GURU KASHI UNIVERSITY

Master of Pharmacy
(Pharmaceutics)

Session: 2023-24

Department of
Pharmacy

GRADUATE ATTRIBUTE

Graduates will acquire knowledge and research skills to identify and solve complex drug based issues across a broad range of application areas, integrate knowledge and skills to provide healthcare solutions for the benefit of the society prove leadership qualities and entrepreneurship skills by working and communicating effectively in a combined surrounding conditions either independently or in a team,aware and able to reply and respond to health care needs of the community and possess a commitment to continuously improve knowledge and abilities

PROGRAMME LEARNING OUTCOMES

- Apply knowledge to create newer technology and skills.
- Apply knowledge of excipients, dosage forms, production, quality improvements, safety and production management to optimize pharmaceutical products and drug delivery systems.
- Use modern Pharmaceutical tools, software and equipments to analyze and solve problems.
- Demonstrate an ability to design formulation and drug delivery systems as per need and establish new specifications in Pharmaceutical Industries.
- Develop an ability to visualize and work on multidisciplinary tasks in the Pharma Industry and research.
- Analyze problems with current drug therapy, formulate solutions and identify risks associated with the solutions in order to deliver the best pharmaceutical care to the patient.
- Assume participatory roles as responsible citizens or leadership roles when appropriate to facilitate improvement of health and well- being of society.
- Communicate and comprehend effectively with the pharmacy community and society for making effective presentation, documentation, guidance and counselling.
- Engage in doctoral and post – doctoral research activities for the benefit of mankind.
- Apply knowledge and skills to register drug products in different countries in order to deliver best products in the world

Course Structure of the Program

Semester- I						
Course Code	**Course Title**	**Type of Course**	**L**	**T**	**P**	**Credit**
MPH101T	Modern Pharmaceutical Analytical Techniques	Core course	4	0	0	4
MPH102T	Drug Delivery System	Core course	4	0	0	4
MPH103T	Modern Pharmaceutics	Core course	4	0	0	4
MPH104T	Regulatory Affair	Core course	4	0	0	4
MPH105P	PharmaceuticsPractical	Technical Enhancement	0	0	12	6
SEM-I	Seminar/Assignment		0	0	8	4
Total			16	0	20	26

Semester- II						
Course Code	**Course Title**	**Type of Course**	**L**	**T**	**P**	**Credit**
MPH201T	MolecularPharmaceutics (NanoTechandTargetedDDS)	Core course	4	0	0	4
MPH202T	AdvancedBiopharmaceutics& Pharmacokinetics	Core course	4	0	0	4
MPH203T	ComputerAidedDrugDeliverySystem	Core course	4	0	0	4
MPH204T	CosmeticandCosmeceuticals	Core course	4	0	0	4
MPH205P	PharmaceuticsPracticalII	Technical enhancement	0	0	12	6
SEM-II	Seminar/Assignment		0	0	8	4
Total			16	0	20	26

Semester- III						
Course Code	**Course Title**	**Type of Course**	**L**	**T**	**P**	**Credit**
MRM301T	Research Methodology and Biostatistics*	Foundation Compulsory	4	0	0	4
JCLUB-I	Journal club	-	0	0	2	1
DIS-I	Discussion/Presentation (Proposal Presentation)	-	0	0	4	2
RES-I	ResearchWork	-	0	0	28	14
Total			**4**		**34**	**21**

*NonUniversityExam

Semester- IV						
Course Code	**Course Title**	**Type of Course**				
			L	**T**	**P**	**Credit**
JCLUB-II	Journal Club		0	0	2	1
RES-II	Research Work		0	0	32	16
DIS-II	Discussion /Final Presentation		0	0	6	3
Total			**0**	**-**	**40**	**20**

Credit PointsforCo-CurricularActivities

Semester	**Credit points**
I	26
II	26
III	21
IV	20
Attendng co – curricular activities Conference, Scientific Presentations and other scholarly activities	Minimum=02 Maximum=07*
Total Credit Points	**Minimum=95** **Maximum=100***

1.1. Internalassessment: Continuousmode

The marks allocated for Continuous mode of Internal Assessment shall beawardedasper theschemegivenbelow.

