

Course	Master of Pharmacy (M.Pharm)	Semester - 1
Type of Course	-	
Prerequisite		
Course Objective	-	

Teaching Scheme (Contact Hours)				Examination Scheme				
Lecture	Tutorial	Lab	Credit	Theory Marks		Practical Marks		Total Marks
				External Mark (T)	Internal Marks (T)	External Mark (P)	Internal Marks (P)	
4	-	-	4	75	25	-	-	100

SEE - Semester End Examination, CIA - Continuous Internal Assessment (It consists of Assignments/Seminars/Presentations/MCQ Tests, etc.)

Course Content		T - Teaching Hours W - Weightage	
Sr.	Topics	T	W
1	Modern Pharmaceutical Analytical Techniques UV-Visible spectroscopy: Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV-Visible spectroscopy. 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. Spectrofluorimetry: Theory of Fluorescence, Factors affecting fluorescence, Quenchers, Instrumentation and Applications of fluorescence spectrophotometer. Flame emission spectroscopy and Atomic absorption spectroscopy: Principle, Instrumentation, Interferences and Applications	11	18
2	NMR spectroscopy NMR spectroscopy: Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and ¹³ C NMR. Applications of NMR spectroscopy	11	18
3	Mass Spectroscopy Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules, Meta stable ions, Isotopic peaks and Applications of Mass spectroscopy	11	18
4	Chromatography Chromatography: Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution and applications of the following: a) Paper chromatography, b) Thin Layer chromatography, c) Ion exchange chromatography, d) Column chromatography, e) Gas chromatography, f) High Performance Liquid chromatography, g) Affinity chromatography.	11	18
5	Electrophoresis	11	18

Course Content		T - Teaching Hours W - Weightage	
Sr.	Topics	T	W
	a. Electrophoresis: Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following: a) Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresis d) Zone electrophoresis e) Moving boundary electrophoresis f) Iso electric focusing b. X ray Crystallography: Production of X rays, Different X ray diffraction methods, Bragg's law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of Xray diffraction.		
6	Immunological assays RIA (Radio immuno assay), ELISA, Bioluminescence assays.	5	10
Total		60	100

Course Outcomes	
At the end of this course, students will be able to:	
CO1	To procure the insight about fundamentals of UV-visible, IR, Fluorescence, Flame emission, Atomic absorption Spectroscopy
CO2	To acquire knowledge of principle, instrumentation and application of NMR spectroscopy
CO3	To achieve expertise about principle, instrumentation and application of Mass spectroscopy
CO4	To extend knowledge about different type of Chromatography techniques.
CO5	To understand Electrophoresis, X-ray crystallography and Immunological assay.

Course	Master of Pharmacy (M.Pharm)	Semester - 1
Type of Course	-	
Prerequisite		
Course Objective	-	

Teaching Scheme (Contact Hours)				Examination Scheme				Total Marks
Lecture	Tutorial	Lab	Credit	Theory Marks		Practical Marks		
				External Mark (T)	Internal Marks (T)	External Mark (P)	Internal Marks (P)	
4	-	-	4	75	25	-	-	100

SEE - Semester End Examination, CIA - Continuous Internal Assessment (It consists of Assignments/Seminars/Presentations/MCQ Tests, etc.)

Course Content		T - Teaching Hours W - Weightage	
Sr.	Topics	T	W
1	Sustained Release (SR) and Controlled Release (CR) formulations Introduction & basic concepts, advantages/disadvantages, factors influencing, Physicochemical & biological approaches for SR/CR formulation, Mechanism of Drug Delivery from SR/CR formulation. Polymers: introduction, definition, classification, properties and application Dosage Forms for Personalized Medicine: Introduction, Definition, Pharmacogenetics, Categories of Patients for Personalized Medicines: Customized drug delivery systems, Bioelectronic Medicines, 3D printing of pharmaceuticals, Telepharmacy.	10	16
2	Rate Controlled Drug Delivery Systems Principles & Fundamentals, Types, Activation; Modulated Drug Delivery Systems; Mechanically activated, pH activated, Enzyme activated, and Osmotic activated Drug Delivery Systems Feedback regulated Drug Delivery Systems; Principles & Fundamentals.	10	16
3	Gastro-Retentive Drug Delivery Systems Principle, concepts advantages and disadvantages, Modulation of GI transit time approaches to extend GI transit. Buccal Drug Delivery Systems: Principle of muco adhesion, advantages and disadvantages, Mechanism of drug permeation, Methods of formulation and its evaluations.	10	16
4	Ocular Drug Delivery Systems Barriers of drug permeation, Methods to overcome barriers	6	10
5	Transdermal Drug Delivery Systems Structure of skin and barriers, Penetration enhancers, Transdermal Drug Delivery Systems, Formulation and evaluation.	10	16
6	Protein and Peptide Delivery Barriers for protein delivery, Formulation and Evaluation of delivery systems of proteins and other macromolecules.	8	15
7	Vaccine delivery systems Vaccines, uptake of antigens, single shot vaccines, mucosal and transdermal delivery of vaccines.	6	10
Total		60	99

