Integral University, Lucknow

Effective from Session: 2016-17								
Course Code	**MPH101T**	**Title of the Course**	**MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES**	**SDG Goals**	**L**	**T**	**P**	**C**
Year	`I	**Semester**	I		4	-	-	4
Pre-Requisite	B. Pharm.	**Co-requisite**	Knowledge of chemical structures of Pharmaceutical substances					
Course Objectives	After completion of course student is able to know about 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 Outcomes	
CO1	Investigate the pharmaceutical substance by absorption and emission techniques.
CO2	Appraise the pharmaceutical substance by nuclear magnetic spectroscopy techniques.
CO3	Examine the mass spectroscopy involved for the pharmaceutical substances.
CO4	Recognize the principle, instrumentation and applications of chromatographic techniques.
CO5	Sketch the principle, instrumentation and applications of electrophoresis and x ray crystallography.
CO6	Apprehend the fundamentals of immunological assays.

UnitNo.	Title of the Unit	Content of Unit	Contact Hrs.	Mapped CO	SDG Targets
1	**UV-Visible spectroscopy, IR spectroscopy, Spectroflourimetry , Flame emission spectroscopy and Atomic absorption spectroscopy**	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, Difference/ Derivative 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	1	4.3,4.4,4.5,4.6,4.7, 4.c, 9.2, 9.4, 9.5, 9.b
2	**NMR spectroscopy**	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.	11	2	4.3,4.4,4.5,4.6,4.7, 4.c, 9.2, 9.4, 9.5, 9.b
3	**Mass Spectroscopy**	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	3	4.3,4.4,4.5,4.6,4.7, 4.c, 9.2, 9.4, 9.5, 9.b
4	**Chromatography**	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 g) Affinity chromatography	11	4	4.3,4.4,4.5,4.6,4.7, 4.c, 9.2, 9.4, 9.5, 9.b
5	**Electrophoresis and X-ray Crystallography**	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	5	4.3,4.4,4.5,4.6,4.7, 4.c, 9.2, 9.4, 9.5, 9.b

6	**Potentiometry and Thermal Techniques**	a. Potentiometry: Principle, working, Ion selective Electrodes and Application of potentiometry. b. Thermal Techniques: Principle, thermal transitions and Instrumentation (Heat flux and power-compensation and designs), Modulated DSC, Hyper DSC, experimental parameters (sample preparation, experimental conditions, calibration, heating and cooling rates, resolution, source of errors) and their influence, advantage and disadvantages, pharmaceutical applications. Differential Thermal Analysis (DTA): Principle, instrumentation and advantage and disadvantages, pharmaceutical applications, derivative differential thermal analysis (DDTA). TGA: Principle, instrumentation, factors affecting results, advantage and disadvantages, pharmaceutical applications.	10	6	4.3,4.4,4.5,4.6,4.7, 4.c, 9.2, 9.4, 9.5, 9.b

Reference Books:

Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.

Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.

Instrumental methods of analysis – Willards, 7th edition, CBS publishers.

Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi, 1997.

Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.

Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.

Pharmaceutical Analysis - Modern Methods – Part B - J W Munson, Vol 11, Marcel. Dekker Series

Spectroscopy of Organic Compounds, 2nd edn., P.S/Kalsi, Wiley estern Ltd., Delhi.

Textbook of Pharmaceutical Analysis, KA.Connors, 3rd Edition, John Wiley & Sons, 1982.

e-Learning Source:

https://www.classcentral.com/course/swayam-spectroscopic-techniques-for-pharmaceutical-and-biopharmaceutical-industries-14301

https://www.sciencedirect.com/science/article/pii/S1878535213001056

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6258797/

https://www.google.co.in/books/edition/Pharmaceutical_Analysis/Ub8wod1CJ50C?hl=en&gbpv=1&dq=pharmaceutical+analysis+spectral+chromatography&printsec=frontcover

https://www.google.co.in/books/edition/Pharmaceutical_Analysis_E_Book/YExgDAAAQBAJ?hl=en&gbpv=1&dq=pharmaceutical+analysis+spectral+chromatography&printsec=frontcover

	Course Articulation Matrix: (Mapping of COs with POs and PSOs)																
PO-PSO CO	**PO1**	**PO2**	**PO3**	**PO4**	**PO5**	**PO6**	**PO7**	**PO8**	**PO9**	**PO10**	**PO11**	**PSO1**	**PSO2**	**PSO3**	**PSO4**	**PSO5**	**PSO6**
CO1	3	3	3	2	3	2	2	2	3	2	3	3	3	3	-	-	-
CO2	3	3	3	2	3	3	2	3	3	3	3	3	3	3	-	-	-
CO3	3	3	3	2	3	3	2	2	3	2	3	3	3	3	-	-	-
CO4	3	3	3	3	3	2	2	2	3	3	3	3	3	3	-	-	-
CO5	3	3	3	2	3	2	2	2	3	2	3	3	3	3	-	-	-
CO6	3	3	3	2	3	2	2	2	3	2	3	3	3	3	-	-	-

1. Low Correlation; 2- Moderate Correlation; 3- Substantial Correlation

Name & Sign of Program Coordinator	**Sign & Seal of HOD**

Integral University, Lucknow

Effective from Session: 2016-17								
Course Code	**MPH102T**	**Title of the Course**	**DRUG DELIVERY SYSTEM**	**SDG Goals**	**L**	**T**	**P**	**C**
Year	`I	**Semester**	I		4	-	-	4
Pre-Requisite	B. Pharm.	**Co-requisite**	Knowledge of chemical structures of Pharmaceutical substances					
Course Objectives	1. The various approaches for development of novel drug delivery systems. 2. The criterial for selection of drugs and polymers for the development of the delivering system. 3. The formulation and evaluation of novel drug delivery system.							