Table 1. Schemeforawardinginternalassessment: Continuousmode

Theory	
Criteria	MaximumMarks
Attendance (ReferTable– 2	8
Student–Teacherinteraction	2
Total	10

Practical	
Attendance (Refer Table– 2	10
BasedonPracticalRecords,Regularvivavoce,etc.	10
Total	20

Table–2: Guidelines for the allotment of marks for attendance

PercentageofAttendance	Theory	Practical
95–100	8	10
90–94	6	7.5
85–89	4	5
80–84	2	2.5
Lessthan80	0	0

Guidelines for Awarding Credit Points for Co-Curricular Activities

NameoftheActivity	**MaximumCreditPoints Eligible/Activity**
Participation inNational LevelSeminar/Conference/Workshop/Symposium/TrainingPrograms(relatedtothespecializationofthestudent)	01
Participation in International LevelSeminar/Conference/Workshop/Symposium/TrainingPrograms(relatedtothespecializationofthestudent)	02

AcademicAward/ResearchAwardfromState Level/NationalAgencies	01
AcademicAward/ResearchAwardfrom InternationalAgencies	02
Research / Review Publication in National Journals (IndexedinScopus/WebofScience)	01
Research / Review Publication in International Journals (IndexedinScopus/WebofScience)	02

Sessional Exams

Two sessionalexamsshall be conductedforeach theory /practical courseas per the schedule fixed by the college(s). The schemeof question paperfor theory and practical sessional examinations is given in the table. Theaveragemarks of two sessional exams shall be computed for internalassessmentaspertherequirements given by PCI.

Promotionandawardofgrades

A student shall be declared PASSand eligible for getting gradein a course of M.Pharm. programme

if he/she secures at least 50% marks in that particularcourse includinginternalassessment.

1. Carryforwardofmarks

In case a student fails to secure the minimum 50% in any Theory or Practical course as specified in 12, then he/she shall reappear for the end semester examination of that course. However, his/her marks of the Internal Assessment shall be carried over and he/she shall be entitled for grade obtained by him/her on passing.

2. Improvement of internal assessment

A student shall have the opportunity to improve his/her performanceonly oncein thesessional examcomponentof the internal assessment. The re-conductofthe sessional exam shall be completed before the commencement of next endsemestertheoryexaminations.

3. Reexamination of end semester examinations

Reexamination of end semester examination shall be conducted as per theschedule givenin table. The exact dates of examinations shall be notifiedfromtimetotime.

Tentativescheduleofendsemesterexamination

Semester	For Regular Candidates	For failed Candidates
I and III	November/ December	May / June
II and IV	May / June	November / December

A student shallbe eligible to carryforwardall the coursesof I and II semesters tillthe III semester examinations. However, he/she shallnot be eligibleto attendthe coursesof IV semester until all the coursesof I, II and III semesters aresuccessfullycompleted.

A student shall be eligibleto get his/her CGPAupon successful completion ofthe coursesof I to IV semesters within the stipulated time period as per thenorms.

2. Projectwork

All the students shall undertake a project under the supervisionof a teacher inSemester III to IV and submit a report.4 copies of the project report shall be submitted (typed&boundcopynotlessthan75pages).

The internaland externalexaminerappointed by the University shall evaluatethe project at the time of the Practical examinations of other semester(s). The projects shall be evaluatedas per the criteria given below.

Evaluationof DissertationBook:	
Objective(s) of the work done	50Marks
Methodology adopted	150Marks
Results and Discussions	250Marks
Conclusions and Outcomes	50 Marks
Total	500Marks

Evaluationof Presentation

Presentationofwork	100Marks
Communicationskills	50Marks
Questionandanswerskills	100Marks
Total	**250 Marks**

Revaluation orRetotalingof answerpapers

There is no provision for revaluation of the answer papers in any examination. However, the candidates can apply for retotaling by paying prescribed fee.

