SHRI GURU RAM RAI UNIVERSITY

[Estd. by Govt. of Uttarakhand, vide Shri Guru Ram Rai University Act no. 03 of 2017 & recognized by UGC u/s (2f) of UGC Act 1956]

SCHOOL OF PHARMACEUTICAL SCIENCES

PROGRAM: M. PHARM (PHARMACEUTICS)

OUTCOME BASED EDUCATION

COURSE OUTCOMES, PROGRAM OUTCOMES, PROGRAM SPECIFIC OUTCOMES

&

ARTICULATION MATRIX

Program Outcomes- M.Pharm. (PHARMACEUTICS)

PO1	**Advanced Knowledge:** Possess advanced scientific knowledge of the pharmacy profession so as to apply the learning's in providing solutions for complex issues of the Pharmaceutical field.
PO2	**Scientific and Technical Skills:** Develop analytical skills for effective scientific writing/presentation, data compilation & interpretation. Obtain erudite technical skills for applying in research and development for improvement of pharmaceutical process and products.
PO3	**Multidisciplinary Collaborative Research:** Develop interdisciplinary research with other health care communities to provide innovative solutions.
PO4	**Regulatory Professional Skills** Comply and work on rules and regulations involved in the drug discovery & development, manufacture and other allied area of the field.
PO5	**Critical Thinking:** Apply critical thinking skills, including investigation, application, analysis, and creativity, evaluation of information, data and documents related to research.
PO6	**Problem based learning:** Develop problem-based learning approach and analytical thinking in his/her academic and professional life.
PO7	**Professional Identity:** Demonstrate the ability to plan and implement professional activities.
PO8	**Leadership Skills:** Leadership qualities of motivation, team building, time management, organizational skills so as to take lead and responsibilities in order to face the challenges of pharmaceutical sector.
PO9	**Ethical practice and societal concern:** Exercise ethical practices and moral values in personal and professional endeavours.
PO10	**Innovations Leading Skills:** Development of novel analytical techniques for identification, characterization and quantification of drugs, formulation, Pharmacological, Pharmacognostical, and regulatory aspects of drugs and biomolecules.
PO11	**Lifelong learning:** Tackle professional challenges through lifelong learning attitude.
PO12	**Expertise on Medications:** The student should be able to provide an expert opinion on medications to health care professionals on safe and effective medication-use, relevant policies and procedures based on available evidences

Program Specific Outcomes- M.Pharm. (PHARMACEUTICS)

PSO1	**Understanding Pilot plant Scale up Techniques:** understand various Preformulation elements, industrial management and GMP considerations, Pilot Plant Scale Up Techniques, Stability testing, sterilization and packaging of dosage form
PSO2	**Biopharmaceutics &pharmacokinetic models:**Applyskills for dose calculations, dose adjustments and apply biopharmaceutics theories in practical problem solving. The pharmacokinetic models, bioequivalence and potential clinical pharmacokinetic problem analysis
PSO3	**Skill development in Pharmaceutical research:** Develop skills for Pharmacoinformatics in drug development, Computational modelling, Preclinical development, clinical development, Artificial Intelligence, and Robotics,
PSO4	**Gain knowledge in use of advanced instrumentation:**acquire deep knowledge of advanced instrumentation in formulation and evaluation of controlled release formulations, floating drug delivery systems, transdermal drug delivery systems, Micromeritic, and mathematical simulations

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Course Outcomes- M.Pharm. (PHARMACEUTICS)

Semester-I	
COURSE NAME: Modern Pharmaceutical Analytical Techniques	
COURSE CODE: MPH 101T	
MPH 101T: CO 1	Understand the fundamentals of advanced pharmaceutical analytical techniques
MPH 101T: CO 2	Learn about the general principle, theory and instrumentation of advanced pharmaceutical analytical techniques..
MPH 101T: CO 3	Explain about the advanced instruments its techniques and applications in drug analysis
MPH 101T: CO 4	Develop in depth knowledge of instruments in modern pharmaceutical analytical techniques.
MPH 101T: CO 5	Appraise various applications of Modern Pharmaceutical Instruments..
MPH 101T: CO 6	Attain skills in problem solving, critical thinking & analytical reasoning as applied in pharmaceutical analysis.

Semester –I															
COURSE NAME: Modern Pharmaceutical Analytical Techniques															
COURSE CODE: MQA101T															
	PO 1	**PO 2**	**PO 3**	**PO 4**	**PO 5**	**PO 6**	**PO 7**	**PO 8**	**PO 9**	**PO 10**	**PO 11**	**PO 12**	**PSO 1**	**PSO 2**	**PSO 3**	**PSO 4**
CO 1	3	3	2	3	2	3	2	0	0	3	3	1	3	1	3	0
CO 2	3	3	2	3	2	3	2	0	0	3	3	1	3	1	3	0
CO 3	3	3	2	3	2	3	2	0	1	3	3	1	3	2	3	1
CO 4	3	3	2	3	2	3	2	0	1	3	3	1	3	1	3	1
CO 5	3	3	3	3	3	3	2	0	1	3	3	1	3	1	3	1
CO 6	3	3	3	3	3	3	2	2	1	3	3	1	3	1	3	1

