymer behavior, factors affecting and instrumentation, and working, application of TGA	04

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.

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FACULTY OF PHARMACY

Program	Master of Pharmacy		Branch/Spec.	Pharmaceutics					
Semester	I		Version	2.0.0.0					
Effective from Academic Year		2018-19	Effective for the batches Admitted onwards				June 2018		
Subject code	MPH102T	Subject Name	Drug Delivery System						
Teaching scheme		Examination scheme							
Credit	4		CE	SE	ES	Total		SE	ES
Hours	4	Marks	10	15	75	100	Duration	1 hr.	3 hr.

Pre-requisites

Nil

Scope and Objectives:

Upon completion of this course the student should be able to

- 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.

Learning Outcome:

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

Syllabus- Theory

Unit	Content	Hrs
1	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
2	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
3	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 mucoadhesion, advantages and disadvantages, Mechanism of drug permeation, Methods of formulation and its evaluations.	10
4	Occular Drug Delivery Systems: Barriers of drug permeation, Methods to overcome barriers.	6
5	Transdermal Drug Delivery Systems: Structure of skin and barriers, Penetration enhancers, Transdermal Drug Delivery Systems, Formulation and evaluation	10
6	Protein and Peptide Delivery: Barriers for protein delivery. Formulation and Evaluation of delivery systems of proteins and other macromolecules.	8
7	Vaccine delivery systems: Vaccines, uptake of antigens, single shot vaccines, mucosal and transdermal delivery of vaccines.	6

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 Wiley Interscience 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

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Program	Master of Pharmacy		Branch/Spec.	Pharmaceutics						
Semester	I		Version	2.0.0.0						
Effective from Academic Year		2018-19	Effective for the batches Admitted onwards					June 2018		
Subject code	MPH103T	Subject Name	Modern Pharmaceutics							
Teaching scheme		Examination scheme								
Credit	4		CE	SE	ES	Total		SE	ES	
Hours	4	Marks	10	15	75	100	Duration	1 hr.	3 hr.	

Pre-requisites

Nil

Scope and Objectives:

Upon completion of this course the student should be able to

- 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.

Learning Outcome:

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

Syllabus- Theory

Unit	Content	Hrs
1	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. 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	12
2	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.	12
3	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.	12
4	Compression and compaction: Physics of tablet compression, compression, consolidation, effect of friction, distribution of forces, compaction profiles. Solubility.	12
5	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.	12

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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Program	Master of Pharmacy		Branch/Spec.	Pharmaceutics						
Semester	I		Version	2.0.0.0						
Effective from Academic Year		2018-19	Effective for the batches Admitted onwards					June 2018		
Subject code	MPH104T	Subject Name	Regulatory Affair							
Teaching scheme		Examination scheme								
Credit	4		CE	SE	ES	Total		SE	ES	
Hours	4	Marks	10	15	75	100	Duration	1 hr.	3 hr.	

Pre-requisites

Nil

Scope and Objectives:

Upon completion of this course the student should be able to

- 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.

Learning Outcome:

- 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.

Syllabus- Theory

Unit	Content	Hrs
1	a. 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. b. Regulatory requirement for product approval: API, biologics, novel, therapies obtaining NDA, ANDA for generic drugs ways and means of US registration for foreign drugs	15
2	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.	15
3	Non clinical drug development: Global submission of IND, NDA, ANDA. Investigation of medicinal products dossier, dossier (IMPD) and investigator brochure (IB).	15
4	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.	15

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

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FACULTY OF PHARMACY										
Program	Master of Pharmacy			Branch/Spec.	Pharmaceutics					
Semester	I			Version	2.0.0.0					
Effective from Academic Year		2018-19		Effective for the batches Admitted onwards				June 2018		
Subject code	MPH105P	Subject Name	Pharmaceutics Practical I							
Teaching scheme		Examination scheme								
Credit	6		CE	SE	ES	Total		SE	ES	
Hours	12	Marks	20	30	100	150	Duration	1 hr.	3 hr.	
Pre-requisites										
Nil										
List of Practicals:										
	PART A:									
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.									
	PART B:									
1	To perform In-vitro dissolution profile of CR/ SR marketed formulation									
2	Formulation and evaluation of sustained release matrix tablets									
3	Formulation and evaluation osmotically controlled DDS									
4	Preparation and evaluation of Floating DDS- hydro dynamically balanced DDS									
5	Formulation and evaluation of Mucoadhesive tablets.									
6	Formulation and evaluation of trans dermal patches.									
7	To carry out preformulation studies of tablets.									
8	To study the effect of compressional force on tablets disintegration time.									
9	To study Micromeritic properties of powders and granulation.									
10	To study the effect of particle size on dissolution of a tablet.									
11	To study the effect of binders on dissolution of a tablet.									
12	To plot Heckal plot, Higuchi and peppas plot and determine similarity factors.									
13	To perform stability testing of drug in liquid formulation.									
14	To prepare and evaluate self-micro emulsifying drug delivery system (SMEDDS).									
15	To perform calibration study of dissolution test apparatus.									
16	To calculate standard deviation; perform Chi square test, students T-test and ANOVA test for given data.									

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Semester	I		Version	2.0.0.0						
Effective from Academic Year		2018-19	Effective for the batches Admitted onwards					June 2018		
Subject code	MEL106S	Subject Name	Seminar							
Teaching scheme		Examination scheme								
Credit	4		CE	SE	ES	Total		SE	ES	
Hours	8	Marks	-	-	100	100	Duration	-	3 hr.	
Pre-requisites										
Nil										
Scope and Objectives:										
	• To develop know how of the latest development in the area of pharmaceutical science. • To develop the presentation skill for the information collected and compilated in the form of seminar.									
Learning Outcome:										
	• Students will develop latest know how of the latest development in the field of pharmaceutical sciences.									
	• Students able to develop presentation skill utilizing various tools and techniques for the data analysis and meaningful conclusion.									