COURSE BOOK M. PHARM
PHARMACEUTICS I YEAR

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CURRICULUM STRUCTURE & SYLLABUS

Effective from the Session: 2025-26

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1. Teaching Scheme of (M. Pharm. Pharmaceutics I Year)

M. Pharm Pharmaceutics 1st Sem

S No.	Course Type	BOS	Course Code	Course Name	Academic Learning (AL)			Continuous Internal Examination (CIE)		Mid Sem Exam (MSE)	End Semester Examination (ESE)		Total Credit
					L	T	P	MSE	CA	TOTAL		CIE+ESE	Cr
1	M.Pharm	KSOP	MPH101T	Modern Pharmaceutical Analytical Techniques	4	0	0	15	10	25	75	100	4
2	M.Pharm	KSOP	MPH102T	Drug Delivery System	4	0	0	15	10	25	75	100	4
3	M.Pharm	KSOP	MPH103T	Modern Pharmaceutics	4	0	0	15	10	25	75	100	4
4	M.Pharm	KSOP	MPH104T	Regulatory Affairs	4	0	0	15	10	25	75	100	4
5	M.Pharm	KSOP	MPH1 305	Soft Skills	1	0	0	10	-	10	40	50	NC
Lab/Internship/Project work/Workshop													
8	M.Pharm	KSOP	MPH105P	Pharmaceutics Practical I	0	0	12	30	20	50	100	150	6
9	M.Pharm	KSOP	MPH106S	Seminar/Assignment	0	0	7	-	100	100	-	100	4
Total Hours = 36 hrs.					**17**	**0**	**19**					**700**	**26**

M. Pharm Pharmaceutics 2nd Sem

S No.	Course Type	BOS	Course Code	Course Name	Academic Learning (AL)			Continuous Internal Examination (CIE)		Mid Sem Exam (MSE)	End Semester Examination (ESE)		Total Credit
					L	T	P	MSE	CA	TOTAL		CIE+ESE	Cr
1	M.Pharm	KSOP	MPH201T	Molecular Pharmaceutics (Nano Tech and Targeted DDS)	4	0	0	15	10	25	75	100	4
2	M.Pharm	KSOP	MPH202T	Advanced Biopharmaceutics & Pharmacokinetics	4	0	0	15	10	25	75	100	4
3	M.Pharm	KSOP	MPH203T	Computer Aided Drug Delivery System	4	0	0	15	10	25	75	100	4
4	M.Pharm	KSOP	MPH204T	Cosmetic and Cosmeceuticals	4	0	0	15	10	25	75	100	4
Lab/Internship/Project work/Workshop													
5	M.Pharm	KSOP	MPH205P	Pharmaceutics Practical II	0	0	12	30	20	50	100	150	6
6	M.Pharm	KSOP	MPH206S	Seminar/Assignment	0	0	7	-	100	100	-	100	4
7	M.Pharm	KSOP	MPH1 207	Internship on Drug Regulatory Affairs by CPA/DPSRU or QbD by CPA/DPSRU or Product Development/by DPSRU/Any Relevant Industry Internship or 8-12 weeks MOOC Course*	0	0	2	-	25	25	-	25	1
Total Hours: 37 hrs.					**16**	**0**	**21**					**675**	**27**

2. Theory Courses Detail Syllabus

Course Code: MPH101T	Course Name: Modern Pharmaceutical Analytical Techniques	L	T	P	C
Course Offered in: KIET School of Pharmacy		4	0	0	4

Pre-requisite: NA

Course Objectives:

After completion of course student is able to know:

1. Chemicals and excipients.
2. The analysis of various drugs in single and combination dosage forms.
3. Theoretical and practical skills of the instruments.

Course Outcome: After completion of the course, the student will be able to

1. Apply the concepts and applications of UV, IR, Fluorimetry, Flame and AAS.
2. Interpret the basics and applications of NMR.
3. Outline the theory, principle, instrumentation and illustrate the applications of Mass spectroscopy.
4. Acquire theory, principle, instrumentation and applications of chromatography and electrophoresis.
5. Apply the theory, principle, instrumentation, and applications of X-ray crystallography, Potentiometry, thermal techniques and Immunological assays.

CO-PO Mapping (Scale 1: Low, 2: Medium, 3: High)

CO-PO Mapping	PO1	PO2	PO3	PO4	PO5	PO6
CO1	3	1	2	1	2	-
CO2	3	1	2	1	2	-
CO3	3	1	2	1	2	1
CO4	3	1	2	1	2	-
CO5	3	1	2	1	2	1

Unit 1 **UV-Visible, IR, Flame emission spectroscopy** **11 hours**

a) UV-Visible spectroscopy: Introduction, theory, laws, instrumentation associated with UV-Visible spectroscopy. Choice of solvents and solvent effect. 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. 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 2 **NMR Spectroscopy** **11 hours**

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 3 **Mass Spectroscopy** **11 hours**

Mass Spectroscopy: Principle, theory, instrumentation of mass spectroscopy. Different types of ionization like electron impact, chemical, field, FAB and MALDI, APPI analyzers of quadrupole and time of flight. Mass Fragmentation and its rules, meta stable ions, isotopic peaks. Applications of mass spectroscopy.