Course Outcomes

At the end of this course, students will be able to:

CO1	To understand the Sustained Release(SR) and Controlled Release (CR) formulations.
CO2	To study about the Rate Controlled Drug Delivery Systems
CO3	To gain knowledge about the Gastro-Retentive Drug Delivery Systems and Occular Drug Delivery Systems
CO4	To understand about the Transdermal Drug Delivery Systems
CO5	To gain knowledge about the Protein and Peptide Delivery and Vaccine deliverysystems

Reference Books

1.	Novel Drug Delivery Systems (TextBook) By Y W. Chien Marcel Dekker 2nd edition
----	--

Course	Master of Pharmacy (M.Pharm)	Semester - 1
Type of Course	-	
Prerequisite		
Course Objective	-	

Teaching Scheme (Contact Hours)				Examination Scheme				
Lecture	Tutorial	Lab	Credit	Theory Marks		Practical Marks		Total Marks
				External Mark (T)	Internal Marks (T)	External Mark (P)	Internal Marks (P)	
4	-	-	4	75	25	-	-	100

SEE - Semester End Examination, CIA - Continuous Internal Assessment (It consists of Assignments/Seminars/Presentations/MCQ Tests, etc.)

Course Content		T - Teaching Hours W - Weightage	
Sr.	Topics	T	W
1	Preformation Concepts and Optimization techniques in Pharmaceutical Formulation 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. 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	10	20
2	Validation Introduction to Pharmaceutical Validation, Scope and merits of Validation, Validation and calibration of Master plan, ICH & WHO guidelines for calibration and validation of equipments, Validation of specific dosage form, Types of validation. Government regulation, Manufacturing Process Model, URS, DQ, IQ, OQ & P.Q. of facilities.	10	20
3	cGMP & Industrial Management Objectives and policies of current good manufacturing practices, layout of buildings, services, equipments and their maintenance. Production management: Production organization, materials management, handling and transportation, inventory management and control, production and planning control, Sales forecasting, budget and] cost control, industrial and personal relationship. Concept of Total Quality Management.	10	20
4	Compression and compaction Physics of tablet compression, compression, consolidation, effect of friction, distribution of forces, compaction profiles. Solubility.	10	20
5	Study of consolidation parameters Diffusion parameters, Dissolution parameters and Pharmacokinetic parameters, Heckel plots, Similarity factors – f ₂ and f ₁ , Higuchi and Peppas plot, Linearity Concept of significance, Standard deviation, Chi square test, students T-test, ANOVA test.	10	20
Total		50	100

Course Outcomes

At the end of this course, students will be able to:

CO1	To understand the preformulation concepts and optimization techniques in pharmaceutical formulation.
CO2	To understand pharmaceutical validation, its guidelines as per ICH and WHO.
CO3	To study on cGMP and Industrial Management
CO4	To understand the physics of compression
CO5	Study of consolidation parameters

Course	Master of Pharmacy (M.Pharm)	Semester - 1
Type of Course	-	
Prerequisite		
Course Objective	-	

Teaching Scheme (Contact Hours)				Examination Scheme				
Lecture	Tutorial	Lab	Credit	Theory Marks		Practical Marks		Total Marks
				External Mark (T)	Internal Marks (T)	External Mark (P)	Internal Marks (P)	
4	-	-	4	75	25	-	-	100

SEE - Semester End Examination, CIA - Continuous Internal Assessment (It consists of Assignments/Seminars/Presentations/MCQ Tests, etc.)