SEMESTER: I

Course Title: MODERN PHARMACEUTICAL ANALYTICAl TECHNIQUES	L	T	P	Credits
Course Code: MPH 101 T	4	0	0	4

Learning Outcomes of the course: On successful completion of this course, the students will be able to:

1. Recognize chemicals and excipients
2. Analyze of various drugs in single and combination dosage forms
3. Apply Theoretical and practical skills of the instruments
4. Evaluate the the working conditions of instruments

COURSE CONTENT

UNIT – I **11 Hours**

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

Spectroflourimetry: 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

UNIT – II **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 – III **11 Hours**

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

UNIT – IV **11 Hours**

Chromatography: Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution and applications of the following:

- Paper chromatography
- Thin Layer chromatography
- Ion exchange chromatography
- Column chromatography
- Gas chromatography
- High Performance Liquid chromatography
- Affinity chromatography

UNIT – V **16**

Hours

Electrophoresis: Principle, Instrumentation, working conditions, factors affecting separation and applications of the following:

i) Paper electrophoresis
ii) Gel electrophoresis
iii) Capillary electrophoresis
iv) Zone electrophoresis
v) Moving boundary electrophoresis
vi) *Iso electric focusing*

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.

Immunological assays: RIA (Radio immuno assay), ELISA, Bioluminescence assays.

Transaction Mode

Lecture, Seminar, e-Team Teaching, e-Tutoring, Dialogue, Peer Group Discussion, Mobile Teaching, Self-Learning, Collaborative Learning and Cooperative Learning

SuggestedReadings

- *Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.*
- *Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.*
- *Instrumental methods of analysis – Willards, 7th edition, CBS publishers.*
- *Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi, 1997.*
- *Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.*
- *Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.*
- Pharmaceutical Analysis- Modern methods – Part B - J W Munson, Volume 11, Marcel Dekker Series

SEMESTER I

Course Title: DRUG DELIVERY SYSTEMS	L	T	P	Credits
Course Code: MPH 102 T	4	0	0	4

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

1. Recognize the various approaches for development of novel drug delivery systems.
2. Apply the criteria for selection of drugs and polymers for the development of delivering system
3. Formulation and evaluation of Novel drug delivery systems
4. Create the various different sustained release(sr) and controlled release (cr) formulations

COURSE CONTENT

UNIT – I **10 Hours**

Sustained Release(SR) and Controlled Release (CR) formulations: Introduction & basic concepts, advantages/ disadvantages, factors influencing, Physicochemical & biological approaches for SR/CR formulation, Mechanism of Drug Deliveryfrom 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.

UNIT – II **10 Hours**

Rate Controlled Drug Delivery Systems: Principles & Fundamentals, Types, Activation; Modulated Drug Delivery Systems; Mechanically activated, pH activated, Enzyme activated, and Osmotic Activated Drug Delivery Systems Feedback regulated Drug Delivery Systems; Principles & Fundamentals

UNIT – III **10 Hours**

Gastro-Retentive Drug Delivery Systems: Principle, concepts advantages and disadvantages, Modulation of GI transit time approaches to extend GI transit.

Buccal Drug Delivery Systems: Principle of muco adhesion, advantages and disadvantages, Mechanism of drug permeation, Methods of formulation and its evaluations.

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

UNIT – IV **10 Hours**

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

UNIT – V **16 Hours**

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

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

Transaction Mode

Lecture, Seminar, e-Team Teaching, e-Tutoring, Dialogue, Peer Group Discussion, Mobile Teaching, Self-Learning, Collaborative Learning and Cooperative Learning

RECOMMENDED READINGS

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

SEMESTER I

Course Title: MODERN PHARMACEUTICS	L	T	P	Credits
Course Code: MPH 103 T	4	0	0	4

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

1. Recognize the elements of preformulation studies.
2. Investigate active Pharmaceutical Ingredients and Generic Drug Product development
3. Apply Industrial Management and GMP Considerations.
4. Analyse optimization Techniques & Pilot Plant Scale Up Techniques
5. Evaluate stability Testing, sterilization process & packaging of dosage forms

COURSE CONTENT

UNIT – I **20 Hours**

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

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

UNIT – II **10 Hours**

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.