Unit 4 **Chromatography** **11 hours**

Chromatography: Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution and application 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 5	**Electrophoresis, X-ray Crystallography, Thermal techniques**	**11 hours**

a. Electrophoresis: Principle, instrumentation, working conditions, factors affecting separation and applications of the following:
a) Paper electrophoresis
b) Gel electrophoresis
c) Capillary electrophoresis
d) Zone electrophoresis
e) Moving boundary electrophoresis
f) 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 diffraction.
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.

Unit 6	**Immunological Assays**	**5 hours**

Immunological Assays: RIA (Radio immune assay), ELISA, bioluminescence assays.

	Total Lecture Hours	**60 hours**

Textbook:

1. Spectrometric Identification of Organic Compounds by Robert M Silverstein, Sixth Edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis by Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Instrumental Methods of Analysis by Willards, 7th edition, CBS publishers.
4. Practical Pharmaceutical Chemistry by Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi, 1997.
5. Organic Spectroscopy by William Kemp, 3rd Edition, ELBS, 1991.
6. A Text Book of Pharmaceutical Chemistry by Chatten L.G., Vol. I & II, Marcel Dekker, New York.

Reference Books:

1. Quantitative Analysis of Drugs in Pharmaceutical Formulation by P.D. Sethi, 3rd Edition, CBS Publishers New Delhi, 1997.
2. Pharmaceutical Analysis Modern Methods- Part B by J. W. Munson, Volume 11, Marcel Dekker Series.
3. Introduction to Spectroscopy by Pavia D.L., Lampman G.M., and Kriz G.S., 3rd Edition, Harcourt College Publishers, Philadelphia.

Mode of Evaluation

MSE		**CA**					**ESE**	**Total**
MSE1 60	**MSE2 60**	**CA1 2**	**CA2 (ATT) 8**					
Converted to 15		**10**					**75**	**100**

Course Code: MPH102T	Course Name: Drug Delivery Systems	L	T	P	C
Course Offered in: KIET School of Pharmacy		4	0	0	4

Pre-requisite: NA

Course Objectives:

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

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

Course Outcome: After completion of the course, the student will be able to

1. Examine the concept, factors influencing & biological approaches for SR/CR formulation and customized drug delivery systems, bio-electronic medicines, 3D printing of Pharmaceuticals.
2. Identify the principles & fundamentals of Rate Controlled Drug Delivery Systems.
3. Analyze the principles, concepts, and applications of Gastro-Retentive Drug Delivery Systems.
4. Analyze the Ocular Drug Delivery Systems.
5. Analyze the concept of Transdermal, Protein, Peptide, and Vaccine Delivery System.

CO-PO Mapping (Scale 1: Low, 2: Medium, 3: High)

CO-PO Mapping	PO1	PO2	PO3	PO4	PO5	PO6
CO1	3	2	2	3	3	-
CO2	3	-	2	2	3	-
CO3	3	-	2	2	2	-
CO4	3	-	2	1	2	-
CO5	3	2	2	3	3	-

Unit 1	Sustained Release (SR) and Controlled Release (CR) formulations	10 hours

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	Rate Controlled Drug Delivery Systems	10 hours

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	Gastro-Retentive Drug Delivery Systems	10 hours

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 4	Ocular Drug Delivery Systems	06 hours

Barriers of drug permeation, methods to overcome barriers.

Unit 5	Transdermal Drug Delivery Systems	10 hours

Structure of skin and 10 barriers, penetration enhancers, transdermal drug delivery systems, Formulation and evaluation.

Unit 6	Protein and Peptide Delivery	08 hours

Barriers for protein delivery. Formulation and evaluation of delivery systems of proteins and other macromolecules.

Unit 7	Vaccine Delivery Systems	06 hours

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

Total Lecture Hours	60 hours

Textbook:

1. Novel Drug Delivery Systems by Chien, Y W., 2nd edition, revised and expanded, Marcel Dekker, Inc., New York, 1992.
2. Controlled and Novel Drug Delivery by Jain, N.K. CBS Publishers & Distributors, New Delhi, First edition 1997 (reprint in 2001).
3. Controlled Drug Delivery - concepts and advances by Vyas S.P. and Khar, R.K. Vallabh Prakashan, New Delhi, First edition 2002.

4. Modern Pharmaceutics by Banker G.S. and Rhodes C.T., Marcel Dekker, New York.
5. Microparticulate Systems for the Delivery of Proteins and Vaccines by Cohen S. and Bernstein H., Marcel Dekker, New York.

Reference Books:

1. Controlled Drug Delivery Systems by Robinson, J. R., Lee V. H. L, Marcel Dekker,Inc., New York, 1992.
2. Chichester and Weinheim Encyclopedia of controlled delivery, Editor- Edith Mathiowitz, Published by Wiley Interscience Publication, John Wiley and Sons, Inc, New York! Chichester/Weinheim.

Mode of Evaluation

MSE		CA					ESE	Total	
MSE1 60	MSE2 60	CA1 2	CA2 (ATT) 8	CA3					
Converted to 15		10					75	100	

Course Code: MPH103T	Course Name: Modern Pharmaceutics	L	T	P	C
Course Offered in: KIET School of Pharmacy		4	0	0	4

Pre-requisite: NA

Course Objectives:

1. The elements of pre-formulation studies and active pharmaceutical ingredients and generic drug product development.
2. Optimization techniques & pilot plant scale up techniques
3. Stability testing, sterilization process & packaging of dosage forms.