Course Content		T - Teaching Hours W - Weightage	
Sr.	Topics	T	W
1	Documentation in Pharmaceutical industry and Regulatory requirement for product approval Documentation in Pharmaceutical industry: Master formula record, DMF (Drug Master File), distribution records. Generic drugs product development Introduction, Hatch- Waxman act and amendments, CFR (CODE OF FEDERAL REGULATION), drug product performance, in-vitro, ANDA regulatory approval process, NDA approval process, BE and drug product assessment, in-vivo, scale up process approval changes, post marketing surveillance, outsourcing BA and BE to CRO. Regulatory requirement for product approval: API, biologics, novel, therapies obtaining NDA, ANDA for generic drugs ways and means of US registration for foreign drugs	12	25
2	CMC, post approval regulatory affairs CMC, post approval regulatory affairs. Regulation for combination products and medical devices. CTD and ECTD format, industry and FDA liaison. ICH Guidelines of ICH-Q, S E, M. Regulatory requirements of EU, MHRA, TGA and ROW countries.	12	25
3	Non clinical drug development Global submission of IND, NDA, ANDA. Investigation of medicinal products dossier, dossier (IMPD) and investigator brochure (IB).	12	25
4	Clinical trials Developing clinical trial protocols. Institutional review board/ independent ethics committee Formulation and working procedures informed Consent process and procedures. HIPAA- new, requirement to clinical study process, pharmacovigilance safety monitor	12	25
Total		48	100

Course Outcomes	
At the end of this course, students will be able to:	
CO1	Understand the approval process of innovator and generic drugs, drug development Process in India, EU and US market
CO2	Know the chemistry, manufacturing controls and documentation requirements, preparation of Dossiers and their submission to various regulatory agencies
CO3	Learn the importance of Clinical trials requirements for approvals for conducting clinical trials and process of monitoring clinical trials and Pharmacovigilance and post approval regulatory requirements for actives and drug products

Reference Books

1.	Drug Regulatory Affairs (TextBook) By by Sachin Itkar, Dr. N.S. Vyawahare Nirali Prakashan
2.	Drug Regulatory Affairs (TextBook) By by Sachin Itkar, Dr. N.S. Vyawahare Nirali Prakashan
3.	FDA Regulatory Affairs: a guide for prescription drugs, medical devices, and biologics By edited by Douglas J. Pisano, David Mantus.
4.	FDA Regulatory Affairs: a guide for prescription drugs, medical devices, and biologics By edited by Douglas J. Pisano, David Mantus.

Course	Master of Pharmacy (M.Pharm)	Semester - 1
Type of Course	-	
Prerequisite		
Course Objective	-	

Teaching Scheme (Contact Hours)				Examination Scheme				Total Marks
Lecture	Tutorial	Lab	Credit	Theory Marks		Practical Marks		
				External Mark (T)	Internal Marks (T)	External Mark (P)	Internal Marks (P)	
-	-	12	6	-	-	100	50	150

SEE - Semester End Examination, CIA - Continuous Internal Assessment (It consists of Assignments/Seminars/Presentations/MCQ Tests, etc.)

List of Practical

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 tab
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.

Course	Master of Pharmacy (M.Pharm)	Semester - 2
Type of Course	-	
Prerequisite		
Course Objective	-	

Teaching Scheme (Contact Hours)				Examination Scheme				
Lecture	Tutorial	Lab	Credit	Theory Marks		Practical Marks		Total Marks
				External Mark (T)	Internal Marks (T)	External Mark (P)	Internal Marks (P)	
4	-	-	4	75	25	-	-	100

SEE - Semester End Examination, CIA - Continuous Internal Assessment (It consists of Assignments/Seminars/Presentations/MCQ Tests, etc.)