Course Outcomes	
CO1	Explain drug delivery systems which give detailed information on transporting a pharmaceutical compound in the body as needed to safely achieve its desired therapeutic effect. Also about the approaches, formulations, technologies, and systems for transporting a pharmaceutical compound in the body as needed to safely achieve its desired therapeutic effect with suitable drug delivery.
CO2	Know vaccine delivery and different mode of application approaches for clinical use.
CO3	Ability to communicate different types of Drug carrier used in the process of drug delivery which serves to improve the selectivity, effectiveness, and/or safety of drug administration.
CO4	Apply latest drug delivery knowledge and think to develop new formulation based on the individual requirement.
CO5	Create recent developments in protein and peptide for parenteral delivery approaches will give new dimension of drug deliver for antibiotics, insulin, etc.

UnitNo.	Title of the Unit	Content of Unit	Contact Hrs.	Mapped CO	SDG Targets
1	**Sustained Release(SR) and Controlled Release (CR) formulations:**	Introduction and basic concepts, advantages, disadvantages Factors influencing, Physicochemical and biological approaches for SR/CR formulation Mechanism of drug delivery from SR/CR formulation Polymers introduction, definition, classification, properties 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	12	1	9.2 9.4 9.5 9.b
2	**Rate controlled drug delivery systems**	Rate controlled drug delivery systems: principles and fundamentals, types Activation: Modulated drug delivery systems; mechanically activated, pH activated Enzyme activated, osmotic activated drug delivery systems Feedback regulated drug delivery systems; principles and fundamentals Revision Compartment models Pharmacokinetic study Pharmacokinetic study	12	3	9.2 9.4 9.5 9.b
3	**Gastro-retentive dds**	Principle, concepts advantages and disadvantages Modulation of GI transit time approaches to extend GI transit Buccal dds; principle of mucoadhesion, advantages and disadvantages Mechanism of drug permeation, methods of formulations and its evaluation	12	4	9.2 9.4 9.5 9.b
4	**Ocular and Buccal Dds** **Transdermal dds,**	Ocular, Buccal DDS an introduction, advantages, disadvantages, barriers of drug permeation, methods to overcome barriers. structure of skin and barriers Penetration enhancers Formulation and evaluation	12	5	9.2 9.4 9.5 9.b
5	**Protein and peptide delivery Vaccine delivery system**	Barriers for protein delivery Formulation and evaluation Vaccines uptake of antigens Single short vaccines Mucosal and transdermal delivery of vaccines	12	2	9.2 9.4 9.5 9.b

Reference Books:

Y W. Chien, Novel Drug Delivery Systems, 2nd edition, revised and expanded, Marcel Dekker, Inc., New York, 1 992.

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

Encyclopaedia of controlled delivery, Editor- Edith Mathiowitz, Published by Wileylnterscience Publication, John Wiley and Sons, Inc, New York! Chichester/Weinheim

N.K.Jain, Controlled and Novel Drug Delivery, CBS Publishers & Distributors, New Delhi, First edition 1997 (reprint in 2001).
S.P.Vyas and R.K.Khar, Controlled Drug Delivery - concepts and advances, Vallabh Prakashan, New Delhi, First edition 2002
Journals
Indian Journal of Pharmaceutical Sciences (IPA)
Indian drugs (IDMA)
Journal of controlled release (Elsevier Sciences) desirable
Drug Development and Industrial Pharmacy (Marcel & Decker) desirable
e-Learning Source:
https://www.nature.com/articles/s41551-021-00698-w

	Course Articulation Matrix: (Mapping of COs with POs and PSOs)																
PO-PSO CO	**PO1**	**PO2**	**PO3**	**PO4**	**PO5**	**PO6**	**PO7**	**PO8**	**PO9**	**PO10**	**PO11**	**PSO1**	**PSO2**	**PSO3**	**PSO4**	**PSO5**	**PSO6**
CO1	3	3	1	3	1	1	1	2	1	1	1	3	3	3	-	-	-
CO2	3	3	-	1	1	1	-	2	1	1	1	3	3	3	-	-	-
CO3	3	3	-	2	1	-	-	2	1	1	1	3	3	3	-	-	-
CO4	3	3	1	2	1	1	1	2	1	1	1	3	3	3	-	-	-
CO5	3	2	1	3	1	1	1	3	1	1	1	3	3	3	-	-	-

1. Low Correlation; 2- Moderate Correlation; 3- Substantial Correlation

Name & Sign of Program Coordinator	**Sign & Seal of HOD**

Integral University, Lucknow

Effective from Session: 2016-17								
Course Code	**MPH103T**	**Title of the Course**	**MODERN PHARMACEUTICS**	**SDG Goals**	**L**	**T**	**P**	**C**
Year	`I	**Semester**	I		4	-	-	4
Pre-Requisite	B. Pharm.	**Co-requisite**						
Course Objectives	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 Outcomes	
CO1	Apply the concepts of preformulation and optimization techniques during formulation development.
CO2	Recognize the importance of validation of methods, equipments and processes during pharmaceutical manufacturing.
CO3	Describe current good manufacturing practices guidelines and industrial management.
CO4	Analyze the importance of tablet compression and compaction studies.
CO5	Understand different consolidation parameters employed in formulation development and evaluation.