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Semester-I

COURSE NAME: Drug Delivery System	
COURSE CODE: MPH102T	
MPH102T: CO 1	Gain knowledge on novel drug delivery systems like Sustained, Controlled Release, GRDDS, Ocular DDS, TDDS, Protein & Peptide Delivery, Vaccine Delivery Systems
MPH102T: CO 2	Learn & understand the criteria for selection of drugs and polymers for the development of Various Drug delivery systems.
MPH102T: CO 3	Apply the knowledge of polymers to formulate various Novel drug delivery system
MPH102T: CO 4	Organize, compare and differentiate various NDDS.
MPH102T: CO 5	Evaluate Various Drug Delivery systems like Transdermal patches, Buccal Patches etc.
MPH102T: CO 6	Design & Formulate various Novel Drug delivery system

Articulation matrix:

Semester –I															
COURSE NAME: Drug Delivery System															
COURSE CODE: MPH102T															
	PO1	**PO2**	**PO3**	**PO4**	**PO5**	**PO6**	**PO7**	**PO 8**	**PO 9**	**PO 10**	**PO 11**	**PO 12**	**PS O1**	**PSO 2**	**PSO 3**	**PSO4**
CO 1	3	2	2	3	2	1	1	1	0	2	3	2	1	0	1	2
CO 2	3	2	3	2	3	2	1	1	0	2	3	2	1	0	1	2
CO 3	2	2	2	1	2	1	1	0	0	2	3	1	1	0	0	1
CO 4	3	2	2	1	2	2	1	0	0	2	3	2	0	0	1	2
CO 5	3	2	2	1	2	1	1	1	0	3	3	2	1	0	1	3
CO 6	3	2	3	3	2	1	1	0	0	2	3	3	1	1	2	3

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Semester-I

COURSE NAME: Modern Pharmaceutics	
COURSE CODE: MPH 103T	
MPH 103T: CO 1	Gain knowledge and remember about concept of Preformulation, Theories of dispersion, and pharmaceutical dispersion, Optimization techniques in Pharmaceutical Formulation, validation, cGMP & Industrial Management, Physics of tablet compression and compaction, Study of consolidation parameters.
MPH 103T: CO 2	Understand about the Active Pharmaceutical Ingredients, Dispersions, Drug excipient interactions, stability testings, validations, cGmp ,Physics of tablet
MPH 103T: CO 3	Apply knowledge of Optimization techniques and 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 for designing various formulations and release studies
MPH 103T: CO 4	Analyse Dispersion, Preformulation, optimization, Validation, cGMP, Compression, solubility parameters, diffusion, dissolution parameters
MPH 103T: CO 5	Evaluate Emulsion, Suspension, Preformulation study, Physics of tablet, appraise optimization techniques used, select manufacturing process models, Value cGMP &industrial management, Defend use of optimization technique
MPH 103T: CO 6	Design & Formulate different dosage forms using Preformulation study, using different optimization techniques, using physic of tablet

Articulation matrix:

Semester –I																
COURSE NAME: Modern Pharmaceutics																
COURSE CODE: MPH 103T																
	PO1	**PO2**	**PO3**	**PO4**	**PO5**	**PO6**	**PO7**	**PO 8**	**PO 9**	**PO 10**	**PO 11**	**PO 12**	**PS O1**	**PSO 2**	**PSO 3**	**PSO4**
CO 1	3	3	1	1	2	3	2	2	1	2	3	3	3	3	2	3
CO 2	3	2	1	0	3	2	0	3	2	3	2	2	2	1	3	2
CO 3	3	3	0	2	2	2	3	1	2	3	3	1	3	3	2	1
CO 4	2	2	1	3	3	2	2	3	0	1	2	2	2	3	1	0
CO 5	3	2	2	2	1	0	3	3	2	1	1	2	2	2	1	2
CO 6	2	2	3	3	1	2	1	1	1	2	2	2	2	2	3	2

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Semester-I	
COURSE NAME: Regulatory Affairs	
COURSE CODE: MPH 104T	
MPH 104T: CO 1	Remember the Concepts of innovator and generic drugs, drug development process
MPH 104T: CO 2	Understand & Discuss the Regulatory guidance's and guidelines for filing and approval process
MPH 104T: CO 3	Demonstrate the Preparation of Dossiers and their submission to regulatory agencies in different countries
MPH 104T: CO 4	Analyse the post approval regulatory requirements for actives and drug products.
MPH 104T: CO 5	Identify Submission of global documents in CTD/ eCTD format.
MPH 104T: CO 6	Assemble the principle of regulatory affairs in drug development process, Clinical trials requirements for approvals for conducting clinical trials

Articulation matrix:

Semester –I															
COURSE NAME: Regulatory Affairs															
COURSE CODE: MPH 104T															
	PO1	**PO2**	**PO3**	**PO4**	**PO5**	**PO6**	**PO7**	**PO 8**	**PO 9**	**PO 10**	**PO 11**	**PO 12**	**PS O1**	**PSO 2**	**PSO 3**	**PSO4**
CO 1	3	1	2	3	2	3	3	2	1	2	3	1	2	3	1	0
CO 2	3	3	2	2	3	3	3	0	1	3	3	2	3	3	3	3
CO 3	3	1	1	2	2	3	3	0	1	2	3	1	2	3	0	0
CO 4	3	3	0	2	2	3	3	0	1	2	3	2	3	3	3	3
CO 5	3	3	2	3	2	3	2	0	1	2	3	2	0	3	0	3
CO 6	3	2	0	3	2	3	3	2	1	3	3	2	0	3	0	0

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Semester-I	
COURSE NAME: Pharmaceutics Practicals-I	
COURSE CODE: MPH 105P	
MPH 105P: CO 1	Analyze Pharmacopoeial compounds and their formulations by UV Visible Spectrophotometer
MPH 105P: CO 2	Analyse Pharmacopoeial compounds and their formulations by High Performance Liquid Chromatography (HPLC)
MPH 105P: CO 3	Estimate sodium/potassium by flame photometry
MPH 105P: CO 4	Perform In-vitro dissolution profile of CR/ SR marketed formulation.
MPH 105P: CO 5	Formulate and evaluate Muco adhesive tablets.
MPH 105P: CO 6	Plot Heckal plot, Higuchi and peppas plot and determine similarity factors..