Course Outcome: After completion of the course, the student will be able to

1. Explore the concept of pre-formulation, stability testing and theories of pharmaceutical dispersion.
2. Acquire the knowledge of different optimization techniques in pharmaceutical formulation with applications.
3. Illustrate validation, ICH and WHO guidelines for calibration and validation of equipment's.
4. Determine the objectives and policies of cGMP and industrial management.
5. Explain the fundamentals of compression and compaction and principle involved in consolidation parameters in pharmaceutical formulation.

CO-PO Mapping (Scale 1: Low, 2: Medium, 3: High)

CO-PO Mapping	PO1	PO2	PO3	PO4	PO5	PO6
CO1	3	-	3	3	3	-
CO2	3	2	3	3	3	2
CO3	-	3	3	-	3	2
CO4	-	3	3	-	3	2
CO5	3	-	3	3	3	-

Unit 1	Pre-formation concept and Optimization techniques	20 hours

(A). Pre-formation 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 2	Validation	10 hours

Introduction to Pharmaceutical Validation, Scope & merits of validation, validation and calibration of Master plan, ICH & WHO guidelines for calibration and validation of equipments, validation of specific dosage form, types of validation. Government regulation, manufacturing process model, URS, DQ, IQ, OQ & P.Q. of facilities.

Unit 3	cGMP & Industrial Management	10 hours

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	Compression and Compaction	10 hours

Physics of tablet compression, compression, consolidation, effect of friction, distribution of forces, compaction profiles, solubility

Unit 5	Study of Consolidation Parameters	10 hours

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.

Total Lecture Hours	60 hours

Textbook:

1. Theory and Practice of Industrial Pharmacy by Lachmann and Libermann
2. Pharmaceutical Dosage Forms: Tablets Vol. 1-3 by Leon Lachmann.
3. Bentley's Textbook of Pharmaceutics – by Rawlins.
4. Modern Pharmaceutics by Gillbert and S. Banker.
5. Physical Pharmacy by Alfred Martin

Reference Books:

1. Pharmaceutical Dosage Forms: Disperse systems, Vol, 1-2 by Leon Lachmann. 4. Pharmaceutical Dosage Forms: Parenteral Medications Vol. 1-2 by Leon Lachman

2. Quality Assurance Guide by Organization of Pharmaceutical producers of India.
3. Applied Production and Operations Management by Evans, Anderson, Sweeney and Williams.

Mode of Evaluation

MSE		CA					ESE	Total	
MSE1 60	MSE2 60	CA1 2	CA2 (ATT) 8						
Converted to 15		10					75	100	

Course Code: MPH104T	Course Name: Regulatory Affairs	L	T	P	C
Course Offered in: KIET School of Pharmacy		4	0	0	4

Pre-requisite: NA

Course Objectives:

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

Course Outcome: After completion of the course, the student will be able to

1. Understand the concept of generic drug and their development.
2. Analyze the requirement of different phases of clinical trials and submitting regulatory documents.
3. Apply the filing process of IND, NDA and ANDA.
4. Analyze chemistry, manufacturing controls and their regulatory importance.
5. Apply the documentation requirements for regulatory bodies.

CO-PO Mapping (Scale 1: Low, 2: Medium, 3: High)

CO-PO Mapping	PO1	PO2	PO3	PO4	PO5	PO6
CO1	3	2	1	1	1	1
CO2	3	1	2	1	2	1
CO3	3	1	2	1	2	2
CO4	3	1	2	2	2	1
CO5	3	1	1	2	1	1

Unit 1	Documentation in Pharmaceutical industry	12 hours

Master formula record, DMF (Drug Master File), distribution records. Generic drugs product development Introduction, Hatch- Waxman act and amendments, CFR (CODE OF FEDERAL REGULATION), drug product performance, in-vitro, ANDA regulatory approval process, NDA approval process, BE and drug product assessment, in –vivo, scale up process approval changes, post marketing surveillance, outsourcing BA and BE to CRO.

Unit 2	Regulatory requirement for product approval	12 hours

API, biologics, novel, therapies obtaining NDA, ANDA for generic drugs ways and means of US registration for foreign drugs.

Unit 3	Regulatory requirements for approval	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 4	Non clinical drug development	12 hours

Global submission of IND, NDA, ANDA. Investigation of medicinal products dossier, dossier (IMPD) and investigator brochure (IB).

Unit 5	Clinical trials	12 hours

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.

Total Lecture Hours	60 hours

Textbook:

1. Generic Drug Product Development, Solid Oral Dosage forms, Leon Shargel and IsaderKaufer,Marcel Dekker series, Vol.143
2. The Pharmaceutical Regulatory Process, Second Edition Edited by Ira R. Berry and Robert P.Martin, Drugs and the Pharmaceutical Sciences,Vol.185, Informa Health care Publishers.
3. New Drug Approval Process: Accelerating Global Registrations By Richard A Guarino, MD,5th edition, Drugs and the Pharmaceutical Sciences,Vol.190.
4. Guidebook for drug regulatory submissions / Sandy Weinberg. By John Wiley & Sons.Inc.