UnitNo.	Title of the Unit	Content of Unit	Contact Hrs.	Mapped CO	SDG Targets
1	**Preformulation concepts and optimization techniques**	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. 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	20	1	9.2 9.4 9.5 9.b
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 & P.Q. of facilities	10	2	9.1 9.2 9.4 9.5 9.b
3	**cGMP and 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	3	9.2 9.4 9.5 9.b
4	**Compression and compaction**	Physics of tablet compression, compression, consolidation, effect of friction, distribution of forces, compaction profiles. Solubility	10	4	9.2 9.4 9.5 9.b
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	10	5	9.2 9.4 9.5 9.b

Reference Books:

Theory and Practice of Industrial Pharmacy by Lachmann and Libermann

Pharmaceutical Dosage forms: Parenteral medications Vol. 1-2; By Leon Lachmann.

Modern Pharmaceutics; By Gillbert and S. Banker.

Remington's Pharmaceutical Sciences.

Physical Pharmacy; By Alfred martin

Pharmaceutical Dosage Form: Tablets Vol. 1-3 by Leon Lachmann.

e-Learning Source:

. https://www.taylorfrancis.com/books/edit/10.1201/9780824744694/modern-pharmaceutics-gilbert-banker-juergen-siepmann-christopher-rhodes

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	Course Articulation Matrix: (Mapping of COs with POs and PSOs)																
PO-PSO CO	**PO1**	**PO2**	**PO3**	**PO4**	**PO5**	**PO6**	**PO7**	**PO8**	**PO9**	**PO10**	**PO11**	**PSO1**	**PSO2**	**PSO3**	**PSO4**	**PSO5**	**PSO6**
CO1	3	3	3	3	2	3	3	3	3	2	3	3	3	3	-	-	-
CO2	3	3	3	2	2	3	3	3	3	3	3	3	3	3	-	-	-
CO3	3	3	3	2	3	3	3	3	3	3	3	3	3	3	-	-	-
CO4	3	3	3	2	2	3	2	3	3	3	3	3	3	3	-	-	-
CO5	3	3	3	3	3	3	3	3	3	2	3	3	3	3	-	-	-

1. Low Correlation; 2- Moderate Correlation; 3- Substantial Correlation

Name & Sign of Program Coordinator	**Sign & Seal of HOD**

Integral University, Lucknow

Effective from Session: 2016-17								
Course Code	**MPH104T**	**Title of the Course**	**REGULATORY AFFAIRS**	**SDG Goals**	**L**	**T**	**P**	**C**
Year	`I	**Semester**	I		4	-	-	4
Pre-Requisite	B. Pharm.	**Co-requisite**						
Course Objectives	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 product 5. Submission of global documents in CTD/ eCTD formats 6. Clinical trials requirements for approvals for conducting clinical trial 7. Pharmacovigilence and process of monitoring in clinical trials.							

Course Outcomes	
CO1	Understand the concepts of innovator and generic drugs, drug development process, regulatory guidance's and guidelines for filing and approval process.
CO2	Know the preparation of dossiers and their submission to regulatory agencies in different countries
CO3	Analyse thepost-approval regulatory requirements for actives and drug products, and submission of global documents in CTD/ eCTD formats.
CO4	Apply the Regulatory guidance's and guidelines for filing and approval process in different countries.
CO5	Identify the regulatory requirements for conducting clinical trials, pharmacovigilance and process of monitoring in clinical trials

UnitNo.	Title of the Unit	Content of Unit	Contact Hrs.	Mapped CO	SDG Targets
1	**Documentation in Pharmaceutical Industry** **Regulatory Requirement for Product Approval:**	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. API, biologics, novel, therapies obtaining NDA, ANDA for generic drugs ways and means of US registration for foreign drugs.	12	1, 2	16.3 16.5 16.6 16.7 16.8 16.b
2	**Regulatory requirements in different 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.	12	3	16.3 16.5 16.6 16.7 16.8 16.b
3	**Non-Clinical DrugDevelopment**	Global submission of IND, NDA, ANDA. Investigation of medicinal products dossier (IMPD) and investigator brochure (IB).	12	4	16.3 16.5 16.6 16.7 16.8 16.b
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 the clinical study process, pharmacovigilance safety monitoring in clinical trials.	12	5	16.1 16.3 16.5 16.6 16.7 16.8 16.b

Reference Books:

Generic Drug Product Development, Solid Oral Dosage Forms by Leon Shargel and Isader Kaufer, Marcel Dekker series, Vol.143.

The Pharmaceutical Regulatory Process, Second Edition Edited by Ira R. Berry and Robert P. Martin, Drugs and the Pharmaceutical Sciences, Vol.185, Informa Healthcare Publishers.

New Drug Approval Process: Accelerating Global Registrations by Richard A Guarino, MD,5th edition, Drugs and the Pharmaceutical Sciences,Vol.190.

e-Learning Source:

. https://www.sciencedirect.com/topics/medicine-and-dentistry/regulatory-affairs

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	Course Articulation Matrix: (Mapping of COs with POs and PSOs)																
PO-PSO CO	**PO1**	**PO2**	**PO3**	**PO4**	**PO5**	**PO6**	**PO7**	**PO8**	**PO9**	**PO10**	**PO11**	**PSO1**	**PSO2**	**PSO3**	**PSO4**	**PSO5**	**PSO6**
CO1	3	2	2	2	2	3	2	1	2	3	3	3	2	3	-	-	-
CO2	3	2	2	2	2	3	2	1	2	3	3	3	2	3	-	-	-
CO3	3	2	2	2	2	3	2	1	2	3	3	3	2	3	-	-	-
CO4	3	2	2	2	2	3	2	1	2	3	3	3	2	3	-	-	-
CO5	3	2	2	2	2	3	2	1	2	3	3	3	2	3	-	-	-

1. Low Correlation; 2- Moderate Correlation; 3- Substantial Correlation

Name & Sign of Program Coordinator	**Sign & Seal of HOD**

Integral University, Lucknow

Effective from Session: 2016-17							
Course Code	**MPH105**	**Title of the Course**	**PHARMACEUTICS PRACTICAL-I**	**L**	**T**	**P**	**C**
Year	`I	**Semester**	I	-	-	12	-
Pre-Requisite	B Pharm	**Co-requisite**	--				
Course Objectives	1. The various approaches for development of novel drug delivery systems 2. The criterial for selection of drugs and polymers for the development of delivering system. 3. The formulation and evaluation of Novel drug delivery systems.						