Articulation matrix:

Semester –I															
COURSE NAME: Pharmaceutics Practicals-I															
COURSE CODE: MPH 105P															
	PO1	**PO2**	**PO3**	**PO4**	**PO5**	**PO6**	**PO7**	**PO 8**	**PO 9**	**PO 10**	**PO 11**	**PO 12**	**PS O1**	**PSO 2**	**PSO 3**	**PSO4**
CO 1	3	3	2	1	3	3	3	1	0	1	3	3	3	1	3	1
CO 2	3	3	3	1	3	3	2	1	0	2	3	3	2	1	3	1
CO 3	3	3	1	1	3	3	3	1	0	2	3	3	3	1	3	1
CO 4	2	2	1	1	3	2	3	1	0	1	3	2	2	1	3	1
CO 5	3	3	2	3	2	3	2	0	1	2	3	2	0	3	0	3
CO 6	3	2	0	3	2	3	3	2	1	3	3	2	0	3	0	0

Semester-II	
COURSE NAME: Molecular Pharmaceutics (Nano Technology & Targeted DDS(NTDS)	
COURSE CODE: MPH 201T	
MPH 201T: CO 1	Remember the various approaches for development of novel drug delivery systems
MPH 201T: CO 2	Understand the criteria for selection of drugs and polymers for the development of NTDS
MPH 201T: CO 3	Apply the knowledge gained in making Targeted Drug delivery systems, Micro capsules, Niosomes, Aquasomes, Phytosomes, Electrosomes, Pulmonary drug delivery.
MPH 201T: CO 4	Examine Targeted drug delivery, Microsomes, Pulmonary drug delivery etc..
MPH 201T: CO 5	Evaluate the developed targeted drug delivery systems
MPH 201T: CO 6	Develop, Formulate Nucleic acid based, therapeutic ,Targeted drug delivery system

Articulation matrix:

Semester –II															
COURSE NAME: Molecular Pharmaceutics (Nano Technology & Targeted DDS(NTDS)															
COURSE CODE: MPH 201T															
	PO1	**PO2**	**PO3**	**PO4**	**PO5**	**PO6**	**PO7**	**PO 8**	**PO 9**	**PO 10**	**PO 11**	**PO 12**	**PS O1**	**PSO 2**	**PSO 3**	**PSO4**
CO 1	3	3	3	2	2	3	2	2	3	0	3	3	0	0	2	2
CO 2	3	2	3	2	3	3	3	1	3	3	2	2	0	1	0	1
CO 3	3	2	3	0	2	3	3	2	1	2	2	1	2	1	1	1
CO 4	3	3	3	2	2	2	1	2	3	3	1	2	2	3	2	1
CO 5	2	3	3	1	2	2	3	2	1	1	1	2	2	2	1	1
CO 6	3	3	3	2	3	3	3	2	3	3	2	2	2	2	2	2

Semester-II

COURSE NAME: Advanced Biopharmaceutics & Pharmacokinetics	
COURSE CODE: MPH 202T	
MPH 202T: CO 1	Memories the basic concepts in biopharmaceutics and pharmacokinetics.
MPH 202T: CO 2	Understand raw data and derive the pharmacokinetic models and parameters to describe the process of drug absorption, distribution, metabolism and elimination.
MPH 202T: CO 3	Use official dissolution models for various novel drug delivery systems.
MPH 202T: CO 4	Compare and analyse the in vitro drug release profiles for different marketed products
MPH 202T: CO 5	Appraise the applications of biopharmaceutics and pharmacokinetics in the development ofbiopharmaceuticals and pharmaceuticals.
MPH 202T: CO 6	Assemble various pharmacokinetic and Pharmacodynamic parameters affecting bioavailability

Articulation matrix:

Semester –II															
COURSE NAME: Advanced Biopharmaceutics & Pharmacokinetics															
COURSE CODE: MPH 202T															
	PO1	**PO2**	**PO3**	**PO4**	**PO5**	**PO6**	**PO7**	**PO 8**	**PO 9**	**PO 10**	**PO 11**	**PO 12**	**PS O1**	**PSO 2**	**PSO 3**	**PSO4**
CO 1	3	2	1	2	1	1	0	0	0	0	3	2	0	3	0	2
CO 2	3	3	2	3	2	3	1	2	2	2	3	2	2	2	3	2
CO 3	3	3	2	3	3	3	2	2	1	2	3	1	1	2	2	2
CO 4	3	3	2	3	3	3	2	2	1	3	3	2	2	2	3	2
CO 5	3	3	2	3	2	2	2	2	1	1	3	2	1	2	2	2
CO 6	3	3	2	3	2	2	1	1	1	0	3	2	0	3	0	3

Semester-II	
COURSE NAME: Computer Aided Drug Development	
COURSE CODE: MPH 203T	
MPH 203T: CO 1	Remember history of Computers in Pharmaceutical Research and Development. computational modelling, Computer aided formulation development, Computer aided biopharmaceutical characterization, Artificial intelligence(AI).
MPH 203T: CO 2	Understand Computer aided formulation development, Computer aided biopharmaceutical characterization, Artificial intelligence(AI).
MPH 203T: CO 3	Apply use of Computers in Preclinical Development, Formulation development, computer simulation in pharmacokinetics. AI, etc.
MPH 203T: CO 4	Analyse Computers in Preclinical Development, Formulation development, computer simulation in pharmacokinetics. AI, etc
MPH 203T: CO 5	Evaluate computer simulation in pharmacokinetics. AI, Computers in Preclinical Development, Formulation development.
MPH 203T: CO 6	Investigate computer simulation in pharmacokinetics, AI, Computers in Preclinical Development, Formulation development

Articulation matrix:

Semester –II																
COURSE NAME: Computer Aided Drug Development																
COURSE CODE: MPH 203T																
	PO1	**PO2**	**PO3**	**PO4**	**PO5**	**PO6**	**PO7**	**PO 8**	**PO 9**	**PO 10**	**PO 11**	**PO 12**	**PS O1**	**PSO 2**	**PSO 3**	**PSO4**
CO 1	3	3	0	3	0	2	1	0	2	0	3	2	0	3	1	3
CO 2	3	3	0	3	0	3	3	0	2	0	3	2	0	3	1	3
CO 3	3	2	0	3	0	1	3	0	2	0	3	1	0	3	1	3
CO 4	3	2	0	3	2	1	3	0	2	0	3	1	0	3	1	3
CO 5	3	3	0	3	2	1	3	0	2	0	3	2	0	3	1	3
CO 6	2	3	0	3	2	2	3	0	3	0	3	2	0	3	1	3

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Semester-II	
COURSE NAME: Cosmetics and Cosmeceuticals	
COURSE CODE: MPH 204T	
MPH 204T: CO 1	Remember Key ingredients used in cosmetics and cosmeceuticals.
MPH 204T: CO 2	Understand building blocks for various formulations.
MPH 204T: CO 3	Apply Various key ingredients and basic science to develop cosmetics and cosmeceuticals
MPH 204T: CO 4	Analyse the developed cosmetics and cosmeceuticals with desired Safety, stability, and efficacy.
MPH 204T: CO 5	Evaluate recent trends and advances in cosmetics and cosmeceuticals.
MPH 204T: CO 6	Develop various herbal cosmetics, Perfumes, Design various cosmeceutical products.

Articulation matrix:

Semester –II															
COURSE NAME: Cosmetics and Cosmeceuticals															
COURSE CODE: MPH 204T															
	PO1	**PO2**	**PO3**	**PO4**	**PO5**	**PO6**	**PO7**	**PO 8**	**PO 9**	**PO 10**	**PO 11**	**PO 12**	**PS O1**	**PSO 2**	**PSO 3**	**PSO4**
CO 1	2	1	1	2	1	0	0	0	2	1	3	2	1	3	1	3
CO 2	3	2	2	1	0	0	0	0	0	1	3	2	2	2	1	2
CO 3	2	2	1	1	1	2	0	0	1	2	2	1	2	2	1	2
CO 4	2	1	1	1	1	0	0	0	0	2	1	1	2	2	1	1
CO 5	2	2	1	0	0	0	0	0	0	1	2	2	1	1	1	1
CO 6	3	2	2	2	2	2	1	2	1	1	3	1	2	3	1	3

Semester-II	
COURSE NAME: Pharmaceutics Practicals-II	
COURSE CODE: MPH 205P	
MPH 205P: CO 1	Formulate and evaluate gelatin /albumin microspheres..
MPH 205P: CO 2	Improve dissolution characteristics of slightly soluble drug by Solid dispersion technique
MPH 205P: CO 3	Perform in vitro cell studies for permeability and metabolism.
MPH 205P: CO 4	Prepare and evaluate Alginate beads.
MPH 205P: CO 5	Analyse Formulation Data Using Design Expert® Software.
MPH 205P: CO 6	Develop and evaluate Creams, shampoos, tooth paste.

Articulation matrix:

Semester –II																
COURSE NAME: Pharmaceutics Practicals-II																
COURSE CODE: MPH 205P																
	PO1	**PO2**	**PO3**	**PO4**	**PO5**	**PO6**	**PO7**	**PO 8**	**PO 9**	**PO 10**	**PO 11**	**PO 12**	**PS O1**	**PSO 2**	**PSO 3**	**PSO4**
CO 1	3	3	2	2	2	2	3	1	1	3	3	1	2	2	2	2
CO 2	2	2	1	2	2	2	3	1	2	2	3	2	2	3	2	2
CO 3	2	2	1	1	1	1	2	1	0	1	3	1	1	1	1	1
CO 4	3	3	2	2	3	2	2	1	0	2	3	1	2	2	1	1
CO 5	2	2	1	0	0	0	0	0	0	1	2	2	1	1	1	1
CO 6	3	2	2	2	2	2	1	2	1	1	3	1	2	3	1	3

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Semester-III	
COURSE NAME: Research Methodology & Biostatistics	
COURSE CODE:	
CO 1	Understand the various aspects of research methodology and the use of biostatistics in research.
CO 2	Compare the various statistical techniques and their applications.
CO 3	Selectandperformtheappropriateparametric/nonparametrictests asperthedata,manuallyaswellasusingstatisticalsoftware.
CO 4	Elaboratewith examplestheethicsinvolvedin medicalresearch.
CO 5	Comprehend the guidelines for the experimentation on animals.
CO 6	Know about the genesis of bioethics with special reference to Helsinki declaration.

Articulation matrix:

Semester –III															
COURSE NAME: Research Methodology & Biostatistics															
COURSE CODE:															
	PO 1	**PO 2**	**PO 3**	**PO 4**	**PO 5**	**PO 6**	**PO 7**	**PO 8**	**PO 9**	**PO 10**	**PO 11**	**PO 12**	**PSO 1**	**PSO 2**	**PSO 3**	**PSO 4**
CO 1	3	3	3	0	2	2	3	0	1	1	3	1	3	0	2	2
CO 2	3	2	0	0	2	2	3	2	1	1	3	1	2	1	3	2
CO 3	1	3	0	0	2	2	3	0	1	1	3	0	2	1	3	3
CO 4	1	1	0	0	2	1	1	0	3	0	0	0	1	2	2	3
CO 5	3	1	0	0	2	1	1	0	3	0	0	0	0	0	0	0
CO 6	1	1	0	0	2	1	1	0	3	0	0	1	0	0	1	2

Semester-III	
COURSE NAME: Research Work	
COURSE CODE:	
CO 1	Gain an understanding to identify the research question.
CO 2	Developing skills to define & determine the research problem with the peers to achieve the desired outcome.
CO 3	Gain understanding to establish the research objectives.
CO 4	Developing skills for establishing a suitable methodology to answer the research problem.
CO 5	Gain an understanding to develop a protocol & plan of work to answer the research problem.
CO 6	Demonstration of the plan of work & critically appraised research problem in appropriate forum.

Articulation matrix:

Semester –III															
COURSE NAME: Research Work															
COURSE CODE:															
	PO 1	**PO 2**	**PO 3**	**PO 4**	**PO 5**	**PO 6**	**PO 7**	**PO 8**	**PO 9**	**PO 10**	**PO 11**	**PO 12**	**PSO 1**	**PSO 2**	**PSO 3**	**PSO 4**
CO 1	2	3	2	2	3	2	1	1	0	2	2	2	3	0	0	0
CO 2	3	2	2	1	3	3	2	2	0	2	2	3	2	0	2	2
CO 3	3	0	2	1	3	1	1	1	0	2	1	3	2	1	1	2
CO 4	2	2	2	2	2	2	1	1	2	2	2	2	3	2	2	1
CO 5	2	2	2	2	2	1	1	1	2	1	2	3	2	3	3	2
CO 6	2	2	2	2	2	3	1	2	2	3	2	3	2	3	2	2

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Semester-III	
COURSE NAME: Journal Club	
COURSE CODE:	
CO 1	Search articles from various scientific databases.
CO 2	Critically appraise scientific articles and assess the quality
CO 3	Develop a report on the critically appraised article
CO 4	Prepare a technical presentation for a small audience.
CO 5	Deliver a presentation and address related queries.

Articulation matrix:

Semester –III															
COURSE NAME: Journal Club															
COURSE CODE:															
	PO 1	**PO 2**	**PO 3**	**PO 4**	**PO 5**	**PO 6**	**PO 7**	**PO 8**	**PO 9**	**PO1 0**	**PO 11**	**PO 12**	**PSO 1**	**PSO 2**	**PSO3**	**PSO 4**
CO 1	2	0	3	0	1	2	1	1	1	1	3	3	1	3	1	1
CO 2	2	2	2	2	2	3	3	2	2	2	3	3	3	3	2	2
CO 3	3	2	1	1	3	2	2	2	3	1	3	3	1	2	1	2
CO 4	1	2	2	0	2	2	3	3	3	1	3	3	2	1	1	1
CO 5	2	1	1	0	1	2	3	3	2	2	3	3	1	0	0	0

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Semester-IV	
COURSE NAME: Research Work& Colloquium	
COURSE CODE:	
CO 1	Ability to review scholarly articles critically to collect and formulate the data.
CO 2	Developing skills to conduct research for achieving research objectives.
CO 3	Gain understanding to stratify the collected data and formulate into the research findings.
CO 4	Ability to statistically analyse the critically formulated data and generate the research outcome.
CO 5	Developing skills to propose new ideas or outcomes for the defined research question and create research document of the findings.
CO 6	Appraise and defend the research findings with evidence-based observations.

Articulation matrix:

Semester –IV															
COURSE NAME: Research Work& Colloquium															
COURSE CODE:															
	PO 1	**PO 2**	**PO 3**	**PO 4**	**PO 5**	**PO 6**	**PO 7**	**PO 8**	**PO 9**	**PO 10**	**PO 11**	**PO 12**	**PSO 1**	**PSO 2**	**PSO3**	**PSO 4**
CO 1	3	3	2	1	1	2	2	2	3	2	2	3	2	2	2	2
CO 2	3	3	2	2	2	2	2	2	3	2	3	2	2	3	2	2
CO 3	3	2	2	1	2	2	2	1	2	2	2	2	3	3	2	2
CO 4	2	3	3	2	2	2	2	2	2	2	1	3	2	2	2	3
CO 5	3	3	3	2	2	2	2	2	2	3	1	1	3	3	3	2
CO 6	3	2	2	2	2	2	2	1	2	2	1	1	3	2	3	2

Dean
School of Pharmaceutical Sciences
SGRR University, Dehradun (Uttarakhand)

PHARMACEUTICS(MPH)

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES
(MPH 101T)

Scope

This subject deals with various advanced analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are NMR, Mass spectrometer, IR, HPLC, GC etc.

