R21 Curriculum and Syllabus
Master in Pharmaceutical Technology
(Pharmaceutical Quality Assurance)

JIS University
Agarpara, Kolkata

SEMESTER-#							
Sl. No.	**Type**	**Course No.**	**Course Name**	**L**	**T**	**P**	**Credits**
THEORY							
PRACTICAL							
EMBEDDED(THEORY + PRACTICAL)							
BLENDED(MOOC + INTERNAL ASSESSMENT)							
SESSIONAL(ONLY INTERNAL EVALUATION)							
MANDATORY NON-CGPA COURSE							
TOTAL							

[1]

[1]

SEMESTER-1							
Sl. No.	**Type**	**Course No.**	**Course Name**	**L**	**T**	**P**	**Credits**
THEORY							
1		MQA101T	Modern Pharmaceutical Analytical Techniques - Theory	4	0	0	4
2		MQA102T	Quality management System - Theory	4	0	0	4
3		MQA103T	Quality Control and Quality Assurance - Theory	4	0	0	4
4		MQA104T	Product Development and Technology Transfer - Theory	4	0	0	4
PRACTICAL							
5		MQA105P	Pharmaceutical Quality Assurance I - Practical	0	0	12	6
SESSIONAL							
6		MPH106S	Seminar / Assignment	0	7	0	4
MANDATORY COURSE							
7		MSD1861	Seminar and Group Discussion	0	0	0	1
8		MSD1862	Skill X and Other Activities (MOOCs Courses)	0	0	0	1
TOTAL				**16**	**7**	**12**	**26**

SEMESTER-2							
Sl. No.	**Type**	**Course No.**	**Course Name**	**L**	**T**	**P**	**Credits**
THEORY							
1		MQA201T	Hazards and Safety Management - Theory	4	0	0	4
2		MQA202T	Pharmaceutical Validation - Theory	4	0	0	4
3		MQA203T	Audits and Regulatory Compliance - Theory	4	0	0	4
4		MQA204T	Pharmaceutical Manufacturing Technology - Theory	4	0	0	4
PRACTICAL							
5		MQA205P	Pharmaceutical Quality Assurance II - Practical	0	0	12	6
SESSIONAL							
6		MQA206S	Seminar / Assignment	0	0	7	4
MANDATORY CREDIT COURSE							
7	MC	MSD2861	Seminar and Group Discussion	0	0	0	1
8	MC	MSD2862	Skill X and Other activities (MOOCs courses)	0	0	0	1
TOTAL				**16**	**7**	**12**	**26**

SEMESTER-3							
Sl. No.	**Type**	**Course No.**	**Course Name**	**L**	**T**	**P**	**Credits**
THEORY							
1		MRM301T	Research Methodology and Biostatistics – Theory*	4	0	0	4
SESSIONAL							
2		MRM302S	Journal Club	0	1	0	1
3		MRM303S	Discussion / Presentation (Proposal Presentation)	0	2	0	2
4		MRM304S	Research Work	0	0	28	14
MANDATORY CREDIT COURSE							
5	MC	MSD3861	Seminar and Group Discussion	0	0	0	1
6	MC	MSD3862	Skill X and Other activities (MOOCs courses)	0	0	0	1
TOTAL				**4**	**3**	**28**	**21**

SEMESTER-4							
Sl. No.	**Type**	**Course No.**	**Course Name**	**L**	**T**	**P**	**Credits**
SESSIONAL							
1		MRM401S	Journal Club	0	1	0	1
2		MRM402S	Research Work	0	0	31	16
3		MRM403S	Discussion / Presentation (Final Presentation)	0	3	0	3
MANDATORY CREDIT COURSE							
4	MC	MSD4861	Seminar and Group Discussion	0	0	0	1
5	MC	MSD4862	Skill X and Other activities (MOOCs courses)	0	0	0	1
TOTAL				**0**	**4**	**31**	**20**

Credit Distribution Ratio:

Category	Credit Allocation As Per PCI	Credit Allocation As per University
Semester I	26	28
Semester II	26	28
Semester III	21	23
Semester IV	20	22
Total	98	106
Credit Distribution Details		
Professional Core Courses	48	48
Journal Club	2	2
Discussion and Presentation	5	5
Research Work, Project work and internship in industry or elsewhere	30	30
Mandatory Courses [Seminar, Attending Conference, Scientific Presentations and Other Scholarly Activities, Assignment and Skill X	13	16
Total	98	101

Credit Distribution in details:

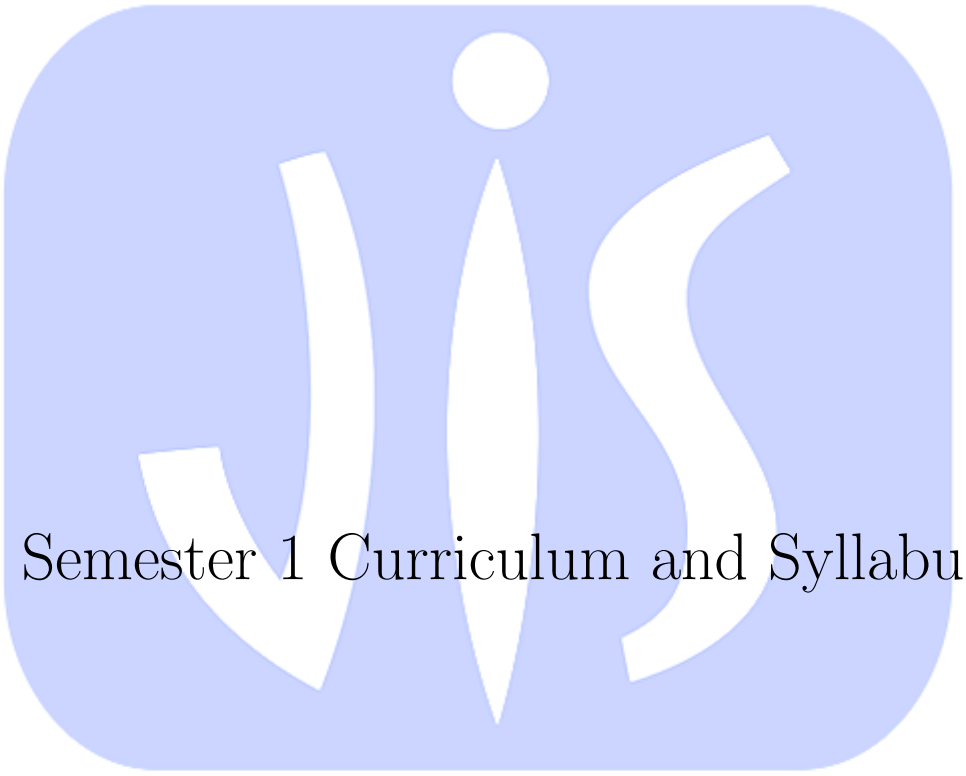
A. Professional Core Courses (PC)							
Sl. No.	**Paper Code**	**Theory & Practical**	**Contact Hours/Week**				**Credit Points**
			L	T	P	Total	
1	MPH101T	Modern Pharmaceutical Analytical Techniques	4	0	0	4	4
2	MPH102T	Drug Delivery System	4	0	0	4	4
3	MPH103T	Modern Pharmaceutics	4	0	0	4	4
4	MPH104T	Regulatory Affair	4	0	0	4	4
5	MPH105P	Pharmaceutics Practical I	0	0	12	6	6
6	MPH201T	Molecular Pharmaceutics (Nano Tech and TDDS)	4	0	0	4	4
7	MPH202T	Advanced Biopharmaceutics & Pharmacokinetics	4	0	0	4	4
8	MPH203T	Computer Aided Drug Delivery System	4	0	0	4	4
9	MPH204T	Cosmetic and cosmeceuticals	4	0	0	4	4
10	MPH205P	Pharmaceutics Practical II	0	0	12	6	6
11	MRM301T	Research Methodology and Biostatistics	4	0	0	4	4
		Total Credit:					**48**

B. Journal Club							
Sl. No.	**Paper Code**	**Theory**	**Contact Hours/Week**				**Credit Points**
			L	T	P	Total	
1	MRM302S	Journal Club	0	1	0	1	1
2	MRM401S	Journal Club	0	1	0	1	1
		Total Credit:					**2**

C. Discussion and Presentation							
Sl. No.	**Paper Code**	**Theory**	**Contact Hours/Week**				**Credit Points**
			L	T	P	Total	
1	MRM303S	Discussion/Presentation (Proposal Presentation)	0	2	0	2	2
2	MRM403S	Discussion/Presentation (Final Presentation)	0	3	0	3	3
		Total Credit:					**5**

D. Research Work, Project work and internship in industry or elsewhere (PW)							
Sl. No.	**Paper Code**	**Practical**	**Contact Hours/Week**				**Credit Points**
			L	T	P	Total	
1	MRM304S	Research Work	0	0	28	14	14
1	MRM402S	Research Work	0	0	31	16	16
		Total Credit:					**30**

E. Mandatory Courses [Attending Conference, Scientific Presentations and Other Scholarly Activities and SkillX Seminar] (MC)							
Sl. No.	**Paper Code**	**Theory**	**Contact Hours/Week**				**Credit Points**
			L	T	P	Total	
1	MPH106S	Seminar/Assignments	0	7	0	4	4
2	MSD 1861	Seminar and Group Discussion	0	0	0	1	1
3	MSD 1862	Skill X and other activities (like MOOCs Courses)	0	0	0	1	1
4	MPH206S	Seminar/Assignments	0	7	0	4	4
5	MSD 2861	Seminar and Group Discussion	0	0	0	1	1
6	MSD 2862	Skill X and other activities (like MOOCs Courses)	0	0	0	1	1
7	MSD 3861	Seminar and Group Discussion	0	0	0	1	1
8	MSD 3862	Skill X and other activities (like MOOCs Courses)	0	0	0	1	1
9	MSD 4861	Seminar and Group Discussion	0	0	0	1	1
10	MSD 4862	Skill X and other activities (like MOOCs Courses)	0	0	0	1	1
		Total Credit:					**16**



Semester 1 Curriculum and Syllabus

UNIVERSITY

SEMESTER-1							
Sl. No.	**Type**	**Course No.**	**Course Name**	**L**	**T**	**P**	**Credits**
THEORY							
1		MQA101T	Modern Pharmaceutical Analytical Techniques - Theory	4	0	0	4
2		MQA102T	Quality management System - Theory	4	0	0	4
3		MQA103T	Quality Control and Quality Assurance - Theory	4	0	0	4
4		MQA104T	Product Development and Technology Transfer - Theory	4	0	0	4
PRACTICAL							
5		MQA105P	Pharmaceutical Quality Assurance I - Practical	0	0	12	6
SESSIONAL							
6		MPH106S	Seminar / Assignment	0	7	0	4
MANDATORY COURSE							
7		MSD1861	Seminar and Group Discussion	0	0	0	1
8		MSD1862	Skill X and Other Activities (MOOCs Courses)	0	0	0	1
TOTAL				**16**	**7**	**12**	**26**

Course Code	MQA101T			
Course Title	MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES			
Category				
LTP & Credits	L	T	P	Credits
	4	0	0	4
Total Contact Hours	60			
Pre-requisites	None			

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.

Course Objective:

Upon completion of the course the students shall be able to:

1. Know about Chemicals and Excipients

2. Analyze various drugs in single and combination dosage forms

3. Execute theoretical and practical skills of the instruments

Course Content:

UNIT I: **[10L]**

UV-Visible spectroscopy: Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV- Visible spectroscopy. Difference/ Derivative spectroscopy

IR 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: **[10L]**

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: **[11L]**

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: **[10L]**

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

Thin Layer chromatography
High Performance Thin Layer Chromatography
Ion exchange chromatography
Column chromatography
Gas chromatography
High Performance Liquid chromatography
Ultra High Performance Liquid chromatography
Affinity chromatography
Gel Chromatography

UNIT V: **[10L]**

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.

UNIT VI: **[10L]**

a. Potentiometry: Principle, working, Ion selective Electrodes and Application of potentiometry.

b. Thermal Techniques: Principle, thermal transitions and Instrumentation (Heat flux and power-compensation and designs), Modulated DSC, Hyper DSC, experimental parameters (sample preparation, experimental conditions, calibration, heating and cooling rates, resolution, source of errors) and their influence, advantage and disadvantages, pharmaceutical applications.
Differential Thermal Analysis (DTA): Principle, instrumentation and advantage and disadvantages, pharmaceutical applications, derivative differential thermal analysis (DDTA).
TGA: Principle, instrumentation, factors affecting results, advantage and disadvantages, pharmaceutical applications.

Recommended Books (Latest Editions):

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

8. Spectroscopy of Organic Compounds, 2nd edn., P.S/Kalsi, Wiley estern Ltd., Delhi.

9. Textbook of Pharmaceutical Analysis, KA.Connors, 3rd Edition, John Wiley & Sons, 1982.

CO-PO Mapping:

CO	Program Outcome										
	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11
MQA101T.1	3	-	2	3	1	-	-	2	-	-	3
MQA101T.2	3	2	2	3	2	2	-	1	-	1	2
MQA101T.3	2	3	2	3	1	2	1	1	1	1	2
MQA101T.4	3	3	1	2	2	-	-	2	-	-	-
MQA101T.5	1	3	1	-	2	2	3	3	3	3	1

Course Code	MQA102T			
Course Title	QUALITY MANAGEMENT SYSTEMS - Theory			
Category				
LTP & Credits	L	T	P	Credits
	4	0	0	4
Total Contact Hours	60			
Pre-requisites	None			

Scope:

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

Course Objective:

At completion of this course it is expected that students will be able to understand:

1. The importance of quality.
2. ISO management systems
3. Tools for quality improvement
4. Analysis of issues in quality
5. Quality evaluation of pharmaceuticals
6. Stability testing of drug and drug substances
7. Statistical approaches for quality

Course Content:

UNIT I: **[12L]**

Introduction to Quality: Evolution of Quality, Definition of Quality, Dimensions of Quality Quality as a Strategic Decision: Meaning of strategy and strategic quality management, mission and vision statements, quality policy, Quality objectives, strategic planning and implementation, McKinsey 7s model, Competitive analysis, Management commitment to quality

Customer Focus: Meaning of customer and customer focus, Classification of customers, Customer focus, Customer perception of quality, Factors affecting customer perception, Customer requirements, Meeting customer needs and expectations, Customer satisfaction and Customer delight, Handling customer complaints, Understanding customer behavior, concept of internal and external customers. Case studies. Cost of Quality: Cost of quality, Categories of cost of Quality, Models of cost of quality, Optimising costs, Preventing cost of quality.

UNIT II: **[12L]**

Pharmaceutical quality Management: Basics of Quality Management, Total Quality Management (TQM), Principles of Six sigma, ISO 9001:2008, 9001:2015, ISO 14001:2004, Pharmaceutical Quality Management – ICH Q10, Knowledge management, Quality Metrics, Operational Excellence and Quality Management Review. OSHAS guidelines, NABL certification and accreditation, CFR-21 part 11, WHO-GMP requirements.

UNIT III: **[12L]**

Six System Inspection model: Quality Management system, Production system, Facility and Equipment system, Laboratory control system, Materials system, Packaging and labeling system. Concept of self inspection.

Quality systems: Change Management/ Change control. Deviations, Out of Specifications (OOS), Out of Trend (OOT), Complaints - evaluation and handling, Investigation and determination of root cause, Corrective & Preventive Actions (CAPA), Returns and Recalls, Vendor Qualification, Annual Product Reviews, Batch Review and Batch Release. Concept of IPQC, area clearance/ Line clearance.

UNIT IV: **[12L]**

Drug Stability: ICH guidelines for stability testing of drug substances and drug products. Study of ICH Q8, Quality by Design and Process development report

Quality risk management: Introduction, risk assessment, risk control, risk review, risk management tools, HACCP, risk ranking and filtering according to ICH Q9 guidelines.

UNIT V: **[8L]**

Statistical Process control (SPC): Definition and Importance of SPC, Quality measurement in manufacturing, Statistical control charts - concepts and general aspects, Advantages of statistical control, Process capability, Estimating Inherent or potential capability from a control chart analysis, Measuring process control and quality improvement, Pursuit of decreased process variability.

UNIT VI: **[4L]**

Regulatory Compliance through Quality Management and development of Quality Culture Benchmarking: Definition of benchmarking, Reasons for benchmarking, Types of Benchmarking, Benchmarking process, Advantages of benchmarking, Limitations of benchmarking.

Recommended Books (Latest Editions

1. Implementing Juran's Road Map for Quality Leadership: Benchmarks and Results, By Al Endres, Wiley, 2000

2. Understanding, Managing and Implementing Quality: Frameworks, Techniques and Cases, By Jiju Antony; David Preece, Routledge, 2002

3. Organizing for High Performance: Employee Involvement, TQM, Reengineering, and Knowledge Management in the Fortune 1000: The CEO Report By Edward E. Lawler; Susan Albers Mohrman; George Benson, Jossey-Bass, 2001

4. Corporate Culture and the Quality Organization By James W. Fairfield-Sonn, Quorum Books, 2001

5. The Quality Management Sourcebook: An International Guide to Materials and Resources By Christine Avery; Diane Zabel, Routledge, 1997

6. The Quality Toolbox, Second Edition, Nancy R. Tague, ASQ Publications

7. Juran's Quality Handbook, Sixth Edition, Joseph M. Juran and Joseph A.De Feo, ASQ Publications

8. Root Cause Analysis, The Core of Problem Solving and Corrective Action,Duke Okes, 2009, ASQ Publications.

CO-PO Mapping:

CO	Program Outcome										
	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11
MQA102T.1	3	-	2	3	1	-	-	2	-	-	3
MQA102T.2	3	2	2	1	1	3	-	1	-	1	2
MQA102T.3	2	1	2	-	2	-	2	2	-	-	2
MQA102T.4	3	3	2	2	1	3	-	-	-	1	1
MQA102T.5	2	3	2	3	1	2	2	2	-	-	2
MQA102T.6	3	3	2	2	1	3	-	-	-	1	1
MQA102T.7	2	3	2	3	1	2	2	2	-	-	2

Course Code	MQA103T			
Course Title	QUALITY CONTROL AND QUALITY ASSURANCE - Theory			
Category				
LTP & Credits	L	T	P	Credits
	4	0	0	4
Total Contact Hours	60			
Pre-requisites	None			

Scope:

This course deals with the various aspects of quality control and quality assurance aspects of pharmaceutical industries. It covers the important aspects like cGMP, QC tests, documentation, quality certifications, GLP and regulatory affairs.

Course Objective:

Upon completion of the course the students shall be able to:

1. Understand the cGMP aspects in a pharmaceutical industry
2. To appreciate the importance of documentation
3. To understand the scope of quality certifications applicable to Pharmaceutical industries
4. To understand the responsibilities of QA & QC departments

Course Content:

UNIT I: **[12L]**

Introduction: Concept and evolution and scopes of Quality Control and Quality Assurance, Good Laboratory Practice, GMP, Overview of ICH Guidelines - QSEM, with special emphasis on Q-series guidelines.

Good Laboratory Practices: Scope of GLP, Definitions, Quality assurance unit, protocol for conduct of non clinical testing, control on animal house, report preparation and documentation.

CPCSEA guidelines.

UNIT II: **[12L]**

cGMP guidelines according to schedule M, USFDA (inclusive of CDER and CBER) Pharmaceutical Inspection Convention(PIC), WHO and EMEA covering: Organization and personnel responsibilities, training, hygiene and personal records, drug industry location, design, construction and plant lay out, maintenance, sanitation, environmental control, utilities and maintenance of sterile areas, control of contamination and Good Warehousing Practice.

UNIT III: **[10L]**

Analysis of raw materials, finished products, packaging materials, in process quality control (IPQC), Developing specification (ICH Q6 and Q3), purchase specifications and maintenance of stores for raw materials. In process quality control and finished products quality control for following dosage forms in Pharma industry according to Indian, US and British pharmacopoeias: tablets, capsules, ointments, suppositories, creams, parenterals, ophthalmic and surgical products (How to refer pharmacopoeias).

UNIT IV: **[12L]**

Documentation in pharmaceutical industry: Three tier documentation, Policy, Procedures and Work instructions, and records (Formats), Basic principles- How to maintain, retention and retrieval etc. Standard operating procedures (How to write), Master Batch Record, Batch Manufacturing Record, Quality audit plan and reports. Specification and test procedures, Protocols and reports. Distribution records. Electronic data handling. Concepts of controlled and uncontrolled documents.

Submission documents for regulators DMFs, as Common Technical Document and Electronic Common Technical Documentation (CTD, eCTD). Concept of regulated and non regulated markets.

UNIT V: **[12L]**

Manufacturing operations and controls: Sanitation of manufacturing premises, mix-ups and cross contamination, processing of intermediates and bulk products, packaging operations, IPQC, release of finished product, process deviations, charge-in of components, time limitations on production, drug product inspection, expiry date calculation, calculation of yields, production record review, change control, sterile products, aseptic process control, packaging, reprocessing, salvaging, handling of waste and scrap disposal.

Introduction, scope and importance of intellectual property rights. Concept of trade mark, copyright and patents.

Recommended Books (Latest Editions

1. Quality Assurance Guide by organization of Pharmaceutical Procedures of India, 3rd revised edition, Volume I II, Mumbai, 1996.
2. Good Laboratory Practice Regulations, 2nd Edition, Sandy Weinberg Vol.69, Marcel Dekker Series, 1995.
3. Quality Assurance of Pharmaceuticals- A compedium of Guide lines and Related materials Vol I II, 2nd edition, WHO Publications, 1999.
4. How to Practice GMP's – P P Sharma, Vandana Publications, Agra, 1991.
5. The International Pharmacopoeia – vol I, II, III, IV V - General Methods of Analysis and Quality specification for Pharmaceutical Substances, Excepients and Dosage forms, 3rd edition, WHO, Geneva, 2005.
6. Good laboratory Practice Regulations – Allen F. Hirsch, Volume 38, Marcel Dekker Series, 1989.

7. ICH guidelines
8. ISO 9000 and total quality management
9. The drugs and cosmetics act 1940 – Deshpande, Nilesh Gandhi, 4th edition, Susmit Publishers, 2006.
10. QA Manual – D.H. Shah, 1st edition, Business Horizons, 2000.
11. Good Manufacturing Practices for Pharmaceuticals a plan for total qualitycontrol – Sidney H. Willig, Vol. 52, 3rd edition, Marcel Dekker Series.
12. Steinborn L. GMP/ISO Quality Audit Manual for Healthcare Manufacturers and Their Suppliers, Sixth Edition, (Volume 1 - With Checklists and Software Package). Taylor Francis; 2003.
13. Sarker DK. Quality Systems and Controls for Pharmaceuticals. John Wiley & Sons; 2008.
14. Packaging of Pharmaceuticals.
15. Schedule M and Schedule N.

CO-PO Mapping:

CO	Program Outcome										
	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11
MPH103T.1	3	2	3	2	1	2	-	1	-	-	2
MQA103T.2	1	2	2	-	-	2	3	2	-	-	2
MQA103T.3	2	3	1	-	3	1	2	2	1	2	2
MQA103T.4	2	3	2	3	1	2	1	-	-	-	1

Course Code	MQA104T			
Course Title	PRODUCT DEVELOPMENT & TECHNOLOGY TRANSFER			
Category				
LTP & Credits	L	T	P	Credits
	4	0	0	4
Total Contact Hours	60			
Pre-requisites	None			

Scope:

This deal with technology transfer covers the activities associated with Drug Substance, Drug Product and analytical tests and methods, required following candidate drug selection to completion of technology transfer from R&D to the first receiving site and technology transfer related to post-marketing changes in manufacturing places.

Course Objective:

Upon completion of the course, the students will be able to:

1. To understand the new product development process
2. To understand the necessary information to transfer technology from R&D to actual manufacturing by sorting out various information obtained during RD
3. To elucidate necessary information to transfer technology of existing products between various manufacturing places

Course Content:

UNIT I: **[12L]**

Principles of Drug discovery and development: Introduction, Clinical research process. Development and informational content for Investigational New Drugs Application (IND), New Drug Application (NDA), Abbreviated New Drug Application (ANDA), Supplemental New Drug Application (SNDA), Scale Up Post Approval Changes (SUPAC) and Bulk active chemical Post approval changes (BACPAC), Post marketing surveillance, Product registration guidelines – CDSCO, USFDA.

UNIT II: **[12L]**

Pre-formulation studies: Introduction/concept, organoleptic properties, purity, impurity profiles, particle size, shape and surface area. Solubility,

Methods to improve solubility of Drugs: Surfactants & its importance, co-solvency. Techniques for the study of Crystal properties and polymorphism. Pre-formulation protocol, Stability testing during product development.

UNIT III: **[12L]**

Pilot plant scale up: Concept, Significance, design, layout of pilot plant scale up study, operations, large scale manufacturing techniques (formula, equipment, process, stability and quality control) of solids, liquids, semisolid and parenteral dosage forms.

New era of drug products: opportunities and challenges.

UNIT IV: **[12L]**

Pharmaceutical packaging: Pharmaceutical dosage form and their packaging requirments, Pharmaceutical packaging materials, Medical device packaging, Enteral Packaging, Aseptic packaging systems, Container closure systems, Issues facing modern drug packaging, Selection and evaluation of Pharmaceutical packaging materials.

Quality control test: Containers, closures and secondary packing materials.

UNIT V: **[12L]**

Technology transfer: Development of technology by R & D, Technology transfer from R & D to production, Optimization and Production, Qualitative and quantitative technology models.

Documentation in technology transfer: Development report, technology transfer plan and Exhibit.

Recommended Books (Latest Editions):

1. "Generic Drug Product Development", Solid Oral Dosage forms, Leon Shargel and Isader Kaufer, 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 and 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

CO-PO Mapping:

CO	Program Outcome (PO)										
	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11
MQA104T.1	2	3	2	1	2	1	-	1	-	1	1
MQA104T.2	3	2	1	2	3	-	2	2	-	-	2
MQA104T.3	1	3	1	-	2	1	3	3	3	3	1

Course Code	MPH105P			
Course Title	Pharmaceutics Practical-I (Practical)			
Category				
LTP & Credits	L	T	P	Credits
	0	0	12	6
Total Contact Hours	180			
Pre-requisites	None			

Course Objective:

Upon completion of the course the students shall be able to:

1. Know the estimation of the active pharmaceutical ingredients in formulations by using different modern techniques.
2. Gain the knowledge to apply the concepts of preformulation in the formulation development..
3. Evaluate the effects of different critical parameters on quality of tablets such as disintegration, dissolution, drug release profiles etc.
4. Understand the formulation development and evaluation methods of different novel drug delivery system.

Suggestive List of Experiments:

1. Analysis of pharmacopoeial compounds and their formulations by UV Vis spectrophotometer. **[2 day(s)]**
2. Simultaneous estimation of multi component containing formulations by UV spectrophotometry **[2 day(s)]**

   ⋮
3. Experiments based on HPLC **[2 day(s)]**

   ⋮
4. Experiments based on Gas Chromatography **[1 day(s)]**

   ⋮
5. Estimation of riboflavin/quinine sulphate by fluorimetry **[1 day(s)]**

   ⋮
6. Estimation of sodium/potassium by flame photometry **[1 day(s)]**

   ⋮
7. To perform In-vitro dissolution profile of CR/ SR marketed formulation **[2 day(s)]**

   ⋮

8. Formulation and evaluation of sustained release matrix tablets **[2 day(s)]**

⋮

9. Formulation and evaluation osmotically controlled DDS **[2 day(s)]**

⋮

10. Preparation and evaluation of Floating DDS- hydro dynamically balanced DDS **[2 day(s)]**

⋮

11. Formulation and evaluation of Mucoadhesive tablets. **[2 day(s)]**

⋮

12. Formulation and evaluation of transdermal patches. **[2 day(s)]**

⋮

13. To carry out preformulation studies of tablets. **[1 day(s)]**

⋮

14. To study the effect of compressional force on tablets disintegration time **[2 day(s)]**

⋮

15. To study Micromeritic properties of powders and granulation. **[1 day(s)]**

⋮

16. To study the effect of particle size on dissolution of a tablet. **[2 day(s)]**

⋮

17. To study the effect of binders on dissolution of a tablet. **[2 day(s)]**

⋮

18. To plot Heckal plot, Higuchi and peppas plot and determine similarity factors **[1 day(s)]**

⋮

CO-PO Mapping:

	Program Outcome										
CO	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11
MPH105P.1	2	2	1	3	1	3	-	-	-	-	2
MPH105P.2	2	3	1	3	-	2	-	-	-	-	2
MPH105P.3	3	3	1	3	-	3	-	-	-	-	2
MPH105P.4	2	3	1	3	2	3	-	-	-	-	2

Semester 2 Curriculum and Syllