



**GALGOTIAS  
UNIVERSITY**

**Syllabus of**  
**Master of Pharmacy in Pharmaceutics**

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**Name of School:** School of Medical and Allied Sciences

**Department:** Pharmacy

**Year:** 2021-2023

**Vision:**

To be recognized globally as a premier school in the field of Pharmaceutical Sciences for imparting value based education, and engaged in multidisciplinary and collaborative research.

**Mission:**

**M1.** Establish state-of-the-art facilities to analyze develop test and invent new methods in Pharmaceutical Science by involving multiple stakeholders

**M2.** Establishing center of excellences for multidisciplinary collaborative research by involving industries and academia

**M3.** To train the students and faculties into analytical approach and developing new products specially in Natural and Herbal pharmaceutical products

**Programme Educational Objectives (PEOs):**

**Post-Graduate shall be able:**

**PEO1:** To bear strong professional competence in Pharmaceutical Sciences with innovative approaches in R & D.

**PEO2:** To undertake the responsibilities in health care system with understanding of needs of Industry/ Government organizations.

**PEO3:** To imbibe unique expertise to develop entrepreneurship and acumen for sustainable development.

**Programme Specific Outcomes (PSOs):**

**Post Graduate shall be able:**

**PSO1:** To know the basis of formulation aspects of drugs and excipients in order to design efficacious and stable dosage forms.

**PSO2:** To evolve in the area of novel drug delivery system with reference to formulation development and their optimization.

**PSO3:** To execute the higher education and research projects that lead to develop commercial product /services.

<b>PO1</b>	<b>Pharmacy Knowledge</b>	Possess knowledge and comprehension of the core and basic knowledge associated with the profession of pharmacy, including biomedical sciences; Pharmaceutical sciences; behavioral, social, and administrative issues of Pharmacy sciences.
<b>PO2</b>	<b>Planning Abilities</b>	Demonstrate effective planning abilities including time management, resource management, delegation skills and organizational skills. Develop and implement plans and organize work to meet deadlines.
<b>PO3</b>	<b>Problem Analysis</b>	Utilize the principles of scientific enquiry, thinking analytically, clearly and critically, while solving problems and making decisions during daily practice. Find, analyze, evaluate and apply information systematically and shall make defensible decisions. Modern tool usage: Learn, select, and apply appropriate methods and procedures, resources, and modern pharmacy-related computing tools with an understanding of the limitations.
<b>PO4</b>	<b>Modern Tool Usage</b>	Utilize the principles of scientific enquiry, thinking analytically, clearly and critically, while solving problems and making decisions during daily practice. Find, analyze, evaluate and apply information systematically and shall make defensible decisions.
<b>PO5</b>	<b>Leadership Skills</b>	Understand and consider the human reaction to change, motivation issues, leadership and team-building when planning changes required for fulfillment of practice, professional and societal responsibilities. Assume participatory roles as responsible citizens or leadership roles when appropriate to facilitate improvement in health and wellbeing.
<b>PO6</b>	<b>Professional Identity</b>	Understand, analyze and communicate the value of their professional roles in society (e.g. health care professionals, promoters of health, educators, managers, employers, employees).
<b>PO7</b>	<b>Pharmaceutical Ethics</b>	Honor personal values Use ethical frameworks; apply ethical principles while making decisions and take responsibility for the outcomes associated with the decisions.
<b>PO8</b>	<b>Communication</b>	Communicate effectively with the community and with society, such as, being able to comprehend and write effective reports, make effective presentations and documentation, and give and receive clear instructions.
<b>PO9</b>	<b>The Pharmacist and society</b>	Apply reasoning informed by the contextual knowledge to assess societal, health, safety and legal issues and the consequent responsibilities relevant to the professional pharmacy practice.
<b>PO10</b>	<b>Environment and sustainability</b>	Understand the impact of the professional pharmacy solutions in societal and environmental contexts, demonstrate the knowledge of, and need for sustainable development.
<b>PO11</b>	<b>Life-long learning</b>	Recognize the need for, and have the preparation and ability to engage in independent and life-long learning in the broadest context of technological change. Self access and use feedback effectively from others to identify learning needs and to satisfy these needs on an ongoing basis.

# CURRICULUM & PGROGRAMME STRUCTURE

As per course regulations 2014 and Scheme and syllabus  
implemented from 2016-17 academic sessions

**M.Pharm (Pharmaceutics)**

M.Pharm (Pharmaceutics) Programme Structure (LTPC)

**Semester I**

Course Code	Subject	L	T	P	C	Examinations/Assessments			
						Internal Assessments		End Semester Examination	
						Continu ous Mode	Sessional Exam	End Semester Exams	Total
MPHT1001	Modern Pharmaceutical Analytical Techniques	4	0	0	4	10	15	75	100
MPHT1002	Drug Delivery System	4	0	0	4	10	15	75	100
MPHT1003	Modern Pharmaceutics	4	0	0	4	10	15	75	100
MPHT1004	Regulatory Affair	4	0	0	4	10	15	75	100
MPHP1005	Pharmaceutics Practical I	0	0	12	6	20	30	100	150
MPHA1006	Seminar/Assignment	0	0	7	4	--	--	100	100
	<b>Total</b>	<b>16</b>	<b>0</b>	<b>19</b>	<b>26</b>				650

## Semester II

Course Code	Subject	L	T	P	C	Examinations/Assessments			
						Internal Assessments		End Semester Examinations	
						Continu ous Mode	Sessional Exam	End Semester Exams	Total
MPHT2001	Molecular Pharmaceutics (Nano Tech and Targeted DDS)	4	0	0	4	10	15	75	100
MPHT2002	Advanced Biopharmaceutics & Pharmacokinetics	4	0	0	4	10	15	75	100
MPHT2003	Computer Aided Drug Delivery System	4	0	0	4	10	15	75	100
MPHT2004	Cosmetic and Cosmeceuticals	4	0	0	4	10	15	75	100
MPHP2005	Pharmaceutics Practical II	0	0	12	6	20	30	100	150
MPHA2006	Seminar/Assignment	0	0	7	4	--	--	100	100
	Total	16	0	19	26				650

## Semester III

Course Code	Subject	L	T	P	C	Examinations/Assessments				
						Internal Assessments			End Semester Examinations	
						Contin uous Mode	Session al Exam	Total	End Semeste r Exams	Tota l
MRMT3001	Research Methodology and Biostatistics*	4	0	0	4	10*	15	25	75	100
MPHJ3002	Journal club	1	0	0	1	--	--	25**	--	25
MPHD3003	Discussion / Presentation (Proposal Presentation)	2	0	0	2	--	--	50**	--	50
MPHR3004	Research Work*	0	0	28	14	--	--	--	350	350
	Total	7	0	28	21					525

\*Continuous Mode \*\*Internal Assessment

## Semester IV

Course Code	Subject	L	T	P	C	Examinations/Assessments				
						Internal Assessments			End Semester Examinations	
						Contin uous Mode	Sessiona l Exam	Total	End Semeste r Exams	Tota l
MPHJ4001	Journal Club	1	0	0	1	--	--	25**	--	25
MPHD4002	Discussion / Presentation (Proposal Presentation)	0	0	31	16	--	--	75**	--	75
MPHR4003	Research Work and Colloquium	3	0	0	3	--	--	--	400	400
	Total	4	0	31	20					500

**\*Continuous Mode \*\*Internal Assessment**

## Detailed Syllabus

<b>Name of The Course</b>	Modern Pharmaceutical Analytical Techniques			
<b>Course Code</b>	MPHT1001			
<b>Prerequisite</b>				
<b>Co-requisite</b>				
<b>Anti-requisite</b>				
	<b>L</b>	<b>T</b>	<b>P</b>	<b>C</b>
	4	0	0	4

### Course Objectives

1. After completion of course student is able to know Various spectral techniques of analysis
2. The analysis of various drugs in single and combination dosage forms
3. Theoretical and practical skills of the instruments

### Course Outcomes

<b>CO1</b>	Remembring the Theory, Instrumentation and applications of UV-Visible spectroscopy, IR spectroscopy and Spectrofluorimetry
<b>CO2</b>	Understanding the basic principle of NMR spectroscopy.
<b>CO3</b>	Analyzing the basic principle, instrumentation, chromatographic parameters, factors affecting resolution and applications of Chromatography.
<b>CO4</b>	Analyzing the basic principle, instrumentation, chromatographic parameters, factors affecting resolution and applications of Chromatography.
<b>CO5</b>	Evaluating the basic Principle, Instrumentation, Working conditions, factors affecting separation and applications of Electrophoresis, Immunological assays and X ray Crystallography
<b>CO6</b>	Evaluating the basic Principle of Immunological assays

### Continuous Assessment Pattern

Internal Assessment (IA)	Sessional Exam	End Term Exam (ETE)	Total Marks
10	15	75	100

### Course Content:

<b>Unit I: UV-Visible, IR, Spectrofluorimetry</b> <b>11 Hours</b>
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- a. UV-Visible spectroscopy: Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV-Visible spectroscopy.
- b. IR spectroscopy: Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier - Transform IR Spectrometer, Factors affecting vibrational frequencies and Applications of IR spectroscopy
- c. Spectrofluorimetry: 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.

### Unit II: NMR spectroscopy

#### 11 Hours

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 <sup>13</sup>C NMR. Applications of NMR spectroscopy.

### Unit III: Mass Spectroscopy 11 Hours

: Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules, Meta stable ions, Isotopic peaks and Applications of Mass spectroscopy.

### Unit IV: Chromatography 11 Hours

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

### Unit V: Electrophoresis

#### 11Hours

a.: 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) Isoelectric 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

**Unit VI Immunological assays:**

RIA (Radio-Immuno assay), ELISA, Bioluminescence assays. Chemiluminescence for reactive oxygen species sensing and imaging analysis, high-throughput ADME screening in drug discovery, characterization and quantification of antibody-drug conjugates, nucleic acid detection for coronavirus

## Suggested Readings:

## Text and Reference Books

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, 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, Volume11, Marcel Dekker Series**

Name of The Course	Drug Delivery System			
Course Code	MPHT1002			
Prerequisite				
Co-requisite				
Anti-requisite				
	L	T	P	C
	4	0	0	4

**Course Objectives**

The basic objective of this course is to get familiar with product development. Upon completion of the course, student shall be able to understand,

- The various approaches for development of novel drug delivery systems.
- The criteria for selection of drugs and polymers for the development of delivering system
- The formulation and evaluation of Novel drug delivery systems.

**Course Outcomes**

CO 1	Student will be able to get familiar with Pre-formation and concepts and sustained release and controlled release formulations
CO 2	Students will be able to optimize Pharmaceutical formulation.
CO 3	Students will be able to develop different formulation on rate controlled drug delivery systems.
CO 4	Students will be able to develop the skills to solve different types of problems in solving the drug delivery.
CO 5	Students will be able to learn about the Ocular Drug Delivery Systems & Transdermal Drug Delivery Systems.
CO 6	Students will be able to learn about the recent advancements in Drug Delivery Systems.

**Continuous Assessment Pattern**

Internal Assessment (IA)	Sessional Examination	End Term Exam (ETE)	Total Marks
10	15	75	100

**Course Content:**

UNIT 1:	12 H
<b>Sustained Release (SR) and Controlled Release (CR) formulations:</b>	
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,	

Tele-pharmacy.	
UNIT 2:	12H
<b>Rate Controlled Drug Delivery Systems</b>	
Rate Controlled Drug Delivery Systems: Principles & Fundamentals, Types, Activation; Modulated Drug Delivery Systems; Mechanically activated, Ph activated, Enzyme activated, and Osmotic activated Drug Delivery Systems Feedback regulated Drug Delivery Systems; Principles & Fundamentals.	
UNIT 3:	12 H
<b>Gastro-Retentive Drug Delivery Systems:</b>	
Gastro-Retentive Drug Delivery Systems: Principle, concepts advantages and disadvantages, Modulation of GI transit time approaches to extend GI transit. Buccal Drug Delivery Systems: Principle of muco-adhesion, advantages and disadvantages, Mechanism of drug permeation, Methods of formulation and its evaluations.	
UNIT 4:	12H
<b>Ocular Drug Delivery Systems &amp; Transdermal Drug Delivery Systems:</b>	
Ocular Drug Delivery Systems: Barriers of drug permeation, Methods to overcome barriers. Transdermal Drug Delivery Systems: Structure of skin and barriers, Penetration enhancers, Transdermal Drug Delivery Systems, Formulation and Evaluation.	
UNIT 5:	12H
<b>Protein and Peptide Delivery &amp; Vaccine delivery systems:</b>	
Protein and Peptide Delivery: Barriers for protein delivery. Formulation and evaluation of delivery systems of proteins and other macromolecules. Vaccine delivery systems: Vaccines, uptake of antigens, single shot vaccines, mucosal and transdermal delivery of vaccines.	
UNIT 6:	8H
<b>Recent Advancement in Drug Delivery System:</b>	
Recent advancements in novel drug delivery systems: Novel multifunctional nanoparticles and cancer targeting, Future Opportunities and Challenges in novel drug delivery system, Microwave assisted drug delivery system, Applications and Markets in novel drug delivery system.	

## Suggested Reading:

**Text Books**

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. N.K. Jain, Controlled and Novel Drug Delivery, CBS Publishers & Distributors, New Delhi, First edition 1997 (reprint in 2001).
4. S.P. Vyas and R. K. Khar, Controlled Drug Delivery - concepts and advances, Vallabh Prakashan, New Delhi, First edition 2002.

## Reference Books

1. Encyclopaedia of Pharmaceutical technology, Vol I – III.
2. Encyclopedia of controlled delivery, Editor- Edith Mathiowitz, Published by Wiley Interscience Publication, John Wiley and Sons, Inc, New York. Chichester/Weinheim
3. Drug Development and Industrial Pharmacy (Marcel & Decker) desirable

Name of The Course	Modern Pharmaceutics			
Course Code	MPHT1003			
Prerequisite				
Co-requisite				
Anti-requisite				
	L	T	P	C
	4	0	0	4

**Course Objectives**

Upon completion of the course, the student shall be able to understand:

- The cGMP aspects in a pharmaceutical industry
- To appreciate the importance of documentation
- To understand the scope of quality certifications applicable to Pharmaceutical industries
- To understand the responsibilities of QA & QC departments.

### Course Outcomes

CO1	Student will be able to get familiar with pre-formation concepts.
CO2	Students will be able to optimize pharmaceutical formulation development in the era of modern pharmaceuticals.
CO3	Students will be able to develop validation methods for the different pharmaceutical products.
CO4	Students will be able to develop the skills to solve different types of problems in solving the pharmaceutical research.
CO5	Students will be able to learn the industrial management in pharmacy.
CO6	Students will be able to learn the stability issues and protection of pharmaceutical products.

### Continuous Assessment Pattern

Internal Assessment (IA)	Sessional Exam	End Term Exam (ETE)	Total Marks
10	15	75	100

### Course Content:

<b>Unit-1:</b>	<b>12 Hours</b>
<p><b>Preformulation Concepts-</b> Drug Excipients 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 parenteral- physiological and formulation consideration, Manufacturing and evaluation.</p> <p><b>Optimization techniques in Pharmaceutical Formulation:</b> 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.</p>	
<b>Unit-2</b>	<b>12 hours</b>
<p><b>Validation:</b> Introduction to Pharmaceutical Validation, Scope &amp; merits of Validation, Validation and calibration of Master plan, ICH &amp; 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 &amp; P.Q. of facilities.</p>	
<b>Unit-3</b>	<b>12 hours</b>

**cGMP & Industrial Management:** Objectives and policies of current good manufacturing practices, layout of buildings, services, equipments and their maintenance  
**Production management:** Production organization, materials management, handling and transportation, inventory management and control, production and planning control, Sales forecasting, budget and cost control, industrial and personal relationship. Concept of total Quality Management.

**Unit-4** **12 hours**

**Compression and compaction:** Physics of tablet compression, compression, consolidation, effect of friction, distribution of forces, compaction profiles. Solubility.

**Unit-5** **12 hours**

**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 significance, Standard deviation, Chi square test, students T-test, ANOVA test.

**Unit-6** **8 hours**

**Kinetic Principal and Stability Testing:** Introduction, theoretical consideration, Order of reaction, ICH guidelines, Shelf life testing of drug products, Chemical and Physical Stability Testing of Pharmaceutical dosage forms, Influence of packaging components on dosage forms stability.

### Suggested Reading:

#### Text Books

1. Theory and Practice of Industrial Pharmacy By Lachmann and Libermann
2. Pharmaceutical dosage forms: Tablets Vol. 1-3 by Leon Lachmann.
3. Banker G.S., & Rhodes C.T., Modern Pharmaceutics, Marcel Dekker, New York.
4. Advances in Pharmaceutical Sciences Vol. 1-5; By H.S. Bean & A.H.Beckett.

#### Reference Books

1. Encyclopaedia of Pharmaceutical technology, Vol I – III.

- Good manufacturing practices for Pharmaceuticals: A plan for total quality control, Second edition; By Sidney H. Willig.
- Applied production and operations management; By Evans, Anderson, Sweeney and Williams
- Pharmaceutical Process Validation; By Fra. R. Berry and Robert A. Nash.

Name of The Course	Regulatory Affair			
Course Code	MPHT1004			
Prerequisite				
Co-requisite				
Anti-requisite				
	L	T	P	C
	4	0	0	4

### Course Objectives

The basic objective of this course is to get familiar with Drug Regulatory affairs. Upon completion of the course, it is expected that the students will be able to understand

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

### Course Outcomes

CO1	To know about the Pharmaceutical legislations, documentation & their implications in the development and marketing
CO2	To know the Regulatory guidance's and guidelines of NDA, ANDA etc for filing and approval process
CO3	To know the various Indian pharmaceutical Acts, Laws, schedule and regulatory guidelines for approval/post approval of the product in the market.
CO4	To know the Non clinical drug development i.e., Global submission of IND, NDA, ANDA and investigational brochure etc
CO5	To know the clinical study process and approval of the product as per regulatory guidelines.

CO6	To know recent advancement in regard to Pharmaceutical Legislation as per Indian regulatory perspectives for drug or drug related products to the society as well nations.
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### Continuous Assessment Pattern

Internal Assessment (IA)	Sessional Exam	End Term Exam (ETE)	Total Marks
10	15	75	100

### Course Content:

<b>Unit- 1 &amp; 2:</b>	<b>24 Hours</b>
<p>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, <i>in-vivo</i>, scale up process approval changes, post marketing surveillance, outsourcing BA and BE to CRO.</p> <p>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.</p>	
<b>Unit-3</b>	<b>12 hours</b>
<p>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.</p>	
<b>Unit-4</b>	<b>12 hours</b>
<p>Non clinical drug development: Global submission of IND, NDA, ANDA. Investigation of medicinal products dossier, dossier (IMPD) and investigator brochure (IB).</p>	
<b>Unit-5</b>	<b>12 hours</b>
<p><b>Unit 5:</b> 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.</p>	
<b>Unit-6</b>	<b>12 hours</b>
<p>Recent aspects of Pharmaceutical legislations in India: Hierarchy and working flow of FDA in India, Roles of DCGA and CDSCO in drug control, Drug Control Authority and its documentation in</p>	

the state.

### Suggested Reading:

#### Text Books

1. Generic Drug Product Development, Solid Oral Dosage forms, Leon Shargeland Isader Kaufer, 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.

#### Reference Books

1. FDA regulatory affairs: a guide for prescription drugs, medical devices, and biologics/edited By Douglas J. Pisano, David Mantus
2. Clinical Trials and Human Research: A Practical Guide to Regulatory Compliance By Fay A. Rozovsky and Rodney K. Adams
3. <https://www.tga.gov.au/tga-basics>
4. [europa.eu/index\\_en.htm](http://europa.eu/index_en.htm), [www.fda.gov/](http://www.fda.gov/)

<b>Name of The Course</b>	MOLECULAR PHARMACEUTICS (NANO TECH AND TARGETED DDS)			
<b>Course Code</b>	MPHT2001			
<b>Prerequisite</b>				
<b>Co-requisite</b>				
<b>Anti-requisite</b>				
	<b>L</b>	<b>T</b>	<b>P</b>	<b>C</b>
	4	0	0	4

#### Course Objectives

The basic objective of this course is to get familiar with nanotechnology for targeted delivery approaches. After completion of course student is able to know,

- Novel Drug delivery System
- Targeted drug delivery using adjuvant approaches

- The various approaches for development of novel drug delivery systems.
- The criteria for selection of drugs and polymers for the development of NDDS
- The formulation and evaluation of novel drug delivery systems.

#### Course Outcomes

<b>CO1</b>	To know the concept of targeted drug delivery system
<b>CO2</b>	To know various methodologies for targeted action of the said formulation for better therapeutic effect
<b>CO3</b>	The various approaches for development of Monoclonal antibodies based drug delivery system
<b>CO4</b>	To know the criteria for selection of drugs and polymers for the development of Pulmonary drug delivery system
<b>CO5</b>	To know the preparation of formulation and evaluation as well as Bio-distribution and Pharmacokinetics studies of different antisense molecules and aptamers as drugs of future
<b>CO6</b>	To know the need of drug targeting for Brain and its application for different brain disorders.