Course Content		T - Teaching Hours W - Weightage	
Sr.	Topics	T	W
1	Targeted Drug Delivery Systems Concepts, Events and biological process involved in drug targeting. Tumor targeting and Brain specific delivery.	12	20
2	Targeting Methods Introduction preparation and evaluation. Nano Particles & Liposomes: Types, preparation and evaluation.	12	20
3	Micro Capsules / Micro Spheres Types, preparation and evaluation, Monoclonal Antibodies ; preparation and application, preparation and application of Niosomes, Aquasomes, Phytosomes, Electrosomes.	12	20
4	Pulmonary Drug Delivery Systems Aerosols, propellents, ContainersTypes, preparation and evaluation, Intra Nasal Route Delivery systems; Types, preparation and evaluation.	12	20
5	Nucleic acid based therapeutic delivery system Gene therapy, introduction (ex-vivo & in-vivo gene therapy). Potential target diseases for gene therapy (inherited disorder and cancer). Gene expression systems (viral and nonviral gene transfer). Liposomal gene delivery systems.	12	20
Total		60	100

Course	Master of Pharmacy (M.Pharm)	Semester - 2
Type of Course	-	
Prerequisite		
Course Objective	-	

Teaching Scheme (Contact Hours)				Examination Scheme				
Lecture	Tutorial	Lab	Credit	Theory Marks		Practical Marks		Total Marks
				External Mark (T)	Internal Marks (T)	External Mark (P)	Internal Marks (P)	
4	-	-	4	75	25	-	-	100

SEE - Semester End Examination, CIA - Continuous Internal Assessment (It consists of Assignments/Seminars/Presentations/MCQ Tests, etc.)

Course Content		T - Teaching Hours W - Weightage	
Sr.	Topics	T	W
1	Drug Absorption from the Gastrointestinal Tract Gastrointestinal tract, Mechanism of drug absorption, Factors affecting drug absorption, pH-partition theory of drug absorption. Formulation and physicochemical factors: Dissolution rate, Dissolution process, Noyes-Whitney equation and drug dissolution, Factors affecting the dissolution rate. Gastrointestinal absorption: role of the dosage form: Solution (elixir, syrup and solution) as a dosage form, Suspension as a dosage form, Capsule as a dosage form, Tablet as a dosage form, Dissolution methods, Formulation and processing factors, Correlation of in vivo data with in vitro dissolution data. Transport model: Permeability-Solubility-Charge State and the pH Partition Hypothesis, Properties of the Gastrointestinal Tract (GIT), pH Microclimate Intracellular pH Environment, Tight-Junction Complex.	12	20
2	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.	12	20
3	Pharmacokinetics Basic considerations, pharmacokinetic models, compartment modeling: one compartment model- IV bolus, IV infusion, extra-vascular. Multi compartment model: two compartment - model in brief, non-linear pharmacokinetics: cause of non-linearity, Michaelis - Menten equation, estimation of k_{max} and v_{max} . Drug interactions: introduction, the effect of protein-binding interactions, the effect of tissue-binding interactions, cytochrome p450-based drug interactions, drug interactions linked to transporters.	12	20
4	Drug Product Performance, In Vivo: Bioavailability and Bioequivalence Drug product performance, purpose of bioavailability studies, relative and absolute availability. methods for assessing bioavailability, bioequivalence studies, design and evaluation of bioequivalence studies, study designs, crossover study designs, evaluation of the data, bioequivalence example, study submission and drug review process. biopharmaceutics classification system, methods. Permeability: In-vitro, in-situ and In-vivo methods. generic biologics (biosimilar drug products), clinical significance of bioequivalence studies, special concerns in bioavailability and bioequivalence studies, generic substitution.	12	20
5	Application of Pharmacokinetics	12	20



Course Content		T - Teaching Hours W - Weightage	
Sr.	Topics	T	W
	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		60	100

Course	Master of Pharmacy (M.Pharm)	Semester - 2
Type of Course	-	
Prerequisite		
Course Objective	-	

Teaching Scheme (Contact Hours)				Examination Scheme				
Lecture	Tutorial	Lab	Credit	Theory Marks		Practical Marks		Total Marks
				External Mark (T)	Internal Marks (T)	External Mark (P)	Internal Marks (P)	
4	-	-	4	75	25	-	-	100

SEE - Semester End Examination, CIA - Continuous Internal Assessment (It consists of Assignments/Seminars/Presentations/MCQ Tests, etc.)