Objectives

After completion of course student is able to know,

- Chemicals and Excipients
- The analysis of various drugs in single and combination dosage forms
- Theoretical and practical skills of the instruments

THEORY — 60 HOURS

1. 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. — 11 Hrs

   b. IR spectroscopy: Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier - Transform IR Spectrometer, Factors affecting vibrational frequencies and Applications of IR spectroscopy

   c. Spectroflourimetry: Theory of Fluorescence, Factors affecting fluorescence, Quenchers, Instrumentation and Applications of fluorescence spectrophotometer.

   d. Flame emission spectroscopy and Atomic absorption spectroscopy: Principle, Instrumentation, Interferences and Applications.

2. NMR spectroscopy: Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and 13C NMR. Applications of NMR spectroscopy. — 11 Hrs

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 Hrs
4	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 Hrs
5	a. Electrophoresis: Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following: a) Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresis d) Zone electrophoresis e) Moving boundary electrophoresis f) Iso electric focusing b. X ray Crystallography: Production of X rays, Different X ray diffraction methods, Bragg's law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X-ray diffraction.	11 Hrs
6	Immunological assays : RIA (Radio immuno assay), ELISA, Bioluminescence assays.	5 Hrs

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.
3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.
4. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi, 1997.
5. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis- Modern methods – Part B - J W Munson, Volume 11, Marcel Dekker Series

DRUG DELIVERY SYSTEMS
(MPH 102T)

SCOPE

This course is designed to impart knowledge on the area of advances in novel drug delivery systems.

OBJECTIVES

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

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

THEORY — 60 Hrs

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 Hrs
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 Hrs
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 Hrs
4	Occular Drug Delivery Systems: Barriers of drug permeation, Methods to overcome barriers.	06 Hrs

5	Transdermal Drug Delivery Systems: Structure of skin and barriers, Penetration enhancers, Transdermal Drug Delivery Systems, Formulation and evaluation.	10 Hrs
6	Protein and Peptide Delivery: Barriers for protein delivery. Formulation and Evaluation of delivery systems of proteins and other macromolecules.	08 Hrs
7	Vaccine delivery systems: Vaccines, uptake of antigens, single shot vaccines, mucosal and transdermal delivery of vaccines.	06 Hrs

REFERENCES

1. Y W. Chien, Novel Drug Delivery Systems, 2nd edition, revised and expanded,
Marcel Dekker, Inc., New York, 1992.
2. Robinson, J. R., Lee V. H. L, Controlled Drug Delivery Systems, Marcel Dekker,Inc., New York, 1992.
3. Encyclopedia of controlled delivery, Editor- Edith Mathiowitz, Published by WileyInterscience Publication, John Wiley and Sons, Inc, New York! Chichester/Weinheim
4. N.K. Jain, Controlled and Novel Drug Delivery, CBS Publishers & Distributors, New Delhi, First edition 1997 (reprint in 2001).
5. S.P.Vyas and R.K.Khar, Controlled Drug Delivery - concepts and advances, Vallabh Prakashan, New Delhi, First edition 2002

JOURNALS

1. Indian Journal of Pharmaceutical Sciences (IPA)
2. Indian drugs (IDMA)
3. Journal of controlled release (Elsevier Sciences) desirable
4. Drug Development and Industrial Pharmacy (Marcel & Decker) desirable

MODERN PHARMACEUTICS
(MPH 103T)

Scope

Course designed to impart advanced knowledge and skills required to learn various aspects and concepts at pharmaceutical industries

Objectives

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

- The elements of preformulation studies.
- The Active Pharmaceutical Ingredients and Generic drug Product development
- Industrial Management and GMP Considerations.
- Optimization Techniques & Pilot Plant Scale Up Techniques
- Stability Testing, sterilization process & packaging of dosage forms.

	THEORY	60 HRS
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.	10 Hrs
	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	10 Hrs
2	Validation : Introduction to Pharmaceutical Validation, Scope & merits of Validation, Validation and calibration of Master plan, ICH & WHO guidelines for calibration and validation of equipments, Validation of specific dosage form, Types of validation. Government regulation, Manufacturing Process Model, URS, DQ, IQ, OQ & P.Q. of facilities.	10 Hrs
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 Hrs

4	Compression and compaction: Physics of tablet compression, compression, consolidation, effect of friction, distribution of forces, compaction profiles. Solubility.	10 Hrs
5	Study of consolidation parameters; Diffusion parameters, Dissolution parameters and Pharmacokinetic parameters, Heckel plots, Similarity factors – f2 and f1, Higuchi and Peppas plot, Linearity Concept of significance, Standard deviation , Chi square test, students T-test , ANOVA test.	10 Hrs

REFERENCES

1. Theory and Practice of Industrial Pharmacy By Lachmann and Libermann
2. Pharmaceutical dosage forms: Tablets Vol. 1-3 by Leon Lachmann.
3. Pharmaceutical Dosage forms: Disperse systems, Vol, 1-2; By Leon Lachmann.
4. Pharmaceutical Dosage forms: Parenteral medications Vol. 1-2; By Leon Lachmann.
5. Modern Pharmaceutics; By Gillbert and S. Banker.
6. Remington's Pharmaceutical Sciences.
7. Advances in Pharmaceutical Sciences Vol. 1-5; By H.S. Bean & A.H. Beckett.
8. Physical Pharmacy; By Alfred martin
9. Bentley's Textbook of Pharmaceutics – by Rawlins.
10. Good manufacturing practices for Pharmaceuticals: A plan for total quality control, Second edition; By Sidney H. Willig.
11. Quality Assurance Guide; By Organization of Pharmaceutical producers of India.
12. Drug formulation manual; By D.P.S. Kohli and D.H.Shah. Eastern publishers, New Delhi.
13. How to practice GMPs; By P.P.Sharma. Vandhana Publications, Agra.
14. Pharmaceutical Process Validation; By Fra. R. Berry and Robert A. Nash.
15. Pharmaceutical Preformulations; By J.J. Wells.
16. Applied production and operations management; By Evans, Anderson, Sweeney and Williams.
17. Encyclopaedia of Pharmaceutical technology, Vol I – III.

REGULATORY AFFAIRS
(MPH 104T)

Scope

Course designed to impart advanced knowledge and skills required to learn the concept of generic drug and their development, various regulatory filings in different countries, different phases of clinical trials and submitting regulatory documents : filing process of IND, NDA and ANDA

- To know the approval process of
- To know the chemistry, manufacturing controls and their regulatory importance
- To learn the documentation requirements for
- To learn the importance and

Objectives:

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

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

THEORY 60 Hrs

1. a. Documentation in Pharmaceutical industry: Master formula record, DMF (Drug Master File), distribution records. Generic drugs product development Introduction , Hatch-Waxman act and amendments, CFR (CODE OF FEDERAL REGULATION) ,drug product performance, in-vitro, ANDA regulatory approval process, NDA approval process, BE and drug product assessment, in -vivo, scale up process approval changes, post marketing surveillance, outsourcing BA and BE to CRO. 12 Hrs

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

2	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 Hrs
3	Non clinical drug development: Global submission of IND, NDA, ANDA. Investigation of medicinal products dossier, dossier (IMPD) and investigator brochure (IB).	12 Hrs
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 monitoring in clinical trials.	12 Hrs

REFERENCES

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.
5. FDA regulatory affairs: a guide for prescription drugs, medical devices, and biologics/edited By Douglas J. Pisano, David Mantus.
6. Clinical Trials and Human Research: A Practical Guide to Regulatory Compliance By Fay A.Rozovsky and Rodney K. Adams
7. www.ich.org/
8. www.fda.gov/
9. europa.eu/index_en.htm
10. https://www.tga.gov.au/tga-basics

PHARMACEUTICS PRACTICALS - I
(MPH 105P)

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.

MOLECULAR PHARMACEUTICS (NANO TECHNOLOGY & TARGETED DDS) (NTDS)
(MPH 201T)

Scope

This course is designed to impart knowledge on the area of advances in novel drug delivery systems.

Objectives

Upon completion of the course student shall be able to understand

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

THEORY		60 Hrs
1.	Targeted Drug Delivery Systems: Concepts, Events and biological process involved in drug targeting. Tumor targeting and Brain specific delivery.	12 Hrs
2	Targeting Methods: introduction preparation and evaluation. Nano Particles & Liposomes: Types, preparation and evaluation.	12 Hrs
3	Micro Capsules / Micro Spheres: Types, preparation and evaluation , Monoclonal Antibodies ; preparation and application, preparation and application of Niosomes, Aquasomes, Phytosomes, Electrosomes.	12 Hrs
4	Pulmonary Drug Delivery Systems : Aerosols, propellents, ContainersTypes, preparation and evaluation, Intra Nasal Route Delivery systems; Types, preparation and evaluation.	12 Hrs
5	Nucleic acid based therapeutic delivery system : Gene therapy, introduction (ex-vivo & in-vivo gene therapy). Potential target diseases for gene therapy (inherited disorder and cancer). Gene expression systems (viral and nonviral gene transfer). Liposomal gene delivery systems. Biodistribution and Pharmacokinetics. knowledge of therapeutic antisense molecules and aptamers as drugs of future.	12 Hrs

REFERENCES

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).

ADVANCED BIOPHARMACEUTICS & PHARMACOKINETICS
(MPH 202T)

Scope

This course is designed to impart knowledge and skills necessary for dose calculations, dose adjustments and to apply biopharmaceutics theories in practical problem solving. Basic theoretical discussions of the principles of biopharmaceutics and pharmacokinetics are provided to help the students' to clarify the concepts.

Objectives

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

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

THEORY 60 Hrs

1. Drug Absorption from the Gastrointestinal Tract: Gastrointestinal tract, Mechanism of drug absorption, Factors affecting drug absorption, pH–partition theory of drug absorption. Formuulation 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 Hrs

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 testingperformance of drug products. In vitro–in vivo correlation, dissolution profile comparisons, drug product stability,considerations in the design of a drug product.	12 Hrs
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 Hrs
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 Hrs
5	Application of Pharmacokinetics: Modified-Release Drug Products, Targeted Drug Delivery Systems and Biotechnological Products. Introduction to Pharmacokinetics and pharmacodynamic, drug interactions. Pharmacokinetics and pharmacodynamics of biotechnology drugs. Introduction, Proteins and peptides, Monoclonal antibodies, Oligonucleotides, Vaccines (immunotherapy), Gene therapies.	12 Hrs