Reference Books:

1. 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. www.ich.org/
4. www.fda.gov/
5. europa.eu/index_en.htm
6. https://www.tga.gov.au/tga-basics

Mode of Evaluation

MSE		CA					ESE	Total	
MSE1 60	MSE2 60	CA1 2	CA2 (ATT) 8						
Converted to 15		10					75	100	

Course Code: MPH105P	Course Name: Pharmaceutics Practical -I	L	T	P	C
Course Offered in: KIET School of Pharmacy		0	0	12	6

Pre-requisite: NA

Course Objectives: This course aims to:

1. To equip students with the hands-on skills and knowledge required for designing, formulating, and evaluating various dosage forms.
2. The objectives typically focus on gaining proficiency in conventional and novel drug delivery systems, understanding analytical techniques, and applying pharmaceutical calculations and biopharmaceutics principles.

Course Outcome: After completion of the course, the student will be able to

1. Analyze pharmacopoeial compounds and their formulations by UV-Vis spectrophotometer.
2. Assess the experiments based on different analytical techniques such as chromatography, photometry, and fluorimetry.
3. Perform the pre-formulation studies of solid dosage form and in-vitro evaluations of novel drug delivery systems along with marketed formulation.

CO-PO Mapping (Scale 1: Low, 2: Medium, 3: High)

CO-PO Mapping	PO1	PO2	PO3	PO4	PO5	PO6
CO1	3	3	2	3	3	-
CO2	3	3	-	3	3	2
CO3	3	3	3	3	3	-

List of Experiments (Indicative & not limited to) (MPH105P)

1. Analysis of pharmacopoeial compounds and their formulations by UV Vis spectrophotometer
2. Simultaneous estimation of multi component containing formulations by UV spectrophotometry
3. Experiments based on HPLC
4. Experiments based on Gas Chromatography
5. Estimation of riboflavin/quinine sulphate by fluorimetry
6. Estimation of sodium/potassium by flame photometry
7. To perform In-vitro dissolution profile of CR/ SR marketed formulation
8. Formulation and evaluation of sustained release matrix tablets
9. Formulation and evaluation osmotically controlled DDS
10. Preparation and evaluation of Floating DDS- hydro dynamically balanced DDS
11. Formulation and evaluation of Muco adhesive tablets.
12. Formulation and evaluation of trans dermal patches.
13. To carry out preformulation studies of tablets.
14. To study the effect of compressional force on tablets disintegration time.
15. To study Micromeritic properties of powders and granulation.
16. To study the effect of particle size on dissolution of a tablet.
17. To study the effect of binders on dissolution of a tablet.
18. To plot Heckal plot, Higuchi and Peppas plot and determine similarity factors.

Total Lecture Hours: 12 hrs./week

Mode of Evaluation

MSE		CA			ESE	Total
MSE1 30	MSE2 30	CA1 -	CA2 10	CA3 (ATT) 10		
Avg. of MSE1 & MSE2 and converted to 30		20			100	150

Training Division-CRPC: Soft skills for M. Pharma 1st Sem (MPH1 305)				
S. No.	**Topic Covered**	**Suggested Activity**	**Objective of Activity**	**No. of Hours**
1	The ABCDP of Soft Skills	Tagging themselves with an apt adjective	Enhancing self-awareness	1
2	Creating a Professional Introduction using F-B analysis	Writing & narration of the professional introduction	Introduce themselves in formal contexts	1
3	4Ts of GD	GD Sessions	Awareness & Group Dynamics	2
4	Case-based GDs	Team presentations on VUCA, BANI, RUPT, TUNA	Coping with change by enhancing cognitive flexibility (critical thinking & problem-solving)	2
5	Formal Writing	Paragraph writing on topics related to the healthcare/pharma sector	To enhance creativity and written expression abilities	1
6	Image Building	Resume - Traditional & ATS, LinkedIn Profile, E-portfolio	Networking and personal branding	1
7	4Ts of Interview	Mock Interview	Preparing for recruitment interviews	4
8	Public Speaking	JAM/Extempore	To enhance - Communication & Confidence	1
9	Presentation Skills	Individual presentations on topics related to the healthcare/pharma sector	To enhance - Content, communication, & confidence	2
Total number of hours				15
Note: As per the number of weeks available during this semester - common to all three specializations - QA, Pharmacology, and Pharmaceutics				
Course Outcomes: The students will be able to - 1) express themselves well in professional contexts 2) enhance their employability quotient				
Assessment/Evaluation Methodology: MSE (10 marks) - based on formal introduction; ESE (40 marks) - 20 marks for the interview, 10 marks for the Resume and 10 marks for the presentation.				

Course Code: MPH201T	Course Name: Molecular Pharmaceutics (Nano Technology & Targeted DDS)	L	T	P	C
Course Offered in: KIET School of Pharmacy		4	0	0	4

Pre-requisite: NA

Course Objectives:

1. The various approaches for development of novel drug delivery systems.
2. The criteria for selection of drugs and polymers for the development of NTDS.
3. The formulation and evaluation of novel drug delivery systems.