Course Content		T - Teaching Hours W - Weightage	
Sr.	Topics	T	W
1	Computers in Pharmaceutical Research and Development: A General Overview and Quality-by-Design In Pharmaceutical Development Computers in Pharmaceutical Research and Development: A General Overview: History of Computers in Pharmaceutical Research and Development. Statistical modeling in Pharmaceutical research and development: Descriptive versus Mechanistic Modeling, Statistical Parameters, Estimation, Confidence Regions, Nonlinearity at the Optimum, Sensitivity Analysis, Optimal Design, Population Modeling Quality-by-Design In Pharmaceutical Development: Introduction, ICH Q8 guideline, Regulatory and industry views on QbD, Scientifically based QbD - examples of application.	12	20
2	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.	12	20
3	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.	12	20
4	Computer-aided biopharmaceutical characterization, Computer Simulations in Pharmacokinetics and Pharmacodynamics and Computers in Clinical Development 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 Computer Simulations in Pharmacokinetics and Pharmacodynamics: Introduction, Computer Simulation: Whole Organism, Isolated Tissues, Organs, Cell, Proteins and Genes. Computers in Clinical Development: Clinical Data Collection and Management, Regulation of Computer Systems.	12	20
5	Artificial Intelligence (AI), Robotics and Computational fluid dynamics	12	20

Course Content		T - Teaching Hours W - Weightage	
Sr.	Topics	T	W
	General overview, Pharmaceutical Automation, Pharmaceutical applications, Advantages and Disadvantages. Current Challenges and Future Directions.		
Total		60	100

Course	Master of Pharmacy (M.Pharm)	Semester - 2
Type of Course	-	
Prerequisite		
Course Objective	-	

Teaching Scheme (Contact Hours)				Examination Scheme				
Lecture	Tutorial	Lab	Credit	Theory Marks		Practical Marks		Total Marks
				External Mark (T)	Internal Marks (T)	External Mark (P)	Internal Marks (P)	
4	-	-	4	75	25	-	-	100

SEE - Semester End Examination, CIA - Continuous Internal Assessment (It consists of Assignments/Seminars/Presentations/MCQ Tests, etc.)

Course Content		T - Teaching Hours W - Weightage	
Sr.	Topics	T	W
1	Cosmetics – Regulatory Definition of cosmetic products as per Indian regulation. Indian regulatory requirements for labeling of cosmetics Regulatory provisions relating to import of cosmetics., Misbranded and spurious cosmetics. Regulatory provisions relating to manufacture of cosmetics – Conditions for obtaining license, prohibition of manufacture and sale of certain cosmetics, loan license, offences and penalties	12	20
2	Cosmetics - Biological aspects Structure of skin relating to problems like dry skin, acne, pigmentation, prickly heat, wrinkles and body odor. Structure of hair and hair growth cycle. Common problems associated with oral cavity. Cleansing and care needs for face, eye lids, lips, hands, feet, nail, scalp, neck, body and under-arm.	12	20
3	Formulation Building blocks and Perfumes Building blocks for different product formulations of cosmetics/ cosmeceuticals. Surfactants – Classification and application. Emollients, rheological additives: classification and application. Antimicrobial used as preservatives, their merits and demerits. Factors affecting microbial preservative efficacy. Building blocks for formulation of a moisturizing cream, vanishing cream, cold cream, shampoo and toothpaste. Soaps and syndetbars. Perfumes; Classification of perfumes. Perfume ingredients listed as allergens in EU regulation. Controversial ingredients: Parabens, formaldehyde liberators, dioxane	12	20
4	Design of cosmeceutical products Sun protection, sunscreens classification and regulatory aspects. Addressing dry skin, acne, sun-protection, pigmentation, prickly heat, wrinkles, body odor., dandruff, dental cavities, bleeding gums, mouth odor and sensitive teeth through cosmeceutical formulations.	12	20
5	Herbal Cosmetics	12	20

Course Content		T - Teaching Hours W - Weightage	
Sr.	Topics	T	W
	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		60	100

Course	Master of Pharmacy (M.Pharm)	Semester - 2
Type of Course	-	
Prerequisite		
Course Objective	-	

Teaching Scheme (Contact Hours)				Examination Scheme				Total Marks
Lecture	Tutorial	Lab	Credit	Theory Marks		Practical Marks		
				External Mark (T)	Internal Marks (T)	External Mark (P)	Internal Marks (P)	
-	-	12	6	-	-	100	50	150

SEE - Semester End Examination, CIA - Continuous Internal Assessment (It consists of Assignments/Seminars/Presentations/MCQ Tests, etc.)