Course Outcomes	
CO1	Analyze the pharmacopoeial compounds and their formulations.
CO2	Execute the quantitative & qualitative analysis.
CO3	Interpret the results of spectral and chromatographical techniques.
CO4	Analyze preformulation and consolidation parameters during formulation development.
CO5	Evaluate the effects of different factors on disintegration and dissolution profiles of tablets.
CO6	Solve the issues related to formulation and evaluation of novel drug delivery systems.

Unit No.	Title of the Unit	Content of Unit	Contact Hrs.	Mapped CO
1.	**Compound analysisby UV-Visible spectrophotometry**	Analysis of pharmacopoeial compounds and their formulations by UV Vis spectrophotometer.	12	1
2.	**Compound analysisby UV-Visible spectrophotometry**	Simultaneous estimation of multi component containing formulations by UV Spectrophotometer.	12	1
3.	**HPLC**	Experiments based on HPLC.	12	3
4.	**Gas Chromatography**	Experiments based on Gas Chromatography.	12	3
5.	**Fluorimetry**	Estimation of riboflavin/quinine sulphate by fluorimetry.	12	2,4
6.	**Flame photometry**	Estimation of sodium/potassium by flame photometry	12	2,4
7.	**In-vitro dissolution study**	To perform In-vitro dissolution profile of CR/ SR marketed formulation.	12	5
8.	**In-vitro dissolution study**	To study the effect of particle size on dissolution of a tablet.	12	5
9.	**In-vitro dissolution study**	To study the effect of binders on dissolution of a tablet.	12	5
10.	**Formulation and evaluation of modified tablets**	Formulation and evaluation of sustained release matrix tablets.	12	4,5
11.	**Formulation and evaluation of modified tablets**	Formulation and evaluation osmotically controlled DDS.	12	4,5
12.	**Formulation and evaluation of modified tablets**	Preparation and evaluation of Floating DDS- hydro dynamically balanced DDS	12	4,5
13.	**Formulation and evaluation of modified tablets**	Formulation and evaluation of Muco adhesive tablets.	12	4,5
14.	**Formulation and evaluation of modified tablets**	To study the effect of compressional force on tablets disintegration time.	12	4,5
15.	**Pre-formulation study**	To carry out preformulation studies of tablets.	12	3
16.	**Pre-formulation study**	To study Micromeritic properties of powders and granulation.	12	3
17.	**Trans-dermal patches**	Formulation and evaluation of trans dermal patches.	12	5
18.	**Pharmacokinetic study**	To plot Heckal plot, Higuchi and peppas plot and determine similarity factors.	12	3

e-Learning Source:

https://www.google.co.in/books/edition/INSTRUMENTAL_METHODS_OF_ANALYSIS_LAB_MAN/yOMdEAAAQBAJ?hl=en&gbpv=1&dq=Pharmaceutical+analysis+practical+manual&printsec=frontcover

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https://www.google.co.in/books/edition/Pharmaceutical_Manufacturing_Handbook/4c0Hp3AOi8UC?hl=en&gbpv=1&dq=Pharmaceutical+formulation+and+evaluation+practical+manual&printsec=frontcover

	Course Articulation Matrix: (Mapping of COs with POs and PSOs)																
PO-PSO CO	**PO1**	**PO2**	**PO3**	**PO4**	**PO5**	**PO6**	**PO7**	**PO8**	**PO9**	**PO10**	**PO11**	**PSO1**	**PSO2**	**PSO3**	**PSO4**	**PSO5**	**PSO6**
CO1	3	3	3	3	2	3	2	3	3	2	3	3	3	3	-	-	-
CO2	3	3	3	3	2	3	2	3	3	2	3	3	3	3	-	-	-
CO3	3	3	3	3	3	3	3	3	3	2	3	3	3	3	-	-	-
CO4	3	3	3	3	2	3	3	3	3	3	3	3	3	3	-	-	-
CO5	3	3	3	3	2	3	3	3	3	3	3	3	3	3	-	-	-
CO6	3	3	3	3	2	3	2	3	3	2	3	3	3	3	-	-	-

1. Low Correlation; 2- Moderate Correlation; 3- Substantial Correlation

Name & Sign of Program Coordinator	**Sign & Seal of HOD**

Integral University, Lucknow

Effective from Session: 2016-17								
Course Code	**MPH201T**	**Title of the Course**	**MOLECULAR PHARMACEUTICS (NANOTECHNOLOGY & TARGETED DDS)**	**SDG Goals**	**L**	**T**	**P**	**C**
Year	`I	**Semester**	II		4	-	-	4
Pre-Requisite	B. Pharm.	**Co-requisite**						
Course 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 formulation and evaluation of novel drug delivery systems.							

Course Outcomes	
CO1	Recall the basic aspects and approaches of targeted drug delivery systems
CO2	Describe methods for the preparation and evaluation of polymeric nanoparticles and liposomes
CO3	Outline the preparation methods and applications of monoclonal antibodies and vesicular nanocarriers
CO4	Discuss the different aspects of pulmonary drug delivery systems
CO5	Choose components of nucleic acid based therapeutic delivery systems

UnitNo.	Title of the Unit	Content of Unit	Contact Hrs.	Mapped CO	SDG Targets
1	**Targeted Drug Delivery Systems**	Concepts, Events and biological process involved in drug targeting. Tumor targeting and Brain specific delivery.	12	1	9.1 9.2 9.5 9.b
2	**Targeting Methods**	Introduction, preparation and evaluation. Nanoparticles & Liposomes: Types, preparation and evaluation.	12	2	9.1 9.2 9.5 9.b
3	**Microparticles, monoclonal antibodies and other carrier systems**	Microcapsules/Microspheres: Types, preparation and evaluation Monoclonal Antibodies: Preparation and application Preparation and application of Niosomes, Aquasomes, Phytosomes, Electrosomes.	12	3	9.1 9.2 9.5 9.b
4	**Pulmonary Drug Delivery Systems**	Aerosols, propellants, Container Types, preparation and evaluation; Intra Nasal Route Delivery systems; Types, preparation and evaluation.	12	4	9.1 9.2 9.5 9.b
5	**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.	12	5	9.1 9.2 9.5 9.b

Reference Books:

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, VallabhPrakashan, New Delhi, First edition 2002.
3. N.K. Jain, Controlled and Novel Drug Delivery, CBS Publishers & Distributors, NewDelhi, First edition 1997 (reprint in 2001)
4. Biopharmaceutics and Clinical Pharmacokinetics, An Introduction, 4th edition,revised and expande by Robert. E. Notari, Marcel Dekker Inc, New York and Basel,1987.

Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James. G.Boylan, Marcel Dekker Inc, New York, 1996.

e-Learning Source:

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3571524/

Integral University, Lucknow

	Course Articulation Matrix: (Mapping of COs with POs and PSOs)																
PO-PSO CO	**PO1**	**PO2**	**PO3**	**PO4**	**PO5**	**PO6**	**PO7**	**PO8**	**PO9**	**PO10**	**PO11**	**PSO1**	**PSO2**	**PSO3**	**PSO4**	**PSO5**	**PSO6**
CO1	3	3	3	3	3	2	3	3	2	3	3	3	3	3	-	-	-
CO2	3	3	3	3	3	3	3	3	3	3	3	3	3	3	-	-	-
CO3	3	3	3	3	2	2	3	3	3	3	3	3	3	3	-	-	-
CO4	3	3	2	2	2	2	3	3	2	3	3	3	3	3	-	-	-
CO5	3	3	3	3	3	3	3	3	2	3	3	3	3	3	-	-	-

1. Low Correlation; 2- Moderate Correlation; 3- Substantial Correlation

Name & Sign of Program Coordinator	**Sign & Seal of HOD**

Integral University, Lucknow

Effective from Session: 2016-17								
Course Code	**MPH202T**	**Title of the Course**	**ADVANCED BIOPHARMACEUTICS & PHARMACOKINETICS**	**SDG Goals**	**L**	**T**	**P**	**C**
Year	`I	**Semester**	II		4	-	-	4
Pre-Requisite	B. Pharm.	**Co-requisite**						
Course Objectives	1. The basic concepts in biopharmaceutics and pharmacokinetics. 2. The use of raw data and derive the pharmacokinetic models and parameters that best describe the process of drug absorption, distribution, metabolism and elimination. 3. The critical evaluation of biopharmaceutical studies involving drug product equivalency. 4. The design and evaluation of dosage regimens of the drugs using pharmacokinetic and biopharmaceutical parameters. 5. The potential clinical pharmacokinetic problems and application of basics of pharmacokinetics.							

Course Outcomes	
CO1	Understand basic concepts in biopharmaceutics and pharmacokinetics.
CO2	Explain the design and evaluation of dosage regimens of the drugs using pharmacokinetic and biopharmaceutics parameters.
CO3	Analyze raw data and derive the pharmacokinetic models and parameters that best describes the process of drug absorption, distribution, metabolism and elimination.
CO4	Know critical evaluation of biopharmaceutics studies involving drug product equivalency.
CO5	Identify potential clinical pharmacokinetic problems and apply basic pharmacokinetic principles to solve them.

UnitNo.	Title of the Unit	Content of Unit	Contact Hrs.	Mapped CO	SDG Targets
1	**Drug Absorption from the Gastrointestinal Tract**	Gastrointestinal tract, mechanism of drug absorption, factors affecting drug absorption, pH–partition theory of drug absorption. Formulation and 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.	12	1	9.1 9.2 9.5 9.b
2	**Biopharmaceutical Considerations in Drug Product Design and In Vitro Drug Product Performance**	Introduction, biopharmaceutical 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.	12	2	9.1 9.2 9.5 9.b
3	**Pharmacokinetics**	Basic considerations, pharmacokinetic models, compartment modeling: one compartment model- IV bolus, IV infusion, extra-vascular. Multi compartment model: two compartment -model in brief, non-linear pharmacokinetics: cause of non-linearity, Michaelis–Menten equation, estimation of Kmax and Vmax. Drug interactions: Introduction, the effect of protein binding interactions, the effect of tissue binding interactions, cytochrome p450-based drug interactions, and drug interactions linked to transporters.	12	3	9.1 9.2 9.5 9.b
4	**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, methods. Permeability: In-vitro, in-situ and In-vivo methods. Generic biologics (biosimilar drug products), clinical significance of bioequivalence studies, special concerns in bioavailability and bioequivalence studies, generic substitution.	12	4	9.1 9.2 9.5 9.b