#### Continuous Assessment Pattern

Internal Assessment (IA)	Sessional Exam	End Term Exam (ETE)	Total Marks
10	15	75	100

#### Course Content:

<b>Unit-1:</b>	<b>12 Hours</b>
<b>Targeted Drug Delivery Systems:</b> Concepts, Events and biological process involved in drug targeting. Tumor targeting and Brain specific delivery.	
<b>Unit-2</b>	<b>12 hours</b>
<b>Targeting Methods:</b> Introduction preparation and evaluation. Nanoparticles & Liposomes: Types, preparation and evaluation.	
<b>Unit-3</b>	<b>12 hours</b>
<b>Micro Capsules / Micro Spheres:</b> Types, preparation and evaluation, Monoclonal Antibodies; preparation	

and application, preparation and application of Niosomes, Aquasomes, Phytosomes, Electrosomes.

**Unit-4** **12 hours**

**Pulmonary Drug Delivery Systems** :Aerosols, Propellents, Containers Types, preparation and evaluation, Intra Nasal Route Delivery systems; Types, preparation and evaluation.

**Unit-5** **12 hours**

**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 non-viral gene transfer). Liposomal gene delivery systems. Biodistribution and Pharmacokinetics. knowledge of therapeutic antisense molecules and aptamers as drugs of future.

**Unit-6** **8 hours**

**Advanced Targeted system for Brain:** Introduction, Need of targeting, Formulation advancements, Literature discussion, Applications

#### Suggested Reading:

##### Text Books

1. Y W. Chien, Novel Drug Delivery Systems, 2nd edition, revised and expanded, Marcel Dekker, Inc., New York, 1992
1. Robinson, J. R., Lee V. H. L, Controlled Drug Delivery Systems, Marcel Dekker, Inc., New York, 1992.
2. S.P.Vyas and R.K. Khar, Controlled Drug Delivery - concepts and advances, Vallabh Prakashan, New Delhi, First edition 2002.
3. N.K. Jain, Controlled and Novel Drug Delivery, CBS Publishers & Distributors, New Delhi, First edition 1997

##### Reference Books

1. Encyclopaedia of Pharmaceutical technology, Vol I – III.
2. Encyclopedia of controlled delivery, Editor- Edith Mathiowitz, Published by Wiley Interscience

Publication, John Wiley and Sons, Inc, New York. Chichester/Weinheim

3. Drug Development and Industrial Pharmacy (Marcel & Decker) desirable

Name of The Course	Advanced Biopharmaceutics & Pharmacokinetics			
Course Code	MPHT2002			
Prerequisite				
Co-requisite				
Anti-requisite				
	L	T	P	C
	4	0	0	4

#### Course Objectives

Upon completion of the course, the student shall be able to understand:

- The basic concepts in Biopharmaceutics and Pharmacokinetics.
- The use raw data and derive the pharmacokinetic models and parameters the best describe the process of drug absorption, distribution, metabolism and elimination.
- The critical evaluation of biopharmaceutic studies involving drug product equivalency.
- The design and evaluation of dosage regimens of the drugs using pharmacokinetic and biopharmaceutic parameters.
- The potential clinical pharmacokinetic problems and application of basics of pharmacokinetic

#### Course Outcomes

CO1	Student will be able to understand about absorption, mechanism of absorption and dissolution.
CO2	Student will be able to understand about biopharmaceutical factors affecting dosage form and rate limiting steps.
CO3	Student will be able to Calculate different Pharmacokinetic parameters using Compartmental models.
CO4	Student will be able to Design of Bioavailability & Bioequivalence studies and their Clinical Significance.
CO5	Student will be able to Generalize the concept of Pharmacokinetics and Pharmacodynamics of

	biotechnology drugs. Monoclonal antibodies, Vaccines, Gene therapies.
CO6	Students will be able to solve practical application approach to solve the task and problems.

#### Continuous Assessment Pattern

Internal Assessment (IA)	Mid Term Exam (MTE)	End Term Exam (ETE)	Total Marks
10	15	75	100

#### Course Content:

<b>Unit- 1:</b>	<b>12Hours</b>
<b>Drug Absorption from the Gastrointestinal Tract:</b> 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 <i>in vivo</i> data with <i>in vitro</i> 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.	
<b>Unit-2</b>	<b>12 hours</b>
<b>Rate Controlled Drug Delivery Systems</b> Biopharmaceutic considerations in drug product design and <i>in vitro</i> Drug Product Performance: Introduction, biopharmaceutic factors affecting drug bioavailability, rate-limiting steps in drug absorption, physicochemical nature of the drug formulation factors affecting drug product performance, <i>in vitro</i> : 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.

<b>Unit-3</b>	<b>12 hours</b>
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#### 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  $k_{max}$  and  $V_{max}$ . Drug interactions: introduction, the effect of protein binding interactions, the effect of tissue-binding interactions, cytochrome p450-based drug interactions, drug interactions linked to transporters.

<b>Unit-4</b>	<b>12hours</b>
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#### 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, generics substitution

<b>Unit-5</b>	<b>12 hours</b>
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#### 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.

<b>Unit-6</b>	<b>08 hours</b>
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Applied problems/ questions related to Drug Absorption from the Gastrointestinal Tract, Rate Controlled Drug Delivery Systems, Pharmacokinetics, Drug Product Performance, *in vivo* Bioavailability and Bioequivalence.