List of Practical

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 /brand
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

Course	Master of Pharmacy (M.Pharm)	Semester - 3
Type of Course	-	
Prerequisite		
Course Objective	-	

Teaching Scheme (Contact Hours)				Examination Scheme				
Lecture	Tutorial	Lab	Credit	Theory Marks		Practical Marks		Total Marks
				External Mark (T)	Internal Marks (T)	External Mark (P)	Internal Marks (P)	
4	-	-	4	75	25	-	-	100

SEE - Semester End Examination, CIA - Continuous Internal Assessment (It consists of Assignments/Seminars/Presentations/MCQ Tests, etc.)

Course Content		T - Teaching Hours W - Weightage	
Sr.	Topics	T	W
1	General Research Methodology General Research Methodology General Research Methodology: Research, objective, requirements, practical difficulties, Review of literature: Use of Library, books and journals- Medlines-Internet, and reprints of articles as a source for Literature survey. Selecting a problem and preparing Research proposals. The Research Report, Paper writing/ thesis writing, Different parts of the Research paper/Thesis Presentation oral/poster presentation) Importance, types, different skills, content, format of model, Poster, Gestures, eye contact, facial expressions, stage fright, volume- pitch, speed, pause & language, Visual aids & seating, Questionnaire. Sources for procurement research grants –National/ international agencies, Government and private bodies	12	20
2	Experimental Design	15	25

Course Content		T - Teaching Hours W - Weightage	
Sr.	Topics	T	W
	Experimental Design (15 hours) Terminology and definitions related to experimental design Study design, types of studies, strategies to eliminate errors/bias, controls, randomization, crossover design, placebo, blinding techniques Sampling Designs: Introduction, types of sample designs, steps, criteria of selection, characteristics, random sampling, drop outs. Advantage and disadvantage of conventional design over experimental design. Basic steps in experimental design. Screening Designs: Screening of factors, General properties for independent factor selected for experimental design, Fractional factorial design(FFD): Purpose advantage and disadvantage of fractional factorial design, Concept of Aliased Effects and Design Aliasing Structure and constructing FFD Analysis of fractional factorial design: Concept of Design Resolution for FFD Case study of factorial design Plackett–Burman designs: Purpose advantage and disadvantage and construction of matrix , Comparison between placket-Burman and FFD design, Case study Full factorial design Optimization techniques and various method of optimization Introduction to contour plots Introduction of repose surface design: Classification Characteristic of design Matrix and analysis of design with case study Evolution of full and reduced mathematical models in experimental designs Central composite designs Taguchi and mixture design Application of experimental design in pharmacology for reduction of animal		
3	Biostatistics	8	13
	Biostatistics Definition, application, 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, Kruskal Wallis test, Mann Whitney U test), null hypothesis, P values, degree of freedom, interpretation of P values, post hoc tests for parametric and non-parametric data (Dunnett’s test, Tukey’s test, Dunn’s test)		
4	Regulatory perspectives of Medical research	10	17
	Regulatory perspectives of Medical research History of medical research (Nuremberg code, The declaration of Helsinki), initiation of ICH-GCP guidelines, advantages of ICH-GCP, core principles of ICH -GCP guidelines , Ethical Committee: Institutional Review Board, Ethical Guidelines by ICMR for Biomedical Research and Human Participants(ethical issues- informed consent process, confidentiality, payments, conflict of interest, vulnerable participants), Schedule Y, Preparation of clinical protocol, Investigator Brochure, Case Report Forms		
5	CPCSEA guidelines for laboratory animal facility	5	8

Course Content		T - Teaching Hours W - Weightage	
Sr.	Topics	T	W
	CPCSEA guidelines for laboratory animal facility Objective and functions of IAEC, background and process of evolution of guidelines, statutory provisions regarding scientific experiments of animals, CPCSEA guidelines for animal experimentation and laboratory animal facility 2015, care and handling of animals, concept of 4 R, protocol preparation for Preclinical studies (Form B)		
6	IPR and Patents IPR and Patents Patents: Definition, Need for patenting, scope and importance of patents, Types of Patents, Condition to be satisfied by an invention to be patentable, Introduction to patent search and important websites, The essential elements of patents, Guidelines for preparations of laboratory notebook, non-obviousness in patents, Drafting of patent claims, important patent related websites. Copyrights and Trademark: Brief introduction to trademark protection and WTO patents, Introduction to "The Patents Act 1970" and "The Patents Rule 2003", with special emphasis on the forms to be submitted along with a patent application	10	17
Total		60	100