UNIT – III **10 Hours**

cGMP& Industrial Management: Objectives and policies of current good manufacturing practices, layout of buildings, services, equipments and their

maintenance Production management: Production organization, materials management, handling and transportation, inventory management and control, production and planning control, Sales forecasting, budget and cost control, industrial and personal relationship. Concept of Total Quality Management

UNIT – IV **10 Hours**

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

UNIT – V **10 Hours**

Study of consolidation parameters; Diffusion parameters, Dissolution parameters and Pharmacokinetic parameters, Heckel plots, Similarity factors – f2 and f1, Higuchi and Peppas plot, Linearity Concept of significance, Standard deviation, Chi square test, students T-test, ANOVA test.

Transaction Mode

Lecture, Seminar, e-Team Teaching, e-Tutoring, Dialogue, Peer Group Discussion, Mobile Teaching, Self-Learning, Collaborative Learning and Cooperative Learning

RECOMMENDED READINGS

- *Theory and Practice of Industrial Pharmacy ByLachmann and Libermann*
- *Pharmaceutical dosage forms: Tablets Vol. 1-3 by Leon Lachmann.*
- *Pharmaceutical Dosage forms: Disperse systems, Vol, 1-2; By LeonLachmann.*
- *Pharmaceutical Dosage forms: Parenteral medications Vol. 1-2; By LeonLachmann.*
- *Modern Pharmaceutics; By Gillbert and S. Banker.*
- *Remington"s Pharmaceutical Sciences.*
- *Advances in Pharmaceutical Sciences Vol. 1-5; By H.S. Bean & A.H. Beckett.*
- *Physical Pharmacy; By Alfred martin*
- *Bentley"s Textbook of Pharmaceutics – by Rawlins.*
- *Good manufacturing practices for Pharmaceuticals: A plan for total qualitycontrol, Second edition; By Sidney H. Willig.*
- *Quality Assurance Guide; By Organization of Pharmaceutical producers ofIndia.*
- *Drug formulation manual; By D.P.S. Kohli and D.H. Shah. Easternpublishers, New Delhi.*
- *How to practice GMPs; By P.P. Sharma. Vandhana Publications, Agra.*
- *Pharmaceutical Process Validation; By Fra. R. Berry and Robert A. Nash.*

- Pharmaceutical Preformulations; By J.J. Wells.
- Applied production and operations management; By Evans, Anderson, Sweeney and Williams.
- Encyclopaedia of Pharmaceutical technology, Vol I – III.

SEMESTER I

Course Title: REGULATORY AFFAIRS	L	T	P	Credits
Course Code: MPH 104 T	4	0	0	4

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

1. Recognize The Concepts of innovator and generic drugs, drug development process
2. Apply the The Regulatory guidance"s and guidelines for filing and approval proces
3. Interpret the preparation of Dossiers and their submission to regulatory agencies in different countries
4. Analyze Post approval regulatory requirements for actives and drug products
5. Clinical trials requirements for approvals for conducting clinical trials Pharmacovigilence and process of monitoring in clinical trial

COURSE CONTENT

UNIT – I **12 Hours**

Documentation in Pharmaceutical industry: Master formula record, DMF (Drug Master File), distribution records. Generic drugs product development Introduction, Hatch- Waxman act and amendments, CFR (CODE OF FEDERAL REGULATION), drug product performance, 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 – II **12 Hours**

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

UNIT – III **12 Hours**

CMC, post approval regulatory affairs. Regulation for combination products and medical devices. CTD and ECTD format, industry and FDA liaison. ICH - Guidelines of ICH-Q, S E, M. Regulatory requirements of EU, MHRA, TGA and ROW countries.

UNIT – IV **12 Hours**

Non clinical drug development: Global submission of IND, NDA, ANDA.

Investigation of medicinal products dossier, dossier (IMPD) and investigator brochure (IB).

UNIT – V **12 Hours**

Clinical trials: Developing clinical trial protocols. Institutional review board/ independent ethics committee Formulation and working procedures informed Consent process and procedures. HIPAA- new, requirement to clinical study process, pharmacovigilance safety monitoring in clinical trials.