5	**Application of Pharmacokinetics**	Modified-release drug products, targeted drug delivery Systems and biotechnological products. Introduction to pharmacokinetics and pharmacodynamic, drug interactions. Pharmacokinetics and pharmacodynamics of biotechnology drugs. Introduction, proteins and peptides. Monoclonal antibodies, oligonucleotides, vaccines (immunotherapy), gene therapies.	12	5	9.1 9.2 9.5 9.b
Reference Books:					
Biopharmaceutics and Clinical Pharmacokinetics by Milo Gibaldi, 4th edition, Philadelphia, Lea and Febiger, 1991.					
Biopharmaceutics and Pharmacokinetics, A. Treatise, D .M. Brahmankar and Sunil B. Jaiswal., Vallabh Prakashan, Pitampura, Delhi.					
Applied Biopharmaceutics and Pharmacokinetics by Shargel. Land Yu ABC, 2ndedition, Connecticut Appleton Century Crofts, 1985.					
Pharmacokinetics by Milo Gibaldi and D. Perrier, 2nd edition, Marcel Dekker Inc.,New York, 1982					
e-Learning Source:					
https://fjps.springeropen.com/articles/10.1186/s43094-020-00047-9					

	Course Articulation Matrix: (Mapping of COs with POs and PSOs)																
PO-PSO CO	**PO1**	**PO2**	**PO3**	**PO4**	**PO5**	**PO6**	**PO7**	**PO8**	**PO9**	**PO10**	**PO11**	**PSO1**	**PSO2**	**PSO3**	**PSO4**	**PSO5**	**PSO6**
CO1	3	2	2	2	2	3	2	1	2	3	3	3	2	3	-	-	-
CO2	3	2	2	2	2	3	2	1	2	3	3	3	2	3	-	-	-
CO3	3	2	2	2	2	3	2	1	2	3	3	3	2	3	-	-	-
CO4	3	2	2	2	2	3	2	1	2	3	3	3	2	3	-	-	-
CO5	3	2	2	2	2	3	2	1	2	3	3	3	2	3	-	-	-

1. Low Correlation; 2- Moderate Correlation; 3- Substantial Correlation

Name & Sign of Program Coordinator	**Sign & Seal of HOD**

Integral University, Lucknow

Effective from Session: 2016-17								
Course Code	**MPH203T**	**Title of the Course**	**COMPUTER AIDED DRUG DELIVERY SYSTEM**	**SDG Goals**	**L**	**T**	**P**	**C**
Year	`I	**Semester**	II		4	0	0	4
Pre-Requisite	B. Pharm.	**Co-requisite**						
Course Objectives	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 Outcomes	
CO1	Describe statistical modeling and quality by design in pharmaceutical research and development
CO2	Discuss the descriptors of drug disposition utilized in computational modeling
CO3	Understand the ethics and legal protection of computing in pharmaceutical research
CO4	Defend *in silico* approaches for biopharmaceutical characterization
CO5	Recognize the importance of automation in pharmaceutical development

UnitNo.	**Title of the Unit**	**Content of Unit**	**Contact Hrs.**	**Mapped CO**	**SDG Targets**
1	**Computers and Quality-by-Design in pharmaceutical research and development**	Computers in pharmaceutical research and development: History of computers in pharmaceutical research and development, introduction of statistical modeling in pharmaceutical research and development, different statistical models 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, concept and components of QbD, ICH Q8 guideline, regulatory and industry views on QbD, scientifically based QbD-examples of application	12	1	9.1 9.2 9.4 9.5 9.b
2	**Computational modeling of drug disposition**	Introduction, modeling techniques, drug absorption, solubility, intestinal permeation, drug distribution, drug excretion, active transport, P-glycoprotein (P-gp), breast cancer resistance protein (BCRP), nucleoside transporters, human peptide transporter (hPEPT1), apical sodium dependent bile acid transporter (ASBT), organic cation transporter (OCT), organic anion transporting polypeptide (OATP), blood brain barrier-choline transporter	12	2	9.1 9.2 9.4 9.5 9.b
3	**Computer-aided formulation development**	Concept of optimization, optimization parameters, factorial design, optimization technology and screening design. Computers in pharmaceutical formulation: development of pharmaceutical emulsions, development of microemulsion drug carriers. Legal protection of innovative uses of computers in research and development, The ethics of computing in pharmaceutical research, computers in market analysis	12	3	9.1 9.2 9.4 9.5 9.b
4	**Computer-aided biopharmaceutical and clinical characterization**	Computer-aided biopharmaceutical characterization: Theoretical background of gastrointestinal absorption simulation, 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: Introduction, clinical data collection and management, regulation of computer systems.	12	4	9.1 9.2 9.4 9.5 9.b
5	**Artificial intelligence, robotics and computational fluid dynamics**	General overview, pharmaceutical automation, pharmaceutical applications, advantages and disadvantages, current challenges and future directions	12	5	9.1 9.2 9.4 9.5 9.b

Reference Books:
Computer Applications in Pharmaceutical Research and Development
Computer-Aided Applications in Pharmaceutical Technology
Encyclopedia of Pharmaceutical Technology
Basic Pharmacokinetics
Applied Biopharmaceutics and Pharmacokinetics by Shargel. Land YuABC
e-Learning Source:
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5248982/