## Suggested Readings

### Text Books

1. Biopharmaceutics and Pharmacokinetics, A. Treatise, D .M. Brahmankar and Sunil B. Jaiswal., VallabPrakashan, Pitampura, Delhi
2. Textbook of Biopharmaceutics and Pharmacokinetics, Dr. Shobha Rani R. Hiremath, Prism Book
3. Biopharmaceutics and Pharmacokinetics, Javed Ali, Alka Ahuja, R.K.Khar, Birla Publications, Shahadra, Delhi
4. Basic Pharmacokinetics, 1<sup>st</sup> edition, Sunil S Jambhekar and Philip J Breen, pharmaceutical press, RPS Publishing, 2009.

### Reference Books

1. Biopharmaceutics and Clinical Pharmacokinetics by Milo Gibaldi, 4th edition, Philadelphia, Lea and Febiger, 1991
2. Applied Biopharmaceutics and Pharmacokinetics by Shargel. Land Yu ABC, 2nd edition, Connecticut Appleton Century Crofts, 1985
3. Biopharmaceutics and Clinical Pharmacokinetics, An Introduction, 4th edition, revised and expanded by Robert. E. Notari, Marcel Dekker Inc, New York and Basel, 1987.
4. Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James. G. Boylan, Marcel Dekker Inc, New York, 1996.

Name of The Course	COMPUTER AIDED DRUG DELIVERY SYSTEM			
Course Code	MPHT2003			
Prerequisite				
Co-requisite				
Anti-requisite				
	L	T	P	C
	4	0	0	4

### Course Objectives

1. The students will be able to understand 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

### Course Outcomes

<b>CO1</b>	The student will be able to interpret the basic concept of in-silico studies in the drug discovery
<b>CO2</b>	The student will be able to apply the effect of different parameters of Drug Disposition through computer modeling.
<b>CO3</b>	The student will be able to analyze the concept of optimization for the development of drug formulation.
<b>CO4</b>	The student will be able to assess the role of computer simulation study to get the effective pharmacodynamic and pharmacokinetic parameters
<b>CO5</b>	The student will be able to estimate the importance of artificial intelligence in the future development of pharmaceutical drug research
<b>CO6</b>	The student will be able to analyze the advances in drug delivery systems

### Continuous Assessment Pattern

Internal Assessment (IA)	Sessional Exam	End Term Exam (ETE)	Total Marks
10	15	75	100

### Course Content:

<p><b>Unit I:</b> Computers in Pharmaceutical Research and Development and QBD <b>12 Hours</b></p> <p>a. Computers in Pharmaceutical Research and Development: A General Overview: History of Computers in Pharmaceutical Research and Development. Statistical modeling in Pharmaceutical research and development: Descriptive versus Mechanistic Modeling, Statistical Parameters, Estimation, Confidence Regions, Nonlinearity at the Optimum, Sensitivity Analysis, Optimal Design, Population Modeling .</p> <p>b. Quality-by-Design In Pharmaceutical Development: Introduction, ICH Q8 guideline, Regulatory and industry views on QbD, Scientifically based QbD - examples of application.</p>
<p><b>Unit II: Computational Modeling Of Drug Disposition</b> <b>12 Hours</b></p> <p>Computational Modeling Of Drug Disposition: Introduction, Modeling Techniques: Drug Absorption, Solubility, Intestinal Permeation, Drug Distribution, Drug Excretion, Active Transport; P-gp, BCRP, Nucleoside Transporters, hPEPT1, ASBT, OCT, OATP, BBB-Choline Transporter.</p>

<b>Unit III: Computer-aided formulation development:</b>
<b>12</b>
<b>Hours</b>
Computer-aided formulation development: Concept of optimization, Optimization parameters, Factorial design, Optimization technology & Screening design. Computers in Pharmaceutical Formulation: Development of pharmaceutical emulsions, microemulsion drug carriers Legal Protection of Innovative Uses of computers in R&D, The Ethics of Computing in Pharmaceutical Research, Computers in Market analysis.
<b>Unit IV: Computer-aided biopharmaceutical characterization</b>
<b>12 Hours</b>
a. Computer-aided biopharmaceutical characterization: Gastrointestinal absorption simulation. Introduction, Theoretical background, Model construction, Parameter sensitivity analysis, Virtual trial, Fed vs. fasted state, In vitro dissolution and in-vitro in-vivo correlation, Biowaiver considerations
b. Computer Simulations in Pharmacokinetics and Pharmacodynamics: Introduction, Computer Simulation: Whole Organism, Isolated Tissues, Organs, Cell, Proteins and Genes.
c. Computers in Clinical Development: Clinical Data Collection and Management, Regulation of Computer Systems.
<b>Unit V: Artificial Intelligence (AI),</b>
<b>12 Hours</b>
Robotics and Computational fluid dynamics: General overview, Pharmaceutical Automation, Pharmaceutical applications, Advantages and Disadvantages. Current Challenges and Future Directions.
<b>Unit VI Advances in drug delivery systems 08 Hours</b>
Advances in drug delivery systems with respect to buccal, nasal, ocular, pulmonary, ocular delivery.

### Suggested Reading

1. **Computer Applications in Pharmaceutical Research and Development**, Sean Ekins, 2006, John Wiley & Sons.
2. **Computer-Aided Applications in Pharmaceutical Technology**, 1st Edition, Jelena Djuris, Woodhead Publishing
3. **Encyclopedia of Pharmaceutical Technology**, Vol 13, James Swarbrick, James. G.Boylan, Marcel Dekker Inc, New

<b>Name of The Course</b>	Cosmetic and Cosmeceuticals
<b>Course Code</b>	MPHT2004
<b>Prerequisite</b>	
<b>Co-requisite</b>	
<b>Anti-requisite</b>	

	<b>L</b>	<b>T</b>	<b>P</b>	<b>C</b>
	4	0	0	4

### Course Objectives

Upon completion of the course, the students shall be able to understand

- Key ingredients used in cosmetics and cosmeceuticals.
- Key building blocks for various formulations.
- Current technologies in the market
- Various key ingredients and basic science to develop cosmetics and Cosmeceuticals
- Scientific knowledge to develop cosmetics and cosmeceuticals with desired Safety, stability, and efficacy.

### Course Outcomes

<b>CO1</b>	The students will be able to understand basic definitions of cosmetics and cosmeceuticals and different regulatory provisions relating to import and manufacturing of cosmetic products as per Indian regulatory guidelines
<b>CO2</b>	The students will be able to apply the concepts in regard to biological aspects, to be familiar with cosmetology for different cosmetic related problems in context to human health.
<b>CO3</b>	The students will be able to analyze the properties of different building block materials to formulate the cosmetics and cosmeceutical formulation.
<b>CO4</b>	The students will be able to apply knowledge and skills necessary for cosmetics and cosmeceuticals formulations using current technologies in cosmetic industry
<b>CO5</b>	The students will be able to investigate herbs extracts and the evaluated formulations containing herbs are then passed to get approval for marketing. Students will be able to develop scientific knowledge about cosmetics and cosmeceuticals formulations with desired Safety, stability, and efficacy which are desirable for the human subjects.
<b>CO6</b>	Recent Advancements in Cosmeceutical Formulation: The students will be able to understand recent trends in cosmeceuticals i.e., nanotechnology and artificial intelligence application role in cosmetic industry.

### Continuous Assessment Pattern

<b>Internal</b>	<b>Sessional</b>	<b>End Term</b>	<b>Total</b>
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Assessment (IA)	Exam	Exam (ETE)	Marks
10	15	75	100

**Course Content:**

Unit-1:	12 Hours
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.	
Unit-2	12 hours
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.	
Unit-3	12 hours
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 tooth paste. Soaps and syndet bars. Perfumes; Classification of perfumes. Perfume ingredients listed as allergens in EU regulation. Controversial ingredients: Parabens, formaldehyde liberators, dioxane.	
Unit-4	12 hours
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.	
Unit-5	12 hours
Herbal Cosmetics: Herbal ingredients used in Hair care, skincare 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.	
Unit-6	8 hours

**Recent Advancements in Cosmeceutical Formulation:**

Role of Nanotechnology in Cosmeceuticals, Future Challenges in Cosmeceutical Formulation, Artificial Intelligence for Beauty and Cosmetics, Benefits of Using AI for the Beauty Industry.

**Suggested Reading:****Text Books**

1. Harry's Cosmeticology. 8<sup>th</sup> edition.
2. Poucher's perfume cosmetics and Soaps, 10<sup>th</sup> edition.
3. Cosmetics - Formulation, Manufacture and quality control, P.P. Sharma, 4<sup>th</sup> edition
4. Handbook of cosmetic science and Technology A.O. Barel, M. Paye and H.I. Maibach. 3<sup>rd</sup> edition

**Reference Books**

1. Cosmetic and Toiletries recent suppliers catalogue.
2. CTFA directory

Name of The Course	RESEARCH METHODOLOGY & BIOSTATISTICS			
Course Code	MRMT3001			
Prerequisite				
Co-requisite				
Anti-requisite				
	L	T	P	C
	4	0	0	4

**Course Objectives**

Upon completion of the course, the student shall be able to understand:

The student shall know the introduction, scope of biostatistics and Research work, calculation and present of the data. It also informs the students, how the present research work writing and correlating.

**Course Outcomes**

CO1	Student will be able to get familiar with Research Methodology & Biostatistics.
CO2	Students will be able to develop problem solving skills in research and development.

CO3	Students will be able to develop good presentation skills to their research work.
CO4	Students will be able to develop the skills to solve different types of problems in solving the Pharmaceutical research.
CO5	Students will be developing the listening skills and effective written communication
CO6	Students will be able to explore to create trend/innovation for different novel research methodology and to learn futuristic biostatistics problem solving related to proposed research work.

#### Continuous Assessment Pattern

Internal Assessment (IA)	Sessional Exam	End Term Exam (ETE)	Total Marks
10	15	75	100

#### Course Content:

<b>Unit- 1:</b>	<b>12 Hours</b>
<b>General Research Methodology:</b> 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.	
<b>Unit-2</b>	<b>12 hours</b>
<b>Biostatistics:</b> 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 (Wilcoxon rank tests, analysis of variance, correlation, chi square test), null hypothesis, P values, degree of freedom, interpretation of P values.	
<b>Unit-3</b>	<b>12 hours</b>
<b>Medical Research:</b> 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.	
<b>Unit-4</b>	<b>12 hours</b>
<b>CPCSEA guidelines for laboratory animal facility:</b>	

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.

#### Unit-5 **12 hours**

**Declaration of Helsinki:** History, introduction, basic principles for all medical research, and additional principles for medical research combined with medical care.

#### Unit-6 **8 hours**

**Recent advancement in Research Methodology and Biostatistics:** Innovative trend analysis methodology, The quantity synthesis of single subject research: Methodology and validation, A comparison of online versus on-site training in health research methodology: a randomized study, The future of biostatistics: expecting the unexpected.

#### Suggested Readings:

1. Kapoor R. L. – Qualitative Methods in Mental Health Research, Published by National Institute of Advanced Studies, Bangalore.
2. Kumar- Research Methodology, 2nd Edition 1999, Published by Laxmi Narain Agarwal. Agra.
3. R. Raveendran and B. Gitanjali, A practical approach to P.G. dissertation, 1997, Jaypee Publishers, New Delhi
4. Major R. H. - A History Of Medicine, 2 volumes, Charles Thomas Publishers, Springfield Illinois, U.S.A.

<b>Name of The Course</b>	Pharmaceutics Practical-I			
<b>Course Code</b>	MPHP1005			
<b>Prerequisite</b>				
<b>Co-requisite</b>				
<b>Anti-requisite</b>				
	<b>L</b>	<b>T</b>	<b>P</b>	<b>C</b>
	0	0	12	6

#### Course Objectives

To get familiar with product development of different dosage forms. Product development may involve modification of an existing product or formulation of

an entirely new product. It involves the formulation of different dosage forms and their evaluations.

CO1	Students will be skilled to perform and evaluate pre-formulation and formulation of dosage forms
CO2	Students will be skilled to operate sophisticated instruments.
CO3	Students will be able to formulate different dosage form.
CO4	Students will be able to evaluate different parameters of dosage form.
CO5	Students will be able to analyze and plot different graphs for dosage form.

#### Continuous Assessment Pattern

Internal Assessment (IA)	Sessional Exam	End Term Exam (ETE)	Total Marks
20	30	100	150

#### Course Content:

<b>Experiment No-1:</b> Analysis of Pharmacopoeial compounds and their formulations by UV spectrophotometer
<b>Experiment No-2:</b> Simultaneous estimation of multi component containing formulations by UV spectrophotometry
<b>Experiment No-3:</b> Experiments based on HPLC
<b>Experiment No-4:</b> Experiments based on Gas Chromatography
<b>Experiment No-5:</b> Estimation of riboflavin/quinine sulphate by fluorimetry
<b>Experiment No-6:</b> Estimation of sodium/potassium by flame photometry
<b>Experiment No-7:</b> To perform <i>In-vitro</i> dissolution profile of CR/ SR marketed formulation
<b>Experiment No-8:</b> Formulation and evaluation of sustained release matrix tablets
<b>Experiment No-9:</b> Formulation and evaluation osmotically controlled DDS
<b>Experiment No-10:</b> Preparation and evaluation of Floating DDS- hydro dynamically balanced DDS
<b>Experiment No-11:</b> Formulation and evaluation of mucoadhesive tablets.

<b>Name of The Course</b>	Pharmaceutics Practical-II			
<b>Course Code</b>	MPHP2005			
<b>Prerequisite</b>				
<b>Co-requisite</b>				
<b>Anti-requisite</b>				
	<b>L</b>	<b>T</b>	<b>P</b>	<b>C</b>
	0	0	12	6

#### Course Objectives

The basic objective of this course is to get familiar with product development in Advances in Drug Delivery. It involves the formulation of different dosage forms and their evaluations.

CO1	Students will be skilled to perform and evaluatePre-formulation and formulation of dosage forms.
CO2	Students will be skilled to operate sophisticated instruments.
CO3	Students will be able to formulate different dosage form.
CO4	Students will be able to evaluate different parameters of dosage form.
CO5	Students will be able to analyze and plot different graphs for dosage form.

#### Continuous Assessment Pattern

Internal Assessment (IA)	Sessional Exam	End Term Exam (ETE)	Total Marks
20	30	100	150

#### Course Content:

<b>Experiment No-1:</b> To study the effect of temperature change, non solvent addition, incompatible polymer addition in microcapsules preparation
<b>Experiment No-2:</b> Preparation and evaluation of Alginate beads
<b>Experiment No-3:</b> Formulation and evaluation of gelatin /albumin microspheres
<b>Experiment No-4:</b> Formulation and evaluation of liposomes/niosomes
<b>Experiment No-5:</b> Formulation and evaluation of spherules
<b>Experiment No-6:</b> Improvement of dissolution characteristics of slightly soluble drug by Solid dispersion technique.
<b>Experiment No-7:</b>

Comparison of dissolution of two different marketed products /brands.
<b>Experiment No-8:</b> Protein binding studies of a highly protein bound drug & poorly proteinbound drug.
<b>Experiment No-9:</b> Bioavailability studies of Paracetamol in animals.
<b>Experiment No-10:</b> Pharmacokinetic and IVIVC data analysis by Winnoline R software
<b>Experiment No-11:</b> <i>In vitro</i> cell studies for permeability and metabolism.
<b>Experiment No-12:</b> DoE Using Design Expert® Software
<b>Experiment No-13:</b> Formulation data analysis Using Design Expert® Software.
<b>Experiment No-14:</b> Quality-by-Design in Pharmaceutical Development.
<b>Experiment No-15:</b> . Computer Simulations in Pharmacokinetics and Pharmacodynamics
<b>Experiment No-16:</b> Computational Modeling of Drug Disposition.
<b>Experiment No-17:</b> To develop Clinical Data Collection manual.
<b>Experiment No-18:</b> To carry out Sensitivity Analysis, and Population Modeling.
<b>Experiment No-19:</b> Development and evaluation of Creams.
<b>Experiment No-20:</b> Development and evaluation of Shampoo and Toothpaste base.
<b>Experiment No-21:</b> To incorporate herbal and chemical actives to develop products.
<b>Experiment No-22:</b> To address Dry skin, acne, blemish, Wrinkles, bleeding gums and dandruff.