M.PHARMACY TWO YEAR DEGREE

PROGRAM CURRICULUM-2025

(Applicable for the batches admitted from A.Y 2025-26)

PHARMACEUTICS

ADITYA UNIVERSITY

Aditya Nagar, ADB Road, Surampalem - 533 437

ADITYA UNIVERSITY

Vision

- To be a globally recognized university through excellence in Education, Innovation and Sustainable growth.

Mission

Deliver collaborative education to prepare students for global challenges through

- Transformative learning
- Vibrant research ecosystem
- Sustainable and inclusive community

School of Pharmacy

Vision:

To emerge as a center of excellence producing competent, ethical pharmacists and researchers through holistic education and lifelong learning.

Mission:

- Empower future pharmacists through outcome-based learning for global healthcare challenges.
- Promote collaborative research for national and global healthcare impact.
- Ensure integrity, inclusion, and accountability in global healthcare education.

PROGRAMME EDUCATIONAL OBJECTIVES (PEO)

Postgraduates of the Program will:

PEO 1: Apply scientific knowledge and research skills to develop, evaluate, and ensure the quality of pharmaceuticals.

PEO 2: Lead pharmaceutical R&D and academia while developing advanced analytical techniques across domains.

PEO 3: Utilize cutting-edge technologies and contribute to global healthcare through ethical innovation.

PROGRAMME SPECIFIC OUTCOMES (PSO)

After successful completion of the program, the postgraduates will be able to

PSO1: Design, optimize, and evaluate novel drug delivery systems using advanced techniques.

PSO2: Apply biopharmaceutical principles to improve pharmaceutical product safety and efficacy, ensuring industry readiness

PROGRAMME OUTCOMES (PO)

After successful completion of the program, the post graduates will be able to

PO1: Independently carry out research /investigation and development work to solve practical problems

PO2: Write and present a substantial technical report/document

PO3: Demonstrate a degree of mastery over the area as per the specialization of the program. The mastery should be at a level higher than the requirements in the appropriate bachelor program

PO4: Uphold ethical principles and legal standards in pharmaceutical research, testing, and practice while ensuring drug safety.

PO5: Evaluate pharmaceutical activities' impact on health and environment, advocating for sustainable and safe practices.

PO6: Commit to continuous learning by adapting to advancements in pharmaceutical science, technology, and regulations.

School of Pharmacy

M. Pharmacy (Pharmaceutics) Program Curriculum – 2025

(Applicable for the students admitted from the A.Y 2025-26)

CREDIT DIVISION CATEGORY-WISE:

S. NO	CATEGORY OF COURSE	NUMBER OF CREDITS
1	Major Core Courses (MCC)	40
2	Multidisciplinary Courses (MDC)	4
3	Skill Enhancement Courses (SEC)	4
4	Ability Enhancement Courses (AEC)	$14^{\#}$-$19^{\$}$
5	Full Semester Internship (PROJ)	33
Total Credits to be earned for M. Pharmacy Degree		**$95^{\#}$-$100^{\$}$**

$^{\#}$Minimum Credit required in AEC to earn the M. Pharmacy degree.

$^{\$}$Maximum Credit required in AEC to earn the M. Pharmacy degree.

IC : Intermediate Courses

AC : Advanced Courses

CATEGORY WISE COURSES

Major Core Courses (MCC)

Course Code	Sem	Course Name (Course Code)	Level	L	T	P	C	CIE	SEE	Total
2514PY02	I	Drug Delivery System	IC	4			4	25	75	100
2514PY03		Modern Pharmaceutics	IC	4			4	25	75	100
2514PY05		Pharmaceutics Practical I	AC			3	3	25	50	75
2514PY06		Pharmaceutical Practical II	AC			3	3	25	50	75
2514PY04		Regulatory Affairs	IC	4			4	25	75	100
2514PY08	II	Molecular Pharmaceutics (NTDS)	AC	4			4	25	75	100
2514PY09		Advanced Biopharmaceutics & Pharmacokinetics	AC	4			4	25	75	100
2514PY10		Computer Aided Drug Development	AC	4			4	25	75	100
2514PY11		Formulation Development of Pharmaceutical & Cosmetic Products	AC	4			4	25	75	100
2514PY12		Pharmaceutics Practical III	AC			3	3	25	50	75
2514PY13		Pharmaceutics Practical IV	AC			3	3	25	50	75
			Total	**28**		**12**	**40**			

Multidisciplinary Courses (MDC)

Course Code	Sem	Course Name (Course Code)	Level	L	T	P	C	CIE	SEE	Total
2514PY01	I	Modern Pharmaceutical Analytical Techniques	IC	4			4	25	75	100
			Total	**4**			**4**			

Skill Enhancement Courses (SEC)

Course Code	Sem	Course Name	Level	L	T	P	C	CIE	SEE	Total
2515PY15	III	Research Methodology and Biostatistics*	IC	4			4	25	75	100
			Total	**4**			**4**			

* DLE: Department Level Evaluation

Ability Enhancement Courses (AEC)

Course Code	Sem	Course Name (Course Code)	Level	L	T	P	C	CIE	SEE	Total
2514PY07	I	Seminar/Assignment*	AC			7	4	-	-	100
2514PY14	II	Seminar/Assignment*	AC			7	4	-	-	100
2514PY16	III	Journal Club*	AC			1	1	**25**	-	25
2514PY17	III	Discussion / Presentation (Proposal)*	AC			2	2	**50**	-	50
2514PY19	IV	Journal Club*	AC			1	1	**25**	-	25
2514PY22	IV	Student Activity Based earning (SABL)*	AC							
2514PY23	IV	Co-curricular Activities*	AC				2-7			
			Total			**12**	**$14^{\#}$-$19^{\$}$**			

* DLE: Department Level Evaluation

Project Work (PROJ)

Course Code	Sem	Course Name (Course Code)	Level	L	T	P	C	CIE	SEE	Total
2514PY18	III	PROJ-I*	AC			28	14	-	350	350
2514PY20	IV	PROJ-II	AC			31	16	-	400	400
2514PY21	IV	Discussion / Final Presentation*	AC			3	3	75	-	75
			Total			**33**	**33**	**75**		

* DLE: Department Level Evaluation

LEVEL WISE COURSES

Intermediate Courses:

S.NO	Abbreviation	Course Name
1.	MPAT	Modern Pharmaceutical Analytical Techniques
2.	DDS	Drug Delivery System
3.	MP	Modern Pharmaceutics
4.	RA	Regulatory Affair
5.	RMBS	Research Methodology and Biostatistics

Advanced Courses:

S.No	Abbreviation	Course Name
1.	Pceu-I (P)	Pharmaceutics Practical I
2.	Pceu-II (P)	Pharmaceutical Practical II
3.	S/A-I	Seminar/Assignment – Semester I (-)
4.	MP(NTDS)	Molecular Pharmaceutics (NTDS)
5.	ABPPK	Advanced Biopharmaceutics & Pharmacokinetics
6.	CADD	Computer Aided Drug Development
7.	FDPCP	Formulation Development of Pharmaceutical & Cosmetic Products
8.	Pceu-III (P)	Pharmaceutics Practical III
9.	Pceu-IV (P)	Pharmaceutics Practical IV
10.	S/A-II	Seminar/Assignment – Semester II
11.	JC-I	Journal Club – Semester III
12.	D/P	Discussion / Presentation (Proposal) – Semester III
13.	PROJ-I	PROJ-I– Semester III
14.	JC-II	Journal Club – Semester IV
15.	PROJ-II	PROJ-II – Semester IV
16.	D/FP	Discussion / Final Presentation – Semester IV

SEMESTER WISE CURRICULUM

Semester- I

Course Code	Course Name	Course		Credits				Total Hour
		Category	Level	L	T	P	Total	
2514PY01	Modern Pharmaceutical Analytical Techniques	MDC	IC	4			4	4
2514PY02	Drug Delivery System	MCC	IC	4			4	4
2514PY03	Modern Pharmaceutics	MCC	IC	4			4	4
2514PY04	Regulatory Affair	MCC	IC	4			4	4
2514PY05	Pharmaceutics Practical I	MCC	AC			3	3	6
2514PY06	Pharmaceutical Practical II	MCC	AC			3	3	6
2514PY07	Seminar/Assignment*	AEC	AC			4	4	7
			Total	**16**		**10**	**26**	**35**

* DLE: Department Level Evaluation

Semester- II

Course Code	Course Name	Course		Credits				Total Hours
		Category	Level	L	T	P	Total	
2514PY08	Molecular Pharmaceutics (NTDS)	MCC	AC	4			4	4
2514PY09	Advanced Biopharmaceutics & Pharmacokinetics	MCC	AC	4			4	4
2514PY10	Computer Aided Drug Development	MCC	AC	4			4	4
2514PY11	Formulation Development of Pharmaceutical & Cosmetic Products	MCC	AC	4			4	4
2514PY12	Pharmaceutics Practical III	MCC	AC			3	3	6
2514PY13	Pharmaceutics Practical IV	MCC	AC			3	3	6
2514PY14	Seminar/Assignment*	AEC	AC			4	4	7
			Total	**16**		**10**	**26**	**35**

* DLE: Department Level Evaluation

III Semester

Course Code	Course Name	Course		Credits				Total Hours
		Category	Level	L	T	P	Total	
2514PY15	Research Methodology and Biostatistics*	SEC	IC	4	-	-	4	4
2514PY16	Journal Club*	AEC	AC			1	1	1
2514PY17	Discussion / Presentation (Proposal)*	AEC	AC			2	2	2
2514PY18	PROJ-I*	PROJ	AC			14	14	28
Total				**4**		**17**	**21**	**35**

* DLE: Department Level Evaluation

IV Semester

Course Code	Course Name	Course		Credits				Total Hours
		Category	Level	L	T	P	C	
2514PY19	Journal Club*	AEC	AC			1	1	1
2514PY20	PROJ-II	PROJ	AC			16	16	31
2514PY21	Discussion / Final Presentation*	PROJ	AC			3	3	3
Total						**20**	**20**	**35**

* DLE: Department Level Evaluation

During the Program

Course Code	Course Name	Course		Credits				Total Hours
		Category	Level	L	T	P	C	
2514PY22	Student Activity Based Learning (SABL)*	AEC	AC					
2514PY23	Co-curricular activities*	AEC	AC				2-7	
Total							**2 - 7**	

* DLE: Department Level Evaluation

PHARMACEUTICS

(MPH)

SEMESTER- I

L	T	P	C
4	0	0	4

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES

Subject Code: 2514PY01

Course Objectives: Upon completion of the subject student shall be

COB1: Understand the spectroscopic concept upon pharmaceuticals, NMR with new compounds

COB2: Integrate the mass data for molecules, chromatography methods

COB3: Differentiate Electrophoresis and X-Ray crystallography, the Unknown concentration sample by potentiometry and weight variation by Thermal methods.

Course Outcomes:

COURSE OUTCOME	STATEMENT
CO1	**Understand:** The basic concepts of Spectroscopic method
CO2	**Apply: C**omputation of NMR Spectroscopy
CO3	**Generate:** Mass spectroscopy of compounds by using instrumentation and ionisation techniques
CO4	**Remember:** Quantification methods of Chromatography
CO5	**Classify:** analytical method of electrophoresis and x-ray crystallography
CO6	**Evaluate:** Predict the unknow concentrations of samples using ion selective methods (Potentiometry) and thermal methods for Pharmaceuticals

Mapping of Course Outcomes with Program Outcomes

CO/PO	PO1	PO2	PO3	PO4	PO5	PO6
CO1	3	3	3	2	2	3
CO2	3	3	3	2	2	3
CO3	3	3	3	2	2	3
CO4	3	3	3	2	2	3
CO5	3	3	3	2	2	3
CO6	3	3	3	2	2	3

Mapping of Course Outcomes with Program Specific Outcomes:

CO/PSO	PSO1	PSO2
CO1	3	2
CO2	3	3
CO3	3	3
CO4	3	3
CO5	3	3

Course contents **60Hours**

UNIT-1 **10 Hours**

BASIC METHODS OF 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.

a. 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, Data Interpretation.

b. Spectroflourimetry: Theory of Fluorescence, Factors affecting fluorescence (Characterestics of drugs that can be analysed by flourimetry), Quenchers, Instrumentation and Applications of fluorescence spectrophotometer.

c. Flame emission spectroscopy and atomic absorption spectroscopy: Principle, Instrumentation, Interferences and Applications.

UNIT-II **10Hours**

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.

UNIT-III **10Hours**

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, Metastable ions, Isotopic peaks and Applications of Mass spectroscopy.

UNIT-IV **10Hours**

Chromatography

Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution, isolation of drug from excipients, data interpretation and applications of the following:

a. Thin Layer chromatography

b. High Performance Thin Layer Chromatography
c. Ion exchange chromatography
d. Column chromatography
e. Gas chromatography
f. High Performance Liquid chromatography
g. Ultra High-Performance Liquid chromatography
h. Affinity chromatography
i. Gel Chromatography

UNIT-V **10Hours**

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) Isoelectric focusing

b. X ray Crystallography: Production of X rays, Different X ray methods, Bragg 's law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X-ray diffraction.

UNIT-VI **10Hours**

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.

Textbook References

1. Spectrometric Identification of Organic compounds- Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A.Nieman, 5th edition, Eastern press, Bangalore, 1998.

References

1. Instrumental methods of analysis– Willards, 7th edition, CBS publishers.
2. Practical Pharmaceutical Chemistry– Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi, 1997.
3. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.

Weblinks

W1 https://link.springer.com/chapter/10.1007/978-1-4684-9984-1_5
W2 : https://www.smacgigworld.com/blog/instrumentation-and-methodology-of-electrophoresis.php
W3 : https://archive.nptel.ac.in/content/storage2/courses/102103047/PDF/mod3.pdf
W4 : https://microbenotes.com/affinity-chromatography/
W5: https://www.sciencedirect.com/science/article/pii/S1878535213001056

L	T	P	C
4	0	0	4

DRUG DELIVERY SYSTEMS

Subject Code: 2514PY02

Course objective: Upon completion of the subject student shall be
COB 1: To understand the various approaches for development of novel drug delivery systems.
COB 2: To understand the criteria for selection of drugs and polymers for the development of delivering system.
COB 3: To understand the formulation and evaluation of Novel drug delivery systems.
Course Outcomes:

Course outcome	Statement
CO1	**Describe** the concepts of Sustained release & Controlled release formulations and gain knowledge about the polymers used in Novel formulations and personalized medicines. (Remember)
CO2	**Formulate** and attain knowledge on fundamentals, types and activation of different modulated drug delivery systems. (Create)
CO3	**Formulate and Evaluate** Gastro retentive & Buccal drug delivery systems and Know about the modulation of GI transit time & mechanism of drug permeation. (Create)
CO4	**Recognize** the Barriers involved in ocular and protein drug delivery and mechanisms to overcome the barriers. (Understand)
CO5	**Classify** Transdermal Drug Delivery Systems and Formulate and Evaluate different Transdermal and Protein Drug Delivery Systems. (Analyse)
CO6	**Explain** the mechanism of vaccine uptake and delivery of vaccines through different routes. (Understand)

Mapping of Course Outcomes with Program Outcomes

CO/PO	PO1	PO2	PO3	PO4	PO5	PO6
CO1	3	3	3	3	2	3
CO2	3	3	3	3	2	3
CO3	3	3	3	3	2	3
CO4	3	3	3	3	3	3
CO5	3	3	3	3	3	3
CO6	3	3	3	3	3	3

Mapping of Course Outcomes with Program Specific Outcomes

CO/PSO	PSO1	PSO2
CO1	3	2
CO2	3	2
CO3	3	3
CO4	3	3
CO5	3	3
CO6	2	3

Course contents **60 Hours**

Unit-I **10 Hours**

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-II 10 Hours

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-III **10 Hours**

Gastro-Retentive Drug Delivery Systems: Principle, concepts advantages and disadvantages, Modulation of GI transit time approaches to extend GI transit. Buccal Drug Delivery Systems: Principle of mucoadhesion, advantages and disadvantages, Mechanism of drug permeation, Methods of formulation and its evaluations.

Unit- IV **6 Hours**

Occular Drug Delivery Systems: Barriers of drug permeation, Methods to overcome barriers.

Unit-V **10 Hours**

Transdermal Drug Delivery Systems: Structure of skin and barriers, Penetration enhancers, Transdermal Drug Delivery Systems, Formulation and evaluation.

Unit-VI **8 Hours**

Protein and Peptide Delivery: Barriers for protein delivery. Formulation and Evaluation of delivery systems of proteins and other macromolecules.

Unit-VII 6 Hours

Vaccine delivery systems: Vaccines, uptake of antigens, single shot vaccines, mucosal and transdermal delivery of vaccines.

Textbooks

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..

Reference Books

1. Encyclopedia of controlled delivery, Editor –Edith Mathiowitz, Published by Wiley Inter science Publication, John Wiley and Sons, Inc, New York! Chichester/Weinheim.
2. N.K.Jain, Controlled and Novel Drug Delivery, CBS Publishers & Distributors, New Delhi, First edition 1997 (reprint in 2001).
3. S.P.Vyas and R.K.Khar, Controlled Drug Delivery-concepts and advances, Vallabh Prakashan, New Delhi, First edition 2002.

Web Links

W1: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7250125/
W2: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9958669/
W3:https://www.who.int/docs/default-source/medicines/norms-and-standards/guidelines/production/trs1019-annex3-gmp-validation.pdf
W4:https://www.slideshare.net/slideshow/cgmp-and-industrial-anagement/245604822
W5: https://course.cutm.ac.in/courses/modern-pharmaceutics-cutm1585/

L	T	P	C
4	0	0	4

MODERN PHARMACEUTICS

Subject Code: 2514PY03
Course Objectives: Upon completion of the subject student shall be
COB1: To know basic concepts of preformulation parameters, useful in product formulation and development.
COB 2: To learn the cGMP concepts in manufacturing to get a qualitative product.
COB 3: To understand the concept of consolidation, useful for formulating a tablet with desired performance

Course Outcomes

COURSE OUTCOME	Statement
CO1	**Describe** about the basic concepts of preformulation studies, dispersion systems & parenteral
CO2	**Optimize;** optimization process.
CO3	**Explain** about the validation of process, equipment and product.
CO4	**Describe** the cGMP concepts of layout of building, services and their maintenance & about the production management.
CO5	**Describe** the concepts of compression and compaction.
CO6	**Explain** about the parameters of consolidation and their applications.

Mapping of Course Outcomes with Program Outcomes

CO/PO	PO1	PO2	PO3	PO4	PO5	PO6
CO1	3	3	3	3	3	3
CO2	3	3	3	3	3	3
CO3	3	3	3	3	3	3
CO4	3	3	3	3	3	3
CO5	3	3	3	3	3	3
CO6	3	3	3	3	3	3

Mapping of Course Outcomes with Program Specific Outcomes

CO/PSO	PSO1	PSO2
CO1	3	2
CO2	3	2
CO3	3	3
CO4	3	2
CO5	3	2
CO6	3	2

Course contents **60Hours**

UNIT- I **12 Hours**

1. a. Preformation Concepts – Drug Excipient interactions - different methods, kinetics of stability, Stability testing. Theories of dispersion and pharmaceutical Dispersion (Emulsion and Suspension, SMEDDS) preparation and stability Large and small volume parental – physiological and formulation consideration, Manufacturing and evaluation.

b. Optimization techniques in Pharmaceutical Formulation: Concept and parameters of optimization, Optimization techniques in pharmaceutical formulation and processing. Statistical design, Response surface method, Contour designs, Factorial designs and application in formulation.

UNIT-II **12 Hours**

Validation: Introduction to Pharmaceutical Validation, Scope & merits of Validation, Validation and calibration of Master plan, ICH & WHO guidelines for calibration and validation of equipment, Validation of specific dosage form, Types of validation.

Government regulation, Manufacturing Process Model, URS, DQ, IQ, OQ& P.Q. of facilities.

UNIT-III **12 Hours**

cGMP & Industrial Management: Objectives and policies of current good manufacturing practices, layout of buildings, services, equipment's 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-IV **12 Hours**

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

UNIT-V **12 Hours**

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.

Textbooks

1. Theory and Practice of Industrial Pharmacy By Lachmann and Libermann
2. Pharmaceutical dosage forms: Tablets Vol.1-3 by Leon Lachmann.

Reference Books

1. Pharmaceutical Dosage forms: Disperse systems, Vol, 1-2; By Leon Lachmann.
2. Pharmaceutical Dosage forms: Parenteral medications Vol. 1-2; By Leon Lachmann.
3. Modern Pharmaceutics; By Gillbert and S.Banker.

Weblinks

W1:https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7250125/
W2:https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9958669/
W3:https://www.who.int/docs/default-source/medicines/norms-and-standards/guidelines/production/trs1019-annex3-gmp-validation.pdf
W4:https://www.slideshare.net/slideshow/cgmp-and-industrial- management/245604822
W5: https://course.cutm.ac.in/courses/modern-pharmaceutics-cutm1585/

L	T	P	C
4	0	0	4

REGULATORY AFFAIRS

Subject Code: 2514PY04

Course Objectives: Upon completion of the course the student shall be able to
COB1: The Concepts of innovator and generic drugs, drug development process
COB2: The Regulatory guidance's and guidelines for filing and approval process Preparation of Dossiers and their submission to regulatory agencies in different countries
COB3: 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:

COURSE OUTCOM	STATEMENT
CO1	**Explain** the requirements for development
CO2	**Evaluate**, analyze and apply 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
CO3	**Describe** the post approval regulatory requirements for actives and drug products
CO4	**Apply** the regulatory requirements for submission of global documents in CTD/ eCTD formats
CO5	**Identify** the clinical trials requirements for approvals for conducting clinical trials
CO6	**Assess** the requirements of Pharmacovigilance and process of monitoring in clinical trials.

Mapping of Course Outcomes with Program Outcomes

CO/PO	PO1	PO2	PO3	PO4	PO5	PO6
CO1	3	3	2	3	3	3
CO2	3	3	2	3	3	3
CO3	3	3	2	3	3	3
CO4	3	3	2	3	3	3
CO5	3	3	2	3	3	3
CO6	3	3	2	3	3	3

Mapping of Course Outcomes with Program Specific Outcomes

CO/PSO	PSO1	PSO2
CO1	3	2
CO2	3	3
CO3	3	2
CO4	3	2
CO5	2	3
CO6	2	3

Course contents **60Hours**

UNIT-I **12 Hours**

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, invitro, ANDA regulatory approval process, NDA approval process, BE and drug product assessment, in – vivo, scale up process approval changes, post marketing surveillance, outsourcing BAand BE to CRO.

UNIT-II **12 Hours**

Regulatory requirement for product approval: API, biologics, novel, therapies obtaining NDA, ANDA for generic drugs ways and means of US registration for foreign drugs.

UNIT-III **12 Hours**

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.

UNIT-IV **12 Hours**

Non clinical drug development: Global submission of IND, NDA, ANDA. Investigation of medicinal products dossier, dossier (IMPD) and investigator brochure (IB).

UNIT-V **12 Hours**

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.

Text books

1. Shargel, L., & Kanfer, I. (2005). Generic Drug Product Development: Solid Oral Dosage Forms (Vol. 143). Marcel Dekker. ISBN: 9780824740785
2. Guarino, R. A. (2009). New Drug Approval Process: Accelerating Global Registrations (5th ed.). Informa Healthcare. ISBN: 9781420074052

References

1. Berry, I. R., & Martin, R. P. (2008). The Pharmaceutical Regulatory Process (2nd ed.). Informa Healthcare. ISBN: 9781420073185
2. Pisano, D. J., & Mantus, D. (2008). FDA Regulatory Affairs: A Guide for Prescription Drugs, Medical Devices, and Biologics (2nd ed.). CRC Press. ISBN: 9780849332069
3. Rozovsky, F. A., & Adams, R. K. (2003). Clinical Trials and Human Research: A Practical Guide to Regulatory Compliance. Jossey-Bass. ISBN: 9780787964859

Web links

W1: https://www.fda.gov
W2:https://www.ema.europa.eu
W3:https://www.ich.org
W4:https://www.tga.gov.au
W5:https://www.gov.uk/government/organisations/medicines-and-healthcare-products regulatory-agency

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PHARMACEUTICS PRACTICAL-I

Subject Code: 2514PY05
Course Objectives: Upon completion of the course the student shall be able to
COB1: To recall the principles of analysis and instrumentation for testing of drug products.
COB2: To evaluate preformulation, used in development of various dosage forms.
COB3: To evaluate various compressional parameters to formulate a best tablet dosage form.

COURSE OUTCOMES

Course Outcome	Statement
CO1	**Testing** of drugs and simultaneously multiple drugs estimation using UV Spectrophotometer.
CO2	**Demonstration** of the construction and working of HPLC and GC.
CO3	**Testing** of riboflavin/quinine sulphate using fluorimetry and to estimate potassium/sodium by flame photometry.
CO4	**Evaluation** of the preformulation studies.
CO5	**Evaluation** of effect of binding forces on disintegration of tablets.
CO6	**Testing** of difference in micromeritic properties of granules and powders.

Mapping of Course Outcomes with Program Outcomes

CO/PO	PO1	PO2	PO3	PO4	PO5	PO6
CO1	3	3	3	2	2	3
CO2	3	3	3	2	2	3
CO3	3	3	3	3	3	3
CO4	3	3	3	3	3	3
CO5	3	3	3	3	3	3
CO6	3	3	3	3	3	3

Mapping of Course Outcomes with Program Specific Outcomes

CO/PSO	PSO1	PSO2
CO1	3	3
CO2	3	2
CO3	3	3
CO4	3	2
CO5	3	2
CO6	3	2

List of experiments

S. No	Title of the experiment	CO
1	Analysis of Pharmacopoeial compounds and their formulations by UV Vis spectrophotometer	CO1
2.	Simultaneous estimation of multi component containing formulations by UV spectrophotometry	CO1
3.	Experiments based on HPLC	CO2
4.	Experiments based on Gas Chromatography	CO2
5.	Estimation of riboflavin/quinine sulphate by fluorimetry	CO3
6.	Estimation of sodium/potassium by flame photometry	CO3
7.	To carry out preformulation studies of tablets	CO4
8.	To study the effect of compressional force on tablets disintegration time	CO5
9.	To study Micromeritic properties of powders and granulation	CO6

Textbook

1. Theory and Practice of Industrial Pharmacy by Lachmann and Libermann
2. Modern Pharmaceutics; By Gillbert and S.Banker.

Reference Books

1. Remington's PharmaceuticalSciences.
2. Physical Pharmacy; By Alfredmartin
3. Bentley'sTextbookofPharmaceutics–byRawlins.

Weblinks

W1:https://www.agilent.com/cs/library/primers/public/primer-uv-vis-basics-5980-1397en-agilent.pdf
W2:https://chem.libretexts.org/Courses/University_of_California_Davis/CHE_115%3A_Instrumental_Analysis_Lab_Manual/Lab_2%3A_High_Performance_Liquid_Chromatography
W3: https://en.wikipedia.org/wiki/Gas_chromatography
W4:https://chem.libretexts.org/Bookshelves/Analytical_Chemistry/Instrumental_Analysis/Laboratory_Experiments/Lab_4%3A_Molecular_Fluorescence
W5:https://www.rktech.hu/dokumentaciok/Sherwood/A%20Guide%20to%20Single%20Channel%20Flame%20Photometer%20Analysis.pdf

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Pharmaceutics Practical- II

Subject Code: 2514PY06

Course Objectives: Upon completion of the course the student shall be able to

COB1: To learn the design of dosage forms.

COB2: To learn the optimization of formulae.

COB3: To learn the characterization of various dosage forms.

Course Outcomes

Course Outcome	Statement
CO1	Evaluate the effect of various factors on drug dissolution.
CO2	Study of powder characteristics by constructing heckle plots.
CO3	Study of comparative dissolution studies between various dosage forms.
CO4	Evaluation of different dosage forms.
CO5	Design and evaluation of different oral dosage forms.
CO6	Design and evaluation of different transdermal dosage forms.

Mapping of Course Outcomes with Program Outcomes

CO/PO	PO1	PO2	PO3	PO4	PO5	PO6
CO1	3	3	3	3	3	3
CO2	3	3	3	3	3	3
CO3	3	3	3	3	3	3
CO4	3	3	3	3	3	3
CO5	3	3	3	3	3	3
CO6	3	3	3	3	3	3

Mapping of Course Outcomes with Program Specific Outcomes

CO/PSO	PSO1	PSO2
CO1	3	3
CO2	3	2
CO3	3	3
CO4	3	3
CO5	3	3
CO6	3	3

List of experiments

S. No	Title of the experiment	CO
1.	Study the effect of particle size on dissolution of a tablet.	CO1
2.	Study the effect of binders on dissolution of a tablet.	CO1
3.	Construction of Heckal plot for the given granules	CO2
4.	Construction of Higuchi and peppas plot.	CO3
5.	Determine similarity factor.	CO3
6.	Determine the *in-vitro* dissolution profile of CR/ SR marketed formulation.	CO4
7.	Formulation and evaluation of sustained release matrix tablets.	CO5
8.	Formulation and evaluation osmotically controlled DDS.	CO5
9.	Preparation and evaluation of Floating DDS- hydro dynamically balanced DDS.	CO5
10.	Formulation and evaluation of Mucoadhesive tablets.	CO5
11.	Formulation and evaluation of trans dermal patches.	CO6

Course Content: **6 Hours/ Week**

1	Study the effect of particle size on dissolution of a tablet.
2	Study the effect of binders on dissolution of a tablet.
3	Construction of Heckal plot for the given granules
4	Construction of Higuchi and peppas plot.
5	Determine similarityfactor.
6	Determine the *in-vitro* dissolution profile of CR/ SR marketed formulation.
7	Formulation and evaluation of sustained release matrix tablets.
8	Formulation and evaluation osmotically controlled DDS.
9	Preparation and evaluation of Floating DDS- hydro dynamically balanced DDS .
10	Formulation and evaluation of Muco adhesive tablets.
11	Formulation and evaluation of trans dermal patches.

Textbooks

1. Y.W. Chien, *Novel Drug Delivery Systems*, 2nd edition, revised and expanded, Marcel Dekker, Inc., New York, 1992.
2. J. R. Robinson, V. H. L. Lee, *Controlled Drug Delivery Systems*, Marcel Dekker, Inc., New York, 1992.

References

1. Edith Mathiowitz (Editor), *Encyclopedia of Controlled Delivery*, Wiley Interscience, John Wiley & Sons, New York/Chichester/Weinheim.
2. N. K. Jain, *Controlled and Novel Drug Delivery*, CBS Publishers & Distributors, New Delhi, First edition 1997 (Reprint 2001).

Web links

W1:https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8580464/
W2:https://www.sciencedirect.com/science/article/abs/pii/S0939641121002647
W3:https://www.accessdata.fda.gov/scripts/cder/dissolution/
W4:https://www.pharmatutor.org/articles/review-on-controlled-drug-delivery-system
W5: https://pharmaxchange.info/press/2011/08/dissolution-testing-methods

SEMESTER- II

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MOLECULAR PHARMACEUTICS

(NANO TECHNOLOGY & TARGETED DDS) (NTDS)

Subject Code: **2514PY08**

Course Objectives: Upon completion of the course the student shall be able to

COB1: To understand the various approaches for development of novel drug delivery systems.

COB2: To understand the criteria for selection of drugs and polymers for the development of NTDS

COB3: To understand the formulation and evaluation of novel drug delivery systems.

Course Outcomes

COURSE OUTCOME	STATEMENT
CO1	**Explain** the concepts, events and biological process involved in drug targeting. tumor targeting and brain specific delivery.
CO2	**Understand** the introduction preparation and evaluation. Nanoparticles& liposomes: types, preparation and evaluation.
CO3	**Understand** about the Microspheres and microcapsules & types, preparation and evaluation, monoclonal Antibodies
CO4	**Characterize** the niosomes, aquasomes, phytosomes, electrosomes.
CO5	**Describe** the pulmonary drug delivery Systems
CO6	**Discuss** the nucleic acid based therapeutic delivery system

Mapping of Course Outcomes with Program Outcomes:

CO/PO	PO1	PO2	PO3	PO4	PO5	PO6
CO1	3	3	3	3	3	3
CO2	3	3	3	3	3	3
CO3	3	3	3	3	3	3
CO4	3	3	3	3	3	3
CO5	3	3	3	3	3	3
CO6	3	3	3	3	3	3

Mapping of Course Outcomes with Program Specific Outcomes

CO/PSO	PSO1	PSO2
CO1	3	2
CO2	3	3
CO3	2	3
CO4	3	3
CO5	3	3
CO6	3	3

Course contents **60 Hours**

Unit-I **12 Hours**

Targeted Drug Delivery Systems: Concepts, Events and biological process involved in drug targeting. Tumor targeting and Brain specific delivery.

Unit-II **12 Hours**

Targeting Methods: introduction preparation and evaluation. NanoParticles& Liposomes: Types, preparation and evaluation.

Unit-III **12 Hours**

Micro Capsules / Micro Spheres: Types, preparation and evaluation, Monoclonal Antibodies; preparation and application, preparation and application of Niosomes, Aquasomes, Phytosomes, Electrosomes.

Unit-IV **12 Hours**

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

Unit-V **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 nonviral genetransfer). Liposomal gene delivery systems.Bio distribution and Pharmacokinetics. Knowledge of therapeutic antisense molecules and aptamers as drugs of future.

Textbooks

1. Y.W. Chien, *Novel Drug Delivery Systems*, 2nd edition, revised and expanded, Marcel Dekker, Inc., New York, 1992.
2. J. R. Robinson, V. H. L. Lee, *Controlled Drug Delivery Systems*, Marcel Dekker, Inc., New York, 1992.

References

1. Edith Mathiowitz (Editor), *Encyclopedia of Controlled Delivery*, Wiley Interscience, John Wiley & Sons, New York/Chichester/Weinheim.
2. N. K. Jain, *Controlled and Novel Drug Delivery*, CBS Publishers & Distributors, New Delhi, First edition 1997 (Reprint 2001).

Weblinks

W1:https://link.springer.com/chapter/10.1007/978-1-4684-9984-1_5
W2: https://www.smacgigworld.com/blog/instrumentation-and-methodology-of-electrophoresis.php
W3 : https://archive.nptel.ac.in/content/storage2/courses/102103047/PDF/mod3.pdf
W4 : https://microbenotes.com/affinity-chromatography/
W5: https://www.sciencedirect.com/science/article/pii/S1878535213001056

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ADVANCED BIOPHARMACETICS & PHARMACOKINETICS

Subject Code: 2514PY09

Course Objectives: Upon completion of the course the student shall be able to

COB1: The basic concepts in Biopharmaceutics and pharmacokinetics, use of raw data and derive the pharmacokinetic models and parameters the best describe the process of drug absorption, distribution, metabolism and elimination.

COB2: To critically evaluate Biopharmaceutics studies involving drug product equivalency, design and evaluate dosage regimens of the drugs using pharmacokinetic and biopharmaceutic parameters**.**

COB3: The potential clinical pharmacokinetic problems and applications of basics of pharmacokinetics

Course Outcomes:

Course outcome	Statement
CO1	**Demonstrate** drug absorption through GIT- Mechanisms, factors & of study
CO2	**Integrate** biopharmaceutical considerations of drug design & *in-vivo* drug product performance
CO3	**Compute** pharmacokinetic models and evaluation of pharmacokinetic parameters by different models
CO4	**Recall** bioavailability and bioequivalence protocols & studies
CO5	**Evaluate** the applications of pharmacokinetics, pharmacokinetic & Pharmacodynamic drug interactions
CO6	**Analyze** Pharmacokinetics and Pharmacodynamics to biotechnological drugs

Mapping of Course Outcomes with Program Outcomes

CO/PO	PO1	PO2	PO3	PO4	PO5	PO6
CO1	3	3	3	2	2	3
CO2	3	3	3	2	2	3
CO3	3	3	3	3	3	3
CO4	3	3	3	3	3	3
CO5	3	3	3	3	3	3
CO6	3	3	3	3	3	3

Mapping of Course Outcomes with Program-Specific Outcomes

CO/PSO	PSO1	PSO2
CO1	2	3
CO2	3	3
CO3	2	3
CO4	2	3
CO5	2	3
CO6	3	3

Course Contents **60 Hours**

Unit-I **12 Hours**

Drug Absorption from The Gastrointestinal Tract: Gastrointestinal tract, Mechanism of drug absorption, Factors affecting, pH–partition theory, Formulation and physicochemical factors: Dissolution rate, Dissolution process, Noyes–Whitney equation anddrug 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. Solubility: Experimental methods. Permeability: In-vitro, in-situ and In-vivo methods.

Unit-II **12 Hours**

Biopharmaceutic Considerations in Drug Product Design and In Vitro 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, 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

Unit-III **12 Hours**

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 Kmax and Vmax. 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.

Unit-IV **12 Hours**

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, The Biopharmaceutics Classification System, Generic Biologics (Biosimilar Drug Products),Clinical Significance of Bioequivalence Studies, Special Concerns in Bioavailability and Bioequivalence Studies, Generic Substitution**.**

Unit-V **12 Hours**

Application of Pharmacokinetics: Modified-Release Drug Products, Targeted Drug Delivery Systems and Biotechnological Products. Relationship between Pharmacokinetics including Pharmacodynamics: Generation of a pharmacokinetic– pharmacodynamic (PKPD) equation, Pharmacokinetic and pharmacodynamic, interactions. Pharmacokinetics and pharmacodynamics of biotechnology drugs: Introduction, Proteins and peptides, Monoclonal antibodies, Oligonucleotides, Vaccines (immunotherapy),Gene therapies

Text Books

1. Biopharmaceutics and Pharmacokinetics , a.Treatise,D.M.Brahmankar andSunil B.Jaiswal.
2. Biophamaceutics and Clinical Pharmacokinetics by Milo Gibaldi

Reference Books

1. Dr.H.P.Tipnis,1st edition 2002.
2. sarfaraz niazi,1st edition 201
3. Biophamaceutics and Clinical Pharmacokinetics by Milo Gibaldi. 7th edition 2006

Web Links

W1:https://www.sciencedirect.com/science/article/abs/pii/S0476527305001983.
W2:https://www.researchgate.net/
W3:https://pubmed.ncbi.nlm.nih.gov/
W4: https://epgp.inflibnet.ac.in/Home/ViewSubject?catid=WR+tSjp4YS3g7BIFEffOcw==
W5: https://www.sciencedirect.com/science/article/pii/B9780128204726000049

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COMPUTER AIDED DRUG DELIVERY SYSTEM

Course Code: 2514PY10

Course Objective: Upon completion of the course the student shall be able to
COB 1: The course aims to provide offering theoretical insights and practical skills in CADDS.
COB 2: Students will learn computational techniques, software tools, and regulatory aspects, empowering them to innovate in drug delivery research and development.
COB 3: Students will learn applications of computers in clinical data management

Course Outcomes:

CO1	**Recall** the basics of computers in pharmaceutical research and development,population modelling, and sensitivity analysis
CO2	**Illustrate** the quality by design principles, computational modelling of drugdisposition, application of drug transporters
CO3	**Determine** the concepts for computer-aided formulation development, ethics of computing in pharmaceutical research
CO4	**Justify** the pharmacokinetic and pharmacodynamic characteristics of drugs by simulations
CO5	**Assess** the applications of computers in clinical data management
CO6	**Discuss** the impact of artificial intelligence, robotics, and computational fluid dynamics

Mapping of Course Outcomes with Program Outcomes

CO/PO	PO1	PO2	PO3	PO4	PO5	PO6
CO1	3	3	3	3	2	3
CO2	3	3	3	3	2	3
CO3	3	3	3	3	2	3
CO4	3	3	3	3	2	3
CO5	3	3	3	3	2	3
CO6	3	3	3	3	2	3

Mapping of Course Outcomes with Program Specific Outcomes

CO/PSO	PSO1	PSO2
CO1	3	2
CO2	3	3
CO3	3	1
CO4	3	2
CO5	3	1
CO6	3	1

Course contents **60 hours**

UNIT-1 12 Hours

a. Computers in Pharmaceutical Research and Development: A General Overview: History of Computers in Pharmaceutical Research and Development. Statistical modelling in pharmaceutical research and development: Descriptive versus Mechanistic Modelling, Statistical Parameters, Estimation, Confidence Regions, Nonlinearity at the Optimum, Sensitivity Analysis, Optimal Design, Population Modelling.

b. Quality–by-Design in Pharmaceutical Development: Introduction, ICH Q8 guideline, Regulatory and industry views on QbD, scientifically based QbD - examples of application.

UNIT II **12 Hours**

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.

UNIT III **12 Hours.**

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.

UNIT IV **12 Hours**

a. Computer-aided biopharmaceutical characterization: Gastrointestinal absorption simulation. Introduction, Theoretical background, Model construction, Parameter sensitivity analysis, Virtual trial, Fedvs. 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

UNIT V **12 Hours**

Artificial Intelligence (AI), Robotics and Computational fluid dynamics: General overview, Pharmaceutical Automation, Pharmaceutical applications, Advantages and Disadvantages. Current Challenges and Future Directions.

Textbooks

1. Computer Aided Drug Design by Anees Ahmed, Siddiqui, Harish Kumar, Subhi Khisl.
2. Computer Applications in Pharmaceutical Research and Development, Sean Ekins, 2006, John Wiley & Sons.

References

1. Computer-Aided Applications in Pharmaceutical Technology, 1st Edition, Jelena Djuris, Woodhead Publishing.
2. Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James. G.Boylan, Marcel Dekker Inc, New York, 1996.

Webinks

W1: https://onlinelibrary.wiley.com/doi/abs/10.1002/0470037237.ch3
W2: http://sciencedirect.com/topics/neuroscience/nucleoside-transporter
W3:https://www.sciencedirect.com/topics/nursing-and-health-professions/factorial- design
W4: https://www.sciencedirect.com/science/article/abs/pii/B9780443186554000042
W5: https://link.springer.com/chapter/10.1007/978-981-16-5180-9_10
W6: https://ijsra.net/content/artificial-intelligence-advanced-pharmacy

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FORMULATION DEVELOPMENT OF PHARMACEUTICAL AND COSMETIC PRODUCTS

Subject Code: 2514PY11

Course Objectives: Upon completion of the course the student shall be able to

COB1: The scheduled activities in a pharmaceutical firm.

COB2: The pre formulation studies of pilot batches of pharmaceutical industry.

COB3: The significance of dissolution and product stability

Course Outcomes:

COURSE OUTCOME	STATEMENT
CO1	**Describe** various drug-excipient compatibility studies. crystal morphology and variations, powder flow, structure modification, drug-excipient compatibility studies, methods of determination.
CO2	**Summarize** the concept of role of formulation additives in the Design of experiments like factorial design for product and process development.
CO3	**Classify** on solubility techniques, Theories and mechanisms of dissolution, in- vitro dissolution testing models – sink and non-sink, Data handling and correction factor. Bio relevant media, in-vitro and in-vivo correlations, levels of correlations.
CO4	**Explain** the salient features protocols, reports and ICH guidelines of drugs stability.
CO5	**Formulate** the following cosmetic products like Dentifrices, Baby care products, Manicure preparations, Shampoos, Creams.
CO6	**Assessment** and packaging of the following cosmetic products like Dentifrices, Baby care products, Manicure preparations, Shampoos, Creams.

Mapping of Course Outcomes with Program Outcomes

CO/PO	PO1	PO2	PO3	PO4	PO5	PO6
CO1	3	3	2	3	2	3
CO2	3	3	2	3	2	3
CO3	3	3	2	3	2	3
CO4	3	3	2	3	2	3
CO5	3	3	2	3	2	3
CO6	3	3	2	3	2	3

Mapping of Course Outcomes with Program Specific Outcomes

CO/PSO	PSO1	PSO2
CO1	3	2
CO2	3	2
CO3	3	3
CO4	3	2
CO5	3	1
CO6	3	2

Course content **60Hours**

UNIT I **12 Hours**

Preformulation Studies: Molecular optimization of APIs (drug substances), crystal morphology and variations, powder flow, structure modification, drug-excipient compatibility studies, methods of determination.

UNIT II **12 Hours**

Formulation Additives: Study of different formulation additives, factors influencing their incorporation, role of formulation development and processing, new developments in excipient science. Design of experiments – factorial design for product and process development.

UNIT III **12 Hours**

Solubility & Dissolution: Importance, experimental determination, phase- solubility analysis, pH-solubility profile, solubility techniques to improve solubility and utilization of analytical methods – cosolvency, salt formation, complexation, solid dispersion, micellar solubilization and hydrotropy. Theories and mechanisms of dissolution, in-vitro dissolution testing models – sink and non-sink. Factor influencing dissolution and intrinsic dissolution studies. Dissolution test apparatus – designs, dissolution testing for conventional and controlled release products. Data handling and correction factor. Bio-relevent media, in-vitro and in- vivo correlations, levels of correlations.

UNIT IV **12 Hours**

Product Stability: Degradation kinetics, mechanisms, stability testing of drugs and pharmaceuticals, factors influencing-media effects and pH effects, accelerated stability studies, interpretation of kinetic data (API & tablets). Solid state stability and shelf life assignment. Stability protocols, reports and ICH guidelines.

UNIT V **12 Hours**

Cosmetics: Formulation, Evaluation and packaging of the following cosmetic products: Dentrifices like tooth powders, pastes and gels. Manicure preparations like nail polish, lipsticks, eye lashes, Baby care products, Moisturizing cream, vanishing cream, cold cream, shampoo, Soaps and syndetbars.

Text books

1. Lachman, L., Lieberman, H. A., & Kanig, J. L. (1987). The Theory and Practice of Industrial Pharmacy (3rd ed.). Mumbai: Varghese Publishing House.

2. Aulton, M. E., & Taylor, K. (Eds.). (2018). Aulton's Pharmaceutics: The Design and Manufacture of Medicines (5th ed.). Edinburgh: Churchill Livingstone, Elsevier.

Reference text books

1. Allen, L. V., Popovich, N. G., & Ansel, H. C. (2013). Ansel's Pharmaceutical Dosage Forms and Drug Delivery Systems (10th ed.). Philadelphia: Wolters Kluwer Health/Lippincott Williams & Wilkins.– A comprehensive text on dosage form design and drug delivery principles.
2. Banker, G. S., & Rhodes, C. T. (Eds.). (2002). Modern Pharmaceutics (4th ed.). New York: Marcel Dekker.– Focuses on formulation strategies, quality assurance, and manufacturing processes.
3. Sinko P.J. – Martin's Physical Pharmacy and Pharmaceutical Sciences, 6th Edition, Lippincott Williams & Wilkins.

Web links

1. https://www.ich.org – International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use
2. https://www.fda.gov – U.S. Food and Drug Administration: Guidelines and resources
3. https://pubchem.ncbi.nlm.nih.gov – Open chemistry database with information on APIs and excipients
4. https://pharmaguideline.com – Resources on GMP, validation, and pharma formulations
5. https://www.sciencedirect.com – Access to journals and scientific publications related to pharmaceutics

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PRACTICAL PHARMACEUTICS-III

Subject Code: 2514PY12

Course Objectives: Upon completion of the course the student shall be able to
COB1: To understand the various factors influencing the design of NTDS.
COB2: To learn the formulation and evaluation of various NTDS.
COB3: To learn the IVIVC studies using software and to calculate various pharmacokinetic parameters.

Course Outcomes:

Course Outcome	STATEMENT
CO1	**Assess** the factors influencing preparation of microparticles.
CO2	**Formulate** the microparticles and beads.
CO3	**Formulate** the niosomes, liposomes & spherules.
CO4	**Understand** the preparation of Solid dispersion technique.
CO5	**Analyse** the Protein binding studies.
CO6	**Determine** *In-vitro*, *in-vivo* parameters and *IVIVC* parameters.

Mapping of Course Outcomes with Program Outcomes

CO/PO	PO1	PO2	PO3	PO4	PO5	PO6
CO1	3	3	3	3	3	3
CO2	3	3	3	3	3	3
CO3	3	3	3	3	3	3
CO4	3	3	3	3	3	3
CO5	3	3	3	3	3	3
CO6	3	3	3	3	3	3

Mapping of Course Outcomes with Program Specific Outcomes

CO/PSO	PSO1	PSO2
CO1	3	2
CO2	3	2
CO3	3	2
CO4	3	2
CO5	2	3
CO6	3	3

List of experiments

Expt. No	Title	CO
1	To study the effect of temperature change, non-solvent addition, incompatible polymeraddition in microcapsules preparation.	**CO1**
2	Preparation and evaluation of Alginate beads.	**CO2**
3	Formulation and evaluation of gelatin /albumin microspheres.	**CO3**
4	Formulation and evaluation of liposomes/niosomes.	**CO3**
5	Formulation and evaluation of spherules.	**CO3**
6	Improvement of dissolution characteristics of slightly soluble drug by Solid dispersiontechnique.	**CO4**
7	Comparison of dissolution of two different marketed products /brands	**CO1**
8	Protein binding studies of a highly protein bound drug & poorly protein bound drug	**CO5**
9	Bioavailability studies of Paracetamol inanimals.	**CO6**
10	Pharmacokinetic and IVIVC data analysis by WinnolineR software	**CO6**
11	In vitro cell studies for permeability and metabolism	**CO6**

Course Content **6 Hours/ Week**

1. To study the effect of temperature change, non-solvent addition, incompatible polymeraddition in microcapsules preparation.
2. Preparation and evaluation of Alginate beads.
3. Formulation and evaluation of gelatin /albumin microspheres.
4. Formulation and evaluation of liposomes/niosomes
5. Formulation and evaluation of spherules.
6. Improvement of dissolution characteristics of slightly soluble drug by Solid dispersiontechnique.
7. Comparison of dissolution of two different marketed products /brands
8. Protein binding studies of a highly protein bound drug & poorly protein bound drug
9. Bioavailability studies of Paracetamol in animals.
10. Pharmacokinetic and *IVIVC* data analysis by Winnoline^{R} software
11. *In-vitro* cell studies for permeability and metabolism

Textbooks

1. Y. W. Chien, Novel Drug Delivery Systems, 2nd edition, Marcel Dekker, Inc., New York.
2. N. K. Jain, Controlled and Novel Drug Delivery, CBS Publishers, New Delhi.

Reference Books

1. S. P. Vyas and R. K. Khar, Targeted and Controlled Drug Delivery, CBS Publishers.
2. Edith Mathiowitz (Ed.), Encyclopedia of Controlled Drug Delivery, Wiley Interscience.
3. Joseph R. Robinson, Modern Pharmaceutics, Marcel Dekker.

Web Link

W1: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5836057/
W2:https://www.sciencedirect.com/topics/pharmacology-toxicology-and-pharmaceutical-science/nanoparticle-drug-delivery
W3: https://www.fda.gov/media/70970/download
W4: https://www.pharmatutor.org/articles/a-review-on-novel-drug-delivery-system
W5: https://www.cabdirect.org/cabdirect/abstract/20073041942

L	T	P	C
0	0	6	3

PRACTICAL PHARMACEUTICS - IV

Subject Code: 2514PY13

COB1: To learn the formulation designing techniques by using different computer software tooling.

COB2: To know how to calculate Pharmacokinetic parameters using the computer software tooling.

COB3: To know how to calculate Pharmacodynamic parameters using the computer software tooling.

COB4: To learn Regulatory and Documentation aspects

COB5: To learn how to design and evaluate cosmetics

Course Outcomes:

Course Outcome	Statement
CO1	**Designing** of formulations using computer software tooling.
CO2	**Calculation** of pharmacokinetic and pharmacodynamic parameters using computer software tooling.
CO3	**Assessment** of QbD in Pharmaceutical Development
CO4	**Development** of models for calculation of pharmacokinetic and pharmacodynamic parameters.
CO5	**Application** of Optimization techniques in formulation development of tablets
CO6	**Formulation** and evaluation of Cosmetics & multivitamin preparations

Mapping of Course Outcomes with Program Outcomes

CO/PO	PO1	PO2	PO3	PO4	PO5	PO6
CO1	3	3	3	3	3	3
CO2	3	3	3	3	3	3
CO3	3	3	3	3	3	3
CO4	3	3	3	3	3	3
CO5	3	3	3	3	3	3

Mapping of Course Outcomes with Program-Specific Outcomes

CO/PSO	PSO1	PSO2
CO1	3	2
CO2	2	3
CO3	3	2
CO4	2	3
CO5	3	2
CO6	3	1

List of experiments

S. No	Title of the experiment	CO
1.	DoE Using Design Expert®Software	CO1
2.	Formulation data analysis Using Design Expert®Software	CO1
3.	Quality-by-Design in Pharmaceutical Development	CO3
4.	Computer Simulations in Pharmacokinetics and Pharmacodynamics	CO2
5.	Computational Modeling of Drug Disposition	CO2
6.	To develop Clinical Data Collection manual	CO4
7.	To carry out Sensitivity Analysis, and Population Modeling.	CO4
8.	Development and evaluation of Creams	CO6
9.	Development and evaluation of Shampoo and Toothpaste base	CO6
10.	Formulation Development of Multi Vitamnin Syrup	CO6
11.	Use of Optimization techniques in Formulation Development of Table	CO5

Text Books

1. Lachman L, Lieberman HA, Kanig JL. The Theory and Practice of Industrial Pharmacy, 3 rd ed., Varghese Publishers, Mumbai1991.
2. Sinko PJ. Martin's physical pharmacy and pharmaceutical sciences, 5 ed., B.I. Publications Pvt. Ltd, Noida, 2006.

Reference Books

1. Lieberman HA, Lachman L, Schwartz JB. Pharmaceutical dosage forms: tablets Vol. I-III, 2nd ed., CBS Publishers & distributors, New Delhi, 2005.
2. Conners KA. A Text book of pharmaceutical analysis Wells JI. Pharmaceutical preformulation: The physicochemical properties of drug substances. Ellis Horwood Ltd.,England,1998.

Web Links

W1:https://www.sciencedirect.com/science/article/abs/pii/S0476527305001983.
W2:https://www.researchgate.net/
W3:https://pubmed.ncbi.nlm.nih.gov/
W4:https://epgp.inflibnet.ac.in/Home/ViewSubject?catid=WR+tSjp4YS3g7BIFEffOcw
W5: https://www.sciencedirect.com/science/article/pii/B9780128204726000049

SEMESTER – III

L	T	P	C
4	0	0	4

Research Methodology & Biostatistics

Subject Code: 2514PY15

Course Objectives: Upon completion of the subject student shall be

COB1: Understand the perceive problem and hypothesis, test hypothesis, report results

COB2: Importance of statistical investigation -collection data, organisation, presentation, analysis of data.

COB3: Understand the interpretation of data.

Course Outcomes:

COURSE OUTCOME	STATEMENT
CO1	**Identify** the General Research Methodology requirements, review of literature. study design
CO2	**Summarise:** Sample size, (students "t" test, ANOVA, Correlation coefficient, regression), nonparametric tests (Wilcoxon rank tests, analysis of variance, correlation, chi square test), null hypothesis, P values, degree of freedom, interpretation of P values.
CO3	**Apply:** Medical Research: confidentiality, criticisms of orthodox medical ethics, importance of communication, control resolution, guidelines, ethics committees
CO4	**Analyse;** conflicts of interest, referral, vendor relationships, treatment of family members, sexual relationships, fatality.
CO5	**Evaluate:** CPCSEA guidelines for laboratory animal facility.
CO6	**Integrate:** basic principles for all medical research related problem.

Mapping of Course Outcomes with Program Outcomes

CO/PO	PO1	PO2	PO3	PO4	PO5	PO6
CO1	3	3	3	3	2	3
CO2	3	3	3	3	3	3
CO3	3	3	3	3	2	3
CO4	2	3	3	3	2	3
CO5	2	2	2	3	2	3
CO6	3	2	3	2	3	3

Mapping of Course Outcomes with Program Specific Outcomes

CO/PSO	PSO1	PSO2
CO1	2	3
CO2	3	3
CO3	3	2
CO4	2	3
CO5	3	2
CO6	2	2

Course Contents **60 Hours**

UNIT-I **10 Hours**

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

UNIT-II **20 Hours**

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 (Wilcoxon rank tests, analysis of variance, correlation, chi square test), null hypothesis, P values, degree of freedom, interpretation of P values.

UNIT-III **15 Hours**

Medical Research: History, values in medical ethics, autonomy, beneficence, nonmaleficence, 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.

UNIT- IV **9 Hours**

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, anaesthesia, physical facilities, environment, animal husbandry, record keeping, SOPs, personnel and training, transport of lab animals.

UNIT-V **6 Hours**

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

Text Books

1. Kothari, C.R., "Research Methodology: Methods and Techniques", New Age International Publishers.
2. Rosner, B., "Fundamentals of Biostatistics", Cengage Learning.

Reference Books

1. Wayne W. Daniel, "Biostatistics: A Foundation for Analysis in the Health Sciences", Wiley.
2. S.K. Gupta, "Biostatistics", Jaypee Brothers Medical Publishers. Beauchamp, T.L., Childress, J.F., "Principles of Biomedical Ethics", Oxford University Press

Web Links

W1: https://researchmethodsresources.nih.gov/
W2: https://www.wma.net/what-we-do/medical-ethics/declaration-of-helsinki/
W3: https://cpcsea.nic.in/
W4: https://www.openintro.org/book/os/
W5: https://www.who.int/ethics/en/