	Course Articulation Matrix: (Mapping of COs with POs and PSOs)																
PO-PSO CO	**PO1**	**PO2**	**PO3**	**PO4**	**PO5**	**PO6**	**PO7**	**PO8**	**PO9**	**PO10**	**PO11**	**PSO1**	**PSO2**	**PSO3**	**PSO4**	**PSO5**	**PSO6**
CO1	3	3	3	3	3	3	2	3	3	2	3	3	3	3	-	-	-
CO2	3	3	3	3	3	3	3	3	3	3	3	3	2	3	-	-	-
CO3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	-	-	-
CO4	3	3	3	3	2	2	2	3	3	2	3	3	3	3	-	-	-
CO5	3	3	3	3	2	3	3	3	3	2	3	3	3	2	-	-	-

1. Low Correlation; 2- Moderate Correlation; 3- Substantial Correlation

Name & Sign of Program Coordinator	**Sign & Seal of HOD**

Integral University, Lucknow

Effective from Session: 2016-17								
Course Code	**MPH204T**	**Title of the Course**	**COSMETICS & COSMECEUTICALS**	**SDG Goals**	**L**	**T**	**P**	**C**
Year	`I	**Semester**	II		4	0	0	4
Pre-Requisite	B. Pharm.	**Co-requisite**						
Course Objectives	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 Outcomes	
CO1	Gain information on key ingredients used in cosmetics and cosmeceuticals
CO2	Understand key building blocks of cosmetics for various formulations
CO3	Know the current technologies in the market
CO4	Understand the scientific principles to develop cosmetics and cosmeceuticals with desired safety
CO5	Understand the regulatory aspects in cosmetics

UnitNo.	**Title of the Unit**	**Content of Unit**	**Contact Hrs.**	**Mapped CO**	**SDG Targets**
1	**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.	12	1, 5	9.1 9.2 9.4 9.5 9.b
2	**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.	12	2, 4	9.5
3	**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 syndetbars. Perfumes; Classification of perfumes. Perfume ingredients listed as allergens in EU regulation. Controversial ingredients: Parabens, formaldehyde liberators, dioxane.	12	1, 2, 5	9.1 9.2 9.4 9.5 9.b
4	**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.	12	1, 2, 4	9.1 9.2 9.4 9.5 9.b
5	**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.	12	1, 3, 4, 5	9.1 9.2 9.4 9.5 9.b

Reference Books:

Harry's Cosmeticology. 8th edition.

Cosmetics - Formulation, Manufacture and quality control, PP.Sharma, 4th edition

Handbook of cosmetic science and Technology A.O.Barel, M.Paye and H.I. Maibach. 3 rd edition

Cosmetic and Toiletries recent suppliers catalogue.

e-Learning Source:

USFDA: **https://www.fda.gov/cosmetics**

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CDSCO: **https://cdsco.gov.in/opencms/opencms/en/Cosmetics/cosmetics/**

	Course Articulation Matrix: (Mapping of COs with POs and PSOs)																
PO-PSO CO	**PO1**	**PO2**	**PO3**	**PO4**	**PO5**	**PO6**	**PO7**	**PO8**	**PO9**	**PO10**	**PO11**	**PSO1**	**PSO2**	**PSO3**	**PSO4**	**PSO5**	**PSO6**
CO1	1	1	-	-	-	3	-	-	2	1	1	2	1	1	-	-	-
CO2	1	1	-	-	-	3	-	-	2	1	1	2	1	1	-	-	-
CO3	1	1	-	-	-	3	-	-	2	1	1	3	1	1	-	-	-
CO4	1	1	-	-	-	3	-	-	2	1	1	3	1	1	-	-	-
CO5	1	1	-	-	-	3	-	-	2	1	1	2	1	1	-	-	-

1. Low Correlation; 2- Moderate Correlation; 3- Substantial Correlation

Name & Sign of Program Coordinator	**Sign & Seal of HOD**

Integral University, Lucknow

Effective from Session: 2016-17							
Course Code	**MPH205**	**Title of the Course**	**PHARMACEUTICS PRACTICAL-II**	**L**	**T**	**P**	**C**
Year	`I	**Semester**	II	-	-	12	-
Pre-Requisite	B Pharm	**Co-requisite**	--				
Course Objectives	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. 4. Scientific knowledge to develop cosmetics and cosmeceuticals with desired Safety, stability, and efficacy.						

Course Outcomes	
CO1	Develop and evaluate different novel formulations by suitable methods.
CO2	Design and optimize formulations by using Design of Experiment approach.
CO3	Solve problems related to protein binding and bioavailability studies.
CO4	Apply *in silico* approach for simulations of pharmacokinetics and pharmacodynamics.
CO5	Use scientific knowledge to develop and evaluate cosmetic formulations

Unit No.	**Title of the Unit**	**Content of Unit**	**Contact Hrs.**	**Mapped CO**
1.	**Microcapsules**	To study the effect of temperature change, non solvent addition, in compatible polymer addition in microcapsules prepararion.	12	1
2.	**Beads**	To prepare and evaluate alginate beads.	12	1
3.	**Microspheres**	Formulation and evaluation of liposomes/niosomes,spherules.	12	1
4.	**Solid dispersion**	Improvement of dissolution characteristic of slightly soluble drug by solid dispersion.	12	1
5.	**Dissolution characters**	Comparison of dissolution of different marketed products.	12	1
6.	**Protein binding**	To study protein binding of highly protein bound drug & poorly protein bound drug.	12	3
7.	**Bioavailability**	To study the bioavailability of given drug.	12	3
8.	**Pharmacokinetic analysis**	Pharmacokineticand IVIVC data analysis by Winnoline software.	12	4
9.	**Permeability**	In vitro cell study for permeability and metabolism.	12	4
10.	**DOE**	Design Expert software, formulation data analysis and Quality-by-design in Pharmaceutical Development..	12	2
11.	**Computer Simulation**	Computer Simulation in Pharmacokinetics & Pharmacodynamics.	12	2,4
12.	**Computational Modeling**	Computational Modeling of Drug Disposition.	12	2
13.	**Clinical Data**	To develop Clinical Data manual.	12	2
14.	**Modeling**	To carry out Sensitivity Analysis, and Population Modeling.	12	2
15.	**Cosmeceuticals**	Development & evaluation of creams, Shampoo & Toothpaste and incorporation of herbal & chemical actives to develop products.	12	5