REFERENCES

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., VallabPrakashan, Pitampura, Delhi
3. Applied Biopharmaceutics and Pharmacokinetics by Shargel. Land YuABC, 2nd edition, Connecticut Appleton Century Crofts, 1985
4. Textbook of Biopharmaceutics and Pharmacokinetics, Dr. Shobha Rani R. Hiremath,Prism Book
5. Pharmacokinetics by Milo Gibaldi and D. Perrier, 2nd edition, Marcel Dekker Inc.,New York, 1982
6. Current Concepts in Pharmaceutical Sciences: Biopharmaceutics, Swarbrick. J, Leaand Febiger, Philadelphia, 1970
7. Clinical Pharmacokinetics, Concepts and Applications 3rd edition by MalcolmRowland and Thom~ N. Tozer, Lea and Febiger, Philadelphia, 1995
8. Dissolution, Bioavailability and Bioequivalence, Abdou. H.M, Mack PublishingCompany, Pennsylvania 1989
9. Biopharmaceutics and Clinical Pharmacokinetics, An Introduction, 4th edition,revised and expande by Robert. E. Notari, Marcel Dekker Inc, New York and Basel,1987.
10. Biopharmaceutics and Relevant Pharmacokinetics by John. G Wagner and M.Pemarowski, 1st edition, Drug Intelligence Publications, Hamilton, Illinois, 1971.
11. Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James. G.Boylan, Marcel Dekker Inc, New York, 1996.
12. Basic Pharmacokinetics,1 st edition,Sunil S JambhekarandPhilip J Breen,pharmaceutical press, RPS Publishing,2009.
13. Absorption and Drug Development- Solubility, Permeability, and Charge State, Alex Avdeef, John Wiley & Sons, Inc,2003.

COMPUTER AIDED DRUG DEVELOPMENT
(MPH 203T)

Scope

This course is designed to impart knowledge and skills necessary for computer Applications in pharmaceutical research and development who want to understand the application of computers across the entire drug research and development process. Basic theoretical discussions of the principles of more integrated and coherent use of computerized information (informatics) in the drug development process are provided to help the students to clarify the concepts.

Objectives

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

- History of Computers in Pharmaceutical Research and Development
- Computational Modeling of Drug Disposition
- Computers in Preclinical Development
- Optimization Techniques in Pharmaceutical Formulation
- Computers in Market Analysis
- Computers in Clinical Development
- Artificial Intelligence (AI) and Robotics
- Computational fluid dynamics(CFD)

THEORY		60 Hrs
1.	a. Computers in Pharmaceutical Research and Development: A General Overview: History of Computers in Pharmaceutical Research and Development. Statistical modeling in Pharmaceutical research and development: Descriptive versus Mechanistic Modeling, Statistical Parameters, Estimation, Confidence Regions, Nonlinearity at the Optimum, Sensitivity Analysis, Optimal Design, Population Modeling b. Quality-by-Design In Pharmaceutical Development: Introduction, ICH Q8 guideline, Regulatory and industry views on QbD, Scientifically based QbD - examples of application.	12 Hrs
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 Hrs

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 Hrs
4	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	12 Hrs
5	Artificial Intelligence (AI), Robotics and Computational fluid dynamics: General overview, Pharmaceutical Automation, Pharmaceutical applications, Advantages and Disadvantages. Current Challenges and Future Directions.	12 Hrs

REFERENCES

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

COSMETICS AND COSMECEUTICALS
(MPH 204T)

Scope

This course is designed to impart knowledge and skills necessary forthefundamental need for cosmetic and cosmeceutical products.

Objectives

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

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

	THEORY	60 Hrs
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 Hrs
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 Hrs
3	Formulation Building blocks: Building blocks for different product formulations of cosmetics/cosmeceuticals. Surfactants - Classification and application. Emollients, rheological additives: classification and application. Antimicrobial used as preservatives, their merits and demerits. Factors affecting microbial preservative efficacy. Building blocks for formulation of a moisturizing cream, vanishing cream, cold cream, shampoo and toothpaste. Soaps and syndetbars. Perfumes; Classification of perfumes. Perfume ingredients listed as allergens in EU regulation.	12 Hrs

Controversial ingredients: Parabens, formaldehyde liberators, dioxane.

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 Hrs
5	Herbal Cosmetics : Herbal ingredients used in Hair care, skin care and oral care. Review of guidelines for herbal cosmetics by private bodies like cosmos with respect to preservatives, emollients, foaming agents, emulsifiers and rheology modifiers. Challenges in formulating herbal cosmetics.	12 Hrs

REFERENCES

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
5. Cosmetic and Toiletries recent suppliers catalogue.
6. CTFA directory.

PHARMACEUTICS PRACTICALS - II
(MPH 205P)

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

Semester III

MRM 301T - Research Methodology & Biostatistics

UNIT – I

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

Biostatistics: Definition, application, sample size, importance of sample size, factors influencing sample size, dropouts, statistical tests of significance, type of significance tests, parametric tests(students "t" test, ANOVA, Correlation coefficient, regression), non-parametric tests (wilcoxan rank tests, analysis of variance, correlation, chi square test), null hypothesis, P values, degree of freedom, interpretation of P values.

UNIT – III

Medical Research: History, values in medical ethics, autonomy, beneficence, non-maleficence, double effect, conflicts between autonomy and beneficence/non-maleficence, euthanasia, informed consent, confidentiality, criticisms of orthodox medical ethics, importance of communication, control resolution, guidelines, ethics committees, cultural concerns, truth telling, online business practices, conflicts of interest, referral, vendor relationships, treatment of family members, sexual relationships, fatality.

UNIT – IV

CPCSEA guidelines for laboratory animal facility: Goals, veterinary care, quarantine, surveillance, diagnosis, treatment and control of disease, personal hygiene, location of animal facilities to laboratories, anesthesia, euthanasia, physical facilities, environment, animal husbandry, record keeping, SOPs, personnel and training, transport of lab animals.

UNIT – V

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