Course Outcome: After completion of the course, the student will be able to

1. Elaborate the concept, factors influencing & biological approaches in Targeted drug delivery systems, Tumor targeting and Brain specific drug delivery systems.
2. Assess the formulation, and evaluation of Nanoparticles and Liposomes.
3. Explore the methods for formulation, preparation and applications of Monoclonal antibodies, Microspheres, Niosomes, Aquasomes, Phytosomes and Electrosomes.
4. Illustrate the recent advancement in Pulmonary drug delivery systems and Intra nasal route of drug delivery systems.
5. Apply the concept of Nucleic acid based therapeutic drug delivery.

CO-PO Mapping (Scale 1: Low, 2: Medium, 3: High)

CO-PO Mapping	PO1	PO2	PO3	PO4	PO5	PO6
CO1	3	2	1	3	-	1
CO2	3	2	2	2	3	1
CO3	3	2	2	2	2	1
CO4	3	2	2	1	2	1
CO5	3	2	2	3	3	1

Unit 1	Targeted Drug Delivery Systems	12 hours

Concepts, Events and biological process involved in drug targeting. Tumor targeting and Brain specific delivery

Unit 2	Targeting Methods	12 hours

Introduction preparation and evaluation. Nano Particles & Liposomes: Types, preparation and evaluation.

Unit 3	Micro Capsules / Micro Spheres	12 hours

Types, preparation and evaluation, Monoclonal Antibodies; preparation and application, preparation and application of Niosomes, Aquasomes, Phytosomes, Electrosomes.

Unit 4	Pulmonary Drug Delivery Systems	12 hours

Aerosols, propellents, Containers Types, preparation and evaluation, Intra Nasal Route Delivery systems; Types, preparation and evaluation.

Unit 5	Nucleic acid based therapeutic delivery system	12 hours

Gene therapy, introduction (ex-vivo & in-vivo gene therapy). Potential target diseases for gene therapy (inherited disorder and cancer). Gene expression systems (viral and nonviral gene transfer). Liposomal gene delivery systems.
Biodistribution and Pharmacokinetics. knowledge of therapeutic antisense molecules and aptamers as drugs of future.

Total Lecture Hours 60 hours

Textbook:

1. Y W. Chien, Novel Drug Delivery Systems, 2nd edition, revised and expanded,Marcel Dekker, Inc., New York, 1992.
2. S.P.Vyas and R.K.Khar, Controlled Drug Delivery - concepts and advances, VallabhPrakashan, New Delhi, First edition 2002.
3. N.K. Jain, Controlled and Novel Drug Delivery, CBS Publishers & Distributors, NewDelhi, First edition 1997 (reprint in 2001)

Reference Books:

1. Controlled Drug Delivery Systems by Robinson, J. R., Lee V. H. L, Marcel Dekker,Inc., New York, 1992.
2. Chichester and Weinheim Encyclopedia of controlled delivery, Editor- Edith Mathiowitz, Published by WileyInterscience Publication, John Wiley and Sons, Inc, New York! Chichester/Weinheim.

Mode of Evaluation								
MSE		CA					ESE	Total
MSE1 60	MSE2 60	CA1 2	CA2 (ATT) 8					
Converted to 15		10					75	100

Course Code: MPH202T	Course Name: Advanced Biopharmaceutics & Pharmacokinetics	L	T	P	C
Course Offered in: KIET School of Pharmacy		4	0	0	4

Pre-requisite: NA

Course Objectives:

1. Demonstrate a comprehensive understanding of drug absorption mechanisms, factors influencing absorption, and the pH-partition theory, while critically analyzing the formulation and physicochemical factors affecting drug dissolution and the role of different dosage forms in drug delivery.
2. Apply their knowledge of permeability, solubility, and charge state to explain drug behavior in the gastrointestinal tract and understand its implications for drug absorption, while evaluating the biopharmaceutical factors impacting drug bioavailability and product performance, and designing appropriate in vitro dissolution tests.
3. Utilize pharmacokinetic models to comprehend the significance of drug interactions, assess the purpose and methods of bioavailability and bioequivalence studies, evaluate the design and data of such studies, classify drugs using the biopharmaceutics classification system, analyze the pharmacokinetics and pharmacodynamics of biotechnology drugs and their therapeutic applications, apply the acquired knowledge to solve problems related to drug formulation, drug interactions, and drug product performance, and effectively communicate and present information related to biopharmaceutics and drug development in a clear and organized manner.

Course Outcome: After completion of the course, the student will be able to

1. Acquire the mechanisms and factors involved in drug absorption and drug dissolutions.
2. Analyze the biopharmaceutical factors, including drug bioavailability and absorption rate, formulation characteristics, dissolution testing methods, and in vitro-in vivo correlation, to optimize drug product performance.
3. Apply the pharmacokinetic models of compartmentalization, non-linear kinetics, and drug interactions to predict and optimize drug behavior and its effects on therapeutic outcomes.
4. Analyze the bioequivalence of drug products.
5. Apply pharmacokinetic principles to the understanding of modified-release drug products, targeted drug delivery systems, and biotechnological products.