e-Learning Source:

https://www.pharmatutor.org/articles/details-on-formulation-and-evaluation-of-microspheres

https://www.scielo.br/j/bjps/a/zwwMpgN95HsPkzTG9B5FpWg/?format=pdf

https://www.researchgate.net/publication/325023106

	Course Articulation Matrix: (Mapping of COs with POs and PSOs)																
PO-PSO CO	**PO1**	**PO2**	**PO3**	**PO4**	**PO5**	**PO6**	**PO7**	**PO8**	**PO9**	**PO10**	**PO11**	**PSO1**	**PSO2**	**PSO3**	**PSO4**	**PSO5**	**PSO6**
CO1	3	3	3	3	3	3	2	3	3	3	3	3	3	3	-	-	-
CO2	3	3	3	3	3	3	3	3	3	3	3	3	3	3	-	-	-
CO3	3	3	3	3	3	3	3	3	3	2	3	3	2	3	-	-	-
CO4	3	3	3	3	3	2	3	3	3	2	3	3	3	3	-	-	-
CO5	3	3	3	3	2	2	3	3	3	3	3	2	3	2	-	-	-
CO6	3	3	3	3	3	3	2	3	3	3	3	3	3	3	-	-	-

1. Low Correlation; 2- Moderate Correlation; 3- Substantial Correlation

Integral University, Lucknow

Name & Sign of Program Coordinator	**Sign & Seal of HOD**

Integral University, Lucknow

Effective from Session: 2017-18								
Course Code	**MPH301T**	**Title of the Course**	**RESEARCH METHODOLOGY & BIOSTATISTICS**	**SDG Goals**	**L**	**T**	**P**	**C**
Year	`I	**Semester**	III		4	-	-	4
Pre-Requisite	B. Pharm.	**Co-requisite**						
Course Objectives	1. Explain the basic requirements for designing the research project. 2. Demonstrate the types of statistical methods. 3. Explain the CPCSEA guidelines for keeping the laboratory animals. 4. Explain the different ethical principles for conducting the clinical trials. 5. Explain the principles declaration of Helsinki and ICG guidelines							

Course Outcomes	
CO1	After studying this subject, students will learn regarding the strategies to eliminate errors/bias, controls, randomization, crossover design, placebo, blinding techniques.
CO2	Students can demonstrate different statistical methods for calculation of data such as t test, ANOVA, wilcoxan rank tests etc.
CO3	Students will learn about history, values in medical ethics, autonomy, beneficence, non–maleficence, double effect, conflicts between autonomy and beneficence/non–maleficence, euthanasia, informed consent, confidentiality etc.
CO4	After studying this subject, students can explain the CPCSEA guidelines for laboratory animal facility.
CO5	After studying this subject, students will know the Declaration of Helsinki: History, introduction, basic principles for all medical research,

Unit No.	**Title of the Unit**	**Content of Unit**	**Contact Hrs.**	**Mapped CO**	**SDG Targets**
1	**General Research Methodology:**	Research, objective, requirements, practical difficulties, review of literature, study design, types of studies, strategies to eliminate errors/bias, controls, randomization, crossover design, placebo, blinding techniques.	12	3	
2	**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.	12	3	
3	**Medical Research:**	History, values in 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.	12	3	
4	**CPCSEA guidelines for laboratory animal facility:**	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.	12	2	
5	**Declaration of Helsinki:**	History, introduction, basic principles for all medical research, and additional principles for medical research combined with medical care.	12	3	

Reference Books:

Central Drugs Standard Control Organization– Good Clinical Practices, Guidelines for Clinical Trials on Pharmaceutical Products in India. New Delhi: Ministry of Health;2001.

International Conference on Harmonization of Technical requirements for registration of Pharmaceuticals for human use. ICH Harmonized Tripartite Guideline. Guideline for Good Clinical Practice.E6; May 1996.

Ethical Guidelines for Biomedical Research on Human Subjects 2000. Indian Council of Medical Research, New Delhi.

Textbook of Clinical Trials edited by David Machin, Simon Day and Sylvan Green, March 2005, John Wiley and Sons.

e-Learning Source:

https://drive.google.com/drive/folders/1W4b4NRhqBQWMC14vsBNZcdc2LWFFmcrd?usp=share_link

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	Course Articulation Matrix: (Mapping of COs with POs and PSOs)																
PO-PSO CO	**PO1**	**PO2**	**PO3**	**PO4**	**PO5**	**PO6**	**PO7**	**PO8**	**PO9**	**PO10**	**PO11**	**PSO1**	**PSO2**	**PSO3**	**PSO4**	**PSO5**	**PSO6**
CO1	2	3	3	3	3	3	3	2	3	3	3	3	2	3	-	-	-
CO2	3	3	3	3	3	2	2	3	2	2	2	2	3	3	-	-	-
CO3	3	2	2	2	2	2	3	1	3	3	3	3	3	3	-	-	-
CO4	3	3	3	3	3	2	2	2	3	2	2	3	3	3	-	-	-
CO5	3	2	3	3	1	1	3	1	2	3	3	2	2	3	-	-	-

1. Low Correlation; 2- Moderate Correlation; 3- Substantial Correlation

Name & Sign of Program Coordinator	**Sign & Seal of HOD**