Transaction Mode

Lecture, Seminar, e-Team Teaching, e-Tutoring, Dialogue, Peer Group Discussion, Mobile Teaching, Self-Learning, Collaborative Learning and Cooperative Learning

RECOMMENDED READINGS

- *Generic Drug Product Development, Solid Oral Dosage forms, Leon Shargeland IsaderKaufer, Marcel Dekker series, Vol.143*
- *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.*
- *New Drug Approval Process: Accelerating Global Registrations by Richard AGuarino, MD,5th edition, Drugs and the Pharmaceutical Sciences, Vol.190.*
- *Guidebook for drug regulatory submissions / Sandy Weinberg. By John Wiley&Sons.Inc.*
- *FDA regulatory affairs: a guide for prescription drugs, medical devices, andbiologics/edited by Douglas J. Pisano, David Mantus.*
- *Clinical Trials and Human Research: A Practical Guide to RegulatoryCompliance by Fay A. Rozovsky and Rodney K. Adams*
- *www.ich.org/*
- *www.fda.gov/*
- *europa.eu/index_en.htm*
- *https://www.tga.gov.au/tga-basics*

SEMESTER I

Course Title: PHARMACEUTICS PRACTICALS - I	L	T	P	Credits
Course Code: MPH105 P	0	0		6

PRACTICALS

1. Analysis of pharmacopoeial compounds and their formulations by UV Visspectrophotometer
2. Simultaneous estimation of multi component containing formulations by UVspectrophotometry
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 balancedDDS
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 similarityfactors.

SEMESTER - II

Course Title: MOLECULAR PHARMACEUTICS (NANO TECHNOLOGY & TARGETED DDS) (NTDS)	L	T	P	Credits
Course Code: MPH 201 T	4	0	0	4

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

1. Recognise the various approaches for development of novel drug delivery systems.
2. Analyse The criteria for selection of drugs and polymers for the development of NTDS
3. Formulate of novel drug delivery systems
4. Evaluation of novel drug delivery systems

UNIT – I **12 Hours**

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

UNIT – II **12 Hours**

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

UNIT – III **12 Hours**

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

UNIT – IV **12Hours**

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

UNIT – V **12 Hours**

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

Transaction Mode

Lecture, Seminar, e-Team Teaching, e-Tutoring, Dialogue, Peer Group

Discussion, Mobile Teaching, Self-Learning, Collaborative Learning and Cooperative Learning

RECOMMENDED READINGS

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

SEMESTER II

Course Title: ADVANCED BIOPHARMACEUTICS & PHARMACOKINETICS	**L**	**T**	**P**	**Credits**
Course Code: MPH 202 T	4	0	0	4

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

1. Recognise the basic concepts in biopharmaceutics and pharmacokinetics.
2. Analyze the use raw data and derive the pharmacokinetic models and parameters the best
3. Interpret the process of drug absorption, distribution, metabolism and elimination.
4. Critical evaluation of biopharmaceutic studies involving drug product equivalency.
5. Design and evaluation of dosage regimens of the drugs using pharmacokinetic and biopharmaceutic parameters.

COURSE CONTENT

UNIT – I **12 Hours**

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, Dissolutionmethods, 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 – II 12Hours

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

UNIT – III 12 Hours

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

UNIT – IV 12 Hours

Drug Product Performance, In Vivo: Bioavailability and Bioequivalence: drug product performance, purpose of bioavailability studies, relative and absolute availability. Methods for assessing bioavailability, bioequivalence studies, design and evaluation of bioequivalence studies, study designs, crossover study designs, evaluation of the data, bioequivalence example, study submission and drug review process. 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 – V 12 Hours

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 andpeptides, Monoclonal antibodies, Oligonucleotides, Vaccines (immunotherapy), Gene therapies

Transaction Mode

Lecture, Seminar, e-Team Teaching, e-Tutoring, Dialogue, Peer Group Discussion, Mobile Teaching, Self-Learning, Collaborative Learning and Cooperative Learning

RECOMMENDED READINGS

- *Biopharmaceutics and Clinical Pharmacokinetics by Milo Gibaldi, 4thedition, Philadelphia, Lea and Febiger, 1991*
- *Biopharmaceutics and Pharmacokinetics, A. Treatise, D.M. Brahmankarand Sunil B. Jaiswal., VallabPrakashan, Pitampura, Delhi*
- *Applied Biopharmaceutics and Pharmacokinetics by Shargel. LandYuABC, 2ndedition, Connecticut Appleton Century Crofts, 1985*
- *Textbook of Biopharmaceutics and Pharmacokinetics, Dr. Shobha Rani R. Hiremath, Prism Book*
- *Pharmacokinetics by Milo Gibaldi and D. Perrier, 2nd edition, MarcelDekker Inc., New York, 1982*
- *Current Concepts in Pharmaceutical Sciences: Biopharmaceutics, Swarbrick. J, LeaandFebiger, Philadelphia, 1970*
- *Clinical Pharmacokinetics, Concepts and Applications 3rd edition byMalcolmRowland and Thom~ N. Tozer, Lea and Febiger, Philadelphia,1995*
- *Dissolution, Bioavailability and Bioequivalence, Abdou. H.M, MackPublishingCompany, Pennsylvania 1989*
- *Biopharmaceutics and Clinical Pharmacokinetics, An Introduction, 4thedition, revised and expande by Robert. E. Notari, Marcel Dekker Inc, NewYork and Basel,1987.*
- *Biopharmaceutics and Relevant Pharmacokinetics by John. G Wagner andM.Pemarowski, 1st edition, Drug Intelligence Publications, Hamilton, Illinois, 1971.*
- *Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James. G. Boylan, Marcel Dekker Inc, New York, 1996.*
- *Basic Pharmacokinetics,1 stedition, Sunil S JambhekarandPhilip JBreen, pharmaceutical press, RPS Publishing,2009. 13. Absorption and Drug Development- Solubility, Permeability, and ChargeState, Alex Avdeef, John Wiley & Sons, Inc,2003.*

SEMESTER II

Course Title: COMPUTER AIDED DRUG DEVELOPMENT	L	T	P	Credits
Course Code: MPH 203 T	4	0	0	4

Learning outcomes: Upon completion of the course, student shall be able to understand
Recognize computational Modeling of Drug Disposition

1. Apply computers in Preclinical Development
2. Optimization Techniques in Pharmaceutical Formulation
3. Analyze the computers in Market
4. Computers in Clinical Development
5. Create Artificial Intelligence (AI) and Robotics

UNIT – I **12 Hours**

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

UNIT – II **12 Hours**

Computational Modeling of Drug Disposition: Introduction, Modeling Techniques: Drug Absorption, Solubility, Intestinal Permeation, Drug Distribution, Drug Excretion, Active Transport; P-gp, BCRP, Nucleoside Transporters, hPEPT1, ASBT, OCT, OATP, BBB-Choline Transporter

UNIT – III **12 Hours**

Computer-aided formulation development: Concept of optimization, Optimization parameters, Factorial design, Optimization technology & Screening design. Computers in Pharmaceutical Formulation: Development of pharmaceutical emulsions, microemulsion drug carriers Legal Protection of Innovative Uses of Computers in R&D, The Ethics of Computing in Pharmaceutical Research, Computers in Market analysis

UNIT – IV **12 Hours**

a. Computer-aided biopharmaceutical characterization: Gastrointestinal absorption simulation. Introduction, Theoretical background, Model construction, Parameter sensitivity analysis, Virtual trial, 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-V **12 Hours**

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

Transaction Mode

Lecture, Seminar, e-Team Teaching, e-Tutoring, Dialogue, Peer Group Discussion, Mobile Teaching, Self-Learning, Collaborative Learning and Cooperative Learning

RECOMMENDED READINGS

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

SEMESTER II

Course Title: COSMETICS AND COSMECEUTICALS	L	T	P	Credits
Course Code: MPH 204 T	4	0	0	4

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

1. Recognize key ingredients used in cosmetics and cosmeceuticals.
2. Analyse building blocks for various formulations.
3. Apply current technologies in the market
4. Interpret 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 CONTENT

UNIT – I **12 Hours**

Cosmetics – Regulatory: Definition of cosmetic products as per Indian regulation. Indian regulatory requirements for labeling of cosmetics Regulatory provisions relating to import of cosmetics., Misbranded and spurious cosmetics. Regulatory provisions relating to manufacture of cosmetics – Conditions for obtaining license, prohibition of manufacture and sale of certain cosmetics, loan license, offences and penalties

UNIT – II **12 HoursCosmetics -**

Biological aspects: Structure of skin relating toproblems 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 – III **12 Hours**

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

EU regulation. Controversial ingredients: Parabens, formaldehyde liberators, dioxane

UNIT – IV **12 Hours**

Design of cosmeceutical products: Sun protection, sunscreens classification and regulatory aspects. Addressing dry skin, acne, sun-protection, pigmentation, prickly heat, wrinkles, body odor., dandruff, dental cavities, bleeding gums, mouth odor and sensitive teeth through cosmeceutical formulations.

UNIT – V **12 Hours**

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.

Transaction Mode

Lecture, Seminar, e-Team Teaching, e-Tutoring, Dialogue, Peer Group Discussion, Mobile Teaching, Self-Learning, Collaborative Learning and Cooperative Learning

RECOMMENDED READINGS

- *Harry"s Cosmeticology. 8th edition.*
- *Poucher"sperfumecosmeticsandSoaps,10th edition.*
- *Cosmetics - Formulation, Manufacture and quality control, PP. Sharma,4thedition*
- *Handbook of cosmetic science and Technology A.O. Barel, M. Paye andH.I. Maibach. 3 rd edition*
- *Cosmetic and Toiletries recent suppliers catalogue.*
- *CTFA directory*

SEMESTER II

Course Title: PHARMACEUTICS PRACTICAL – II	L	T	P	Credits
Course Code: MPH105 P	0	0	12	6

PRACTICALS

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 Soliddispersion technique.

7. Comparison of dissolution of two different marketed products /brands

8. Protein binding studies of a highly protein bound drug & poorly proteinbound drug

9. Bioavailability studies of Paracetamol in animals.

10. Pharmacokinetic and IVIVC data analysis by WinnolineR 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 anddandruff

SEMESTER III

Course Title: RESEARCH METHODOLOGY & BIOSTATISTICS	L	T	P	Credits
Course Code: MRM301T	4	0	0	4

Learning Outcomes

On successful completion of this course, the students will be able to:

1 Recognize about operation of M.S. Excel, SPSS, R and MINITAB, DoE (Design of Experiment).

2 Applydesign of Experiments, Experiential Design Technique, plagiarism**,** Histogram, Pie Chart, Cubic Graph, response surface plot, Counter Plot graph

3 Analyze distinguish the application of statistical in clinical data management

4 Evaluate the sample size determination and Power of a study, Report writing and presentation of data, Protocol, Cohorts studies, Observational studies, Experimental studies, Designing clinical trial, variousphases

5 Create the appreciate statistical techniques in solving the problems

UNIT – I **12 Hours**

General Research Methodology: Research, objective, requirements, practical difficulties, review of literature, study design, types of studies, strategies to eliminate errors/bias, controls, randomization, crossover design, placebo, blinding techniques

UNIT – II **12 Hours**

Biostatistics: Definition, application, sample size, importance of sample size, factors influencing sample size, dropouts, statistical tests of significance, typeof significance tests, parametric tests (students “t” test, ANOVA, Correlationcoefficient, regression), non-parametric tests (wilcoxan rank tests,

analysis ofvariance, correlation, chi square test), null hypothesis, P values, degree offreedom, interpretation of P values.

UNIT – III **12 Hours**

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 **12 Hours**

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 **12 Hours**

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

Transaction Mode

Lecture, Seminar, e-Team Teaching, e-Tutoring, Dialogue, Peer Group Discussion, Mobile Teaching, Self-Learning, Collaborative Learning and Cooperative Learning

RECOMMENDED READINGS

- *Pharmaceutical statistics- Practical and clinical applications, Sanford Bolton, publisher Marcel Dekker Inc. NewYork.*
- *Fundamental of Statistics – Himalaya Publishing House- S.C. Guptha*
- *Design and Analysis of Experiments –PHI Learning Private Limited, R. Pannerselvam,*
- *Design and Analysis of Experiments – Wiley Students Edition, Douglas and C. Montgomery*