CO-PO Mapping (Scale 1: Low, 2: Medium, 3: High)

CO-PO Mapping	PO1	PO2	PO3	PO4	PO5	PO6
CO1	1	-	1	-	-	-
CO2	3	1	2	2	-	-
CO3	3	1	3	2	1	-
CO4	3	1	3	2	1	-
CO5	3	1	3	2	1	-

Unit 1	Drug Absorption from the Gastrointestinal Tract	12 hours

Gastrointestinal tract, mechanism of drug absorption, factors affecting drug absorption, pH–partition theory of drug absorption. Formulation and physicochemical factors: Dissolution rate, dissolution process, Noyes– Whitney equation and drug dissolution, factors affecting the dissolution rate. Gastrointestinal absorption: role of the dosage form: Solution (elixir, syrup and solution) as a dosage form, suspension as a dosage form, capsule as a dosage form, tablet as a dosage form, dissolution methods, formulation and processing factors, correlation of in vivo data with in vitro dissolution data. Transport model: Permeability-solubility-charge state and the pH partition hypothesis, properties of the gastrointestinal tract (GIT), pH microclimate intracellular pH environment, tight-junction complex.

Unit 2	Biopharmaceutical Considerations in Drug Product Design and In Vitro Drug Product Performance	12 hours

Introduction, biopharmaceutical factors affecting drug bioavailability, rate-limiting steps in drug absorption, physicochemical nature of the drug formulation factors affecting drug product performance, in vitro: dissolution and drug release testing, compendial methods of dissolution, alternative methods of dissolution testing, meeting dissolution requirements, problems of variable control in dissolution testing performance of drug products. In vitro–in vivo correlation, dissolution profile comparisons, drug product stability, considerations in the design of a drug product.

Unit 3	Pharmacokinetics	12 hours

Basic considerations, pharmacokinetic models, compartment modeling: one compartment model- IV bolus, IV infusion, extra-vascular. Multi compartment model: two compartment - model in brief, non-linear pharmacokinetics: cause of non-linearity, Michaelis–Menten equation, estimation of kmax and vmax. Drug interactions: Introduction, the effect of protein binding interactions, the effect of tissue binding interactions, cytochrome p450-based drug interactions, and drug interactions linked to

transporters.

Unit 4	Drug Product Performance, in vivo: Bioavailability and Bioequivalence	12 hours

Drug product performance, purpose of bioavailability studies, relative and absolute availability. Methods for assessing bioavailability, bioequivalence studies, design and evaluation of bioequivalence studies, study designs, crossover study designs, evaluation of the data, bioequivalence example, study submission and drug review process. Biopharmaceutics classification system, methods. Permeability: In-vitro, in-situ and In-vivo methods. Generic biologics (biosimilar drug products), clinical significance of bioequivalence studies, special concerns in bioavailability and bioequivalence studies, generic substitution.

Unit 5	Application of Pharmacokinetics	12 hours

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.

Total Lecture Hours	60 hours

Textbook:

1. Biopharmaceutics and Clinical Pharmacokinetics by Milo Gibaldi, 4th edition, Philadelphia, Lea and Febiger, 1991.
2. Biopharmaceutics and Pharmacokinetics, A. Treatise, D .M. Brahmankar and Sunil B. Jaiswal., Vallab Prakashan, Pitampura, Delhi.
3. Applied Biopharmaceutics and Pharmacokinetics by Shargel. Land Yu ABC, 6th edition, Connecticut Appleton Century Crofts, 1985
4. Clinical Pharmacokinetics, Concepts and Applications 3rd edition by Malcolm Rowland and Thom~ N. Tozer, Lea and Febiger, Philadelphia,1995
5. Dissolution, Bioavailability and Bioequivalence, Abdou H.M, Mack Publishing Company, Pennsylvania 1989.

Reference Books:

1. Absorption and Drug Development- Solubility, Permeability, and Charge State, Alex Avdeef, John Wiley & Sons, Inc, 2003.
2. Biopharmaceutics and Relevant Pharmacokinetics by John. G Wagner and M. Pemarowski, 1st edition, Drug Intelligence Publications, Hamilton, Illinois, 1971.
3. Basic Pharmacokinetics, 1st edition, Sunil S Jambhekarand Philip J Breen, Pharmaceutical Press, RPS Publishing, 2009.

Mode of Evaluation

MSE		CA					ESE	Total
MSE1 60	MSE2 60	CA1 2	CA2 (ATT) 8					
Converted to 15		10					75	100

Course Code: MPH203T	Course Name: Computer Aided Drug Delivery System	L	T	P	C
Course Offered in: KIET School of Pharmacy		4	0	0	4

Pre-requisite: NA

Course Objectives:

Upon completion of this course, it is expected that students will be able to understand,

1. History of computers in pharmaceutical research and development.
2. Computational modeling of drug disposition.
3. Computers in preclinical development.
4. Optimization techniques in pharmaceutical formulation.
5. Computers in market analysis.
6. Computers in clinical development.
7. Artificial intelligence (AI) and robotics.
8. Computational fluid dynamics (CFD).

Course Outcome: After completion of the course, the student will be able to

1. Elaborate the concepts of Computers in Pharmaceutical Research and Development; Quality-by-Design in Pharmaceutical Development with its applications.
2. Apply the principles and techniques of Computational Modeling of Drug Disposition.
3. Analyze the various aspects of Computer-Aided Formulation Development with special reference to emulsion and micro-emulsions.
4. Illustrate the concept of Computer-Aided Biopharmaceutical Characterization, Computers in Clinical Development and Computer Simulations in Pharmacokinetics and Pharmacodynamics.
5. Interpret the components of Artificial Intelligence (AI), Robotics and Computational Fluid Dynamics.

CO-PO Mapping (Scale 1: Low, 2: Medium, 3: High)

CO-PO Mapping	PO1	PO2	PO3	PO4	PO5	PO6
CO1	3	-	3	3	-	-
CO2	3	-	3	3	-	-
CO3	3	-	3	3	-	-
CO4	3	2	3	3	1	-
CO5	3	-	3	3	2	-

Unit 1	Computers in Pharmaceutical Research and Development & QbD	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 modeling, statistical parameters, estimation, confidence regions, nonlinearity at the optimum, sensitivity analysis, optimal design, population modeling

b. **Quality-by-Design In Pharmaceutical Development**: Introduction, ICH Q8 guidelines, regulatory and industry views on QbD, scientifically based QbD - Examples of application.

Unit 2	Computational Modeling of Drug Disposition	12 hours

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 3	Computer-Aided Formulation Development	12 hours

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 4	Computer-Aided Biopharmaceutical Characterization	12 hours

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.

Unit 5	Artificial Intelligence (AI), Robotics and Computational Fluid Dynamics	12 hours
General overview, pharmaceutical automation, pharmaceutical applications, advantages and disadvantages. Current challenges and future directions.		
	Total Lecture Hours	60 hours

Textbook:

1. Computer Applications in Pharmaceutical Research and Development by Sean Ekins, 2006, John Wiley & Sons.
2. Computer-Aided Applications in Pharmaceutical Technology, 1st Edition by Jelena Djuris, Woodhead Publishing.
3. Encyclopedia of Pharmaceutical Technology, Vol 13 by James Swarbrick, James. G. Boylan, Marcel Dekker Inc, New York, 1996.

Reference Books:

1. Computer Applications in Pharmaceutical Research and Development by Sean Ekins, 2006, JohnWiley & Sons.
2. Computer-Aided Applications in Pharmaceutical Technology, 1st Edition by Jelena Djuris, Woodhead Publishing.
3. Encyclopedia of Pharmaceutical Technology, Vol 13 by James Swarbrick, James. G. Boylan, Marcel Dekker Inc, New York, 1996.

Mode of Evaluation

MSE		CA					ESE	Total	
MSE1 60	MSE2 60	CA1 2	CA2 (ATT) 8						
Converted to 15		10					75	100	

Course Code: MPH204T	Course Name: Cosmetic and Cosmeceuticals	L	T	P	C
Course Offered in: KIET School of Pharmacy		4	0	0	4

Pre-requisite: NA

Course Objectives:

Upon completion of this course, it is expected that students will be able to understand,

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

Course Outcome: After completion of the course, the student will be able to

1. Understand the. Indian regulatory requirements for labeling of cosmetics Regulatory provisions relating to import and manufacturing of cosmetics.
2. Analyze the skin, Hair & other body parts (oral cavity, r face, eye lids, lips, hands, feet, nail, scalp, neck, body) related problems.
3. Apply the Building blocks for the development different product formulations of cosmetics/cosmeceuticals.
4. Analyze the Design of cosmeceutical products.
5. Apply the herbal ingredients for the development of Hair care, skin care and oral care herbal cosmetics.

CO-PO Mapping (Scale 1: Low, 2: Medium, 3: High)

CO-PO Mapping	PO1	PO2	PO3	PO4	PO5	PO6
CO1	3	1	1	-	2	1
CO2	3	1	2	2	-	1
CO3	3	1	1	1	-	1
CO4	3	1	2	1	1	1
CO5	3	1	1	1	1	1

Unit 1	Cosmetics – Regulatory	12 hours

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	Cosmetics - Biological aspects	12 hours

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	Formulation Building blocks	12 hours

Building blocks for different product formulations of cosmetics/cosmeceuticals. Surfactants Classification and application. Emollients, rheological additives: classification and application. Antimicrobial used as preservatives, their merits and demerits. Factors affecting microbial preservative efficacy. Building blocks for formulation of a moisturizing cream, vanishing cream, cold cream, shampoo and toothpaste. Soaps and syndet bars. Perfumes; Classification of perfumes. Perfume ingredients listed as allergens in EU regulation.

Unit 4	Design of cosmeceutical products	12 hours

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	Herbal Cosmetics	12 hours

Herbal ingredients used in Hair care, skin care and oral care. Review of guidelines for herbal cosmetics by private bodies like cosmos with respect to preservatives, emollients, foaming agents, emulsifiers and rheology modifiers. Challenges in formulating herbal cosmetics.

Total Lecture Hours	60 hours

Textbook:

1. Harry's Cosmeticology. 8th edition.
2. Poucher'sperfumecosmeticsandSoaps,10th edition.
3. Cosmetics - Formulation, Manufacture and quality control, PP.Sharma,4th edition

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

Reference Books:

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

Mode of Evaluation

MSE		CA					ESE	Total	
MSE1 60	MSE2 60	CA1 2	CA2 (ATT) 8						
Converted to 15		10					75	100	

Course Code: MPH205P	Course Name: Pharmaceutics Practical -II	L	T	P	C
Course Offered in: KIET School of Pharmacy		0	0	12	6

Pre-requisite: NA

Course Objectives: This course aims to:

1. This course imparts skill set in developing complex drug products, conventional and cosmetic formulations. Students will learn to design drug delivery systems based on theoretical concepts, develop prototypes at the nano/microscale, and conduct comparative studies using in silico and in vitro methods.
2. It also covers the role of physicochemical characteristics of drugs and excipients in formulation development, optimization, evaluation, and stability studies. Students will learn analytical techniques for drug quantification, characterization, and quality control of pharmaceutical products. Students will get hands-on training in in silico methods to optimize pharmaceutical processes.
3. The course also trains students in formulation of cosmetic products and its evaluation. The course equips students in computing pharmacokinetic parameters using various compartment models. The dissolution behavior of drugs and the release mechanisms are also covered in the subject. The experiments are designed in such a way that the students get an understanding of the concepts of miniaturization of delivery systems and complex pharmaceuticals.

Course Outcome: After completion of the course, the student will be able to

1. Explore experiments on formulation and evaluation of novel drug delivery systems
2. Assess the formulation using quality by design approach and regression analysis of the data
3. Develop the herbal and conventional cosmetics for skin care purpose

CO-PO Mapping (Scale 1: Low, 2: Medium, 3: High)

CO-PO Mapping	PO1	PO2	PO3	PO4	PO5	PO6
CO1	3	2	3	3	3	1
CO2	3	2	3	3	3	1
CO3	3	2	3	3	3	1

List of Experiments (Indicative & not limited to) (MPH105P)

1. To study the effect of temperature change, non-solvent addition, incompatible polymer addition 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 dispersion technique.
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.
12. DoE Using Design Expert® Software.
13. Formulation data analysis Using Design Expert® Software.
14. Quality-by-Design in Pharmaceutical Development.
15. Computer Simulations in Pharmacokinetics and Pharmacodynamics.
16. Computational Modeling Of Drug Disposition.
17. To develop Clinical Data Collection manual.
18. To carry out Sensitivity Analysis, and Population Modeling.
19. Development and evaluation of Creams.
20. Development and evaluation of Shampoo and Toothpaste base.
21. To incorporate herbal and chemical actives to develop products.
22. To address Dry skin, acne, blemish, Wrinkles, bleeding gums and dandruff

Total Lecture Hours: 12 hrs./week

Textbook/ Reference Books:

1. Y Chien, Novel Drug Delivery Systems, 2nd Edn, revised and expanded, Taylor and Francis, Marcel Dekker, Inc., New York, 1992.

2. Shargel, S. Wu-Pong, A. Yu, Applied biopharmaceutics and pharmacokinetics. 7th Edn., Connecticut Appleton Century Crofts, 1985
3. Swarbrick, J. G. Boylan, Encyclopedia of Pharmaceutical Technology, Vol 13, Ist Edn., Marcel Dekker Inc, Taylor & Francis, New York, 1996.
4. Donbrow, Microcapsules and Nanoparticles in Medicine and Pharmacy, CRC Press, 2020.
5. S. Kwon, M. M. de Villiers, P. Aramwit, Nanotechnology in Drug Delivery, Ist Edn., Springer, New York, 2009.
6. L. Wise, R. S. Langer, Medical Applications of Controlled Release, Ist Edn., CRC Press, 2019.
7. Li, B. R. Jasti, Design of Controlled Release Drug Delivery Systems, Ist Edn., McGraw-Hill Education, 2005.

Mode of Evaluation

MSE		CA			ESE	Total
MSE1 30	**MSE2 30**	**CA1 -**	**CA2 10**	**CA3 (ATT) 10**		
Avg. of MSE1 & MSE2 and converted to 30		**20**			**100**	**150**

Annexure-1

Course Evaluation Structure

The evaluation of the M. Pharm Pharmaceutics course consists of both theory and lab assessments. The assessments are divided into multiple components as outlined below.

Theory Evaluation Plan

1.Continuous Assessment (CA) of MPH101T, MPH102T, MPH103T, MPH104T, MPH201T, MPH202T, MPH203T, MPH204T - Total Marks: 10

- CA-1: 2 Marks (Based on Assignment/Quiz/Class test/Presentation/GD/Seminar)
- CA-2: 8 Marks (Based on attendance)

2.Mid-Semester and End-Semester Evaluations of MPH101T, MPH102T, MPH103T, MPH104T, MPH201T, MPH202T, MPH203T, MPH204T - Total Marks: 25 Internal, 75 External

- MSE-1: 60 Marks
- MSE-2: 60 Marks } Average of MSE and converted to 15 marks
- CA: 10 Marks (Based on continuous assessment)
- ESE: 75 Marks (externally evaluated)

Practical Evaluation Plan

1.Continuous Assessment (CA) of MPH105P & MPH205P - Total Marks: 20

- CA-1: NA
- CA-2: 10 Marks (Regular lab activities, Quiz, Viva and Lab work)
- CA-3: 10 Marks (Based on attendance)

2. Internal and External Marks Distribution of MPH105P & MPH205P: 50 + 100 = 150 Marks

- MSE-1: 30 Marks
- MSE-2: 30 Marks } Average of MSE1 and MSE2 30 marks
- CA: 20 Marks
- External: 100 Marks (Practical ESE)