

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:									
Knowledge of principle and instrumentation of molecular spectroscopic methods									
Understand various atomic spectroscopic techniques with its basic principles and instrumentation									
Application of radio immunoassay and laser spectroscopy in drug analysis									
Analyse and select best suitable analytical techniques for the estimation of drugs and pharmaceuticals									
Evaluation of qualitative and quantitative applications of analytical techniques for analysis of organic and inorganic substances									
Create analytical skills for identification and quantification of drugs using modern analytical techniques									
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	Spectrofluorimetry: 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 ¹³ C 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 - Douglas 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, 4 th 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, 3 rd 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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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									
	<ul style="list-style-type: none"> The various approaches for development of novel drug delivery systems. 								
	<ul style="list-style-type: none"> The criteria for selection of drugs and polymers for the development of delivering system. 								
	<ul style="list-style-type: none"> The formulation and evaluation of Novel drug delivery systems. 								
Learning Outcome:									
	Know various types of delivery systems like Sustained Release (SR) and Controlled Release (CR)								
	Understand type and selection criteria of various drugs and excipients for different types of formulations.								
	Apply formulation approaches for design and development of various types of delivery systems.								
	Analyze various type of delivery systems for various parameters which are important with respect to quality, performance and stability.								
	Evaluate various applications of various types of delivery systems.								
	To formulate novel delivery systems for available exciting drugs which give improved therapeutic benefits.								
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	Ocular 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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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									
	<ul style="list-style-type: none"> 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:									
	Know the various concept and aspects of modern pharmaceutics applied in pharmaceutical industries like preformulation, stability, cGMP etc.								
	Understand the various methods for optimization and stable product development								
	Apply methods for optimization in development of most acceptable Pharmaceutical product								
	Analyze various considerations in development of optimized pharmaceutical dosage forms								
	Evaluate the quality control aspects for various modern pharmaceuticals								
	Study various important aspects of formulation and optimization of pharmaceutical dosage forms								
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 – f ₂ and f ₁ , Higuchi and Peppas plot, Linearity Concept of								12

	significance, Standard deviation, Chi square test, students T-test, ANOVA test.	
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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Semester	I			Version	2.0.0.0				
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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									
	<ul style="list-style-type: none"> 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. Pharmacovigilance and process of monitoring in clinical trials. 								
Learning Outcome:									
	Know Indian and International regulatory and legal aspects and quality policies for Pharmaceuticals								
	Understand the process of drug discovery and development in line with regulaory requirements.								
	Apply regulatory compliances on manufacturing and qulity and safety of pharmaceuticals.								
	Analyzing and understanding the regulatory approval process and their registration in Indian and international clinical trial protocols markets.								
	Evaluating clinical trial protocols and applying it to develop new protocols.								
	Learn how to plan pharmacovigilance safety monitoring in clinical trials.								
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,5 th 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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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									
Learning Outcome									
	Know the principles of various types of delivery systems.								
	Understand the formulation characteristics and requirement for the formulations and evaluation parameters for various types of drug delivery.								
	Apply formulation design of novel delivery systems for available existing drugs which give improved therapeutic benefits.								
	Analyze important aspects of formulation and optimization of pharmaceutical dosage forms								
	Formulate various drug delivery system as per optimized conditions.								
	Perform the quality control aspects for various modern pharmaceuticals.								
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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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:										
	<ul style="list-style-type: none"> To develop know how of the latest development in the area of pharmaceutical science. To develop the presentation skill for the information collected and compiled in the form of seminar. 									
Learning Outcome:										
	Knowledge of the latest development in the area of pharmaceutical sciences									
	Understand the use of the library and internet resources for the referencing and literature purpose									
	Apply the knowledge of surfing and referencing to collect and compile relevant data in scientific way									
	Analyse the problems and strengthen ability for presentations and defending the viva voce									
	Evaluate the hypothesis, study design, method and results in a systemic manner									
	Develop presentation skill utilizing various tools and techniques for the data analysis and meaningful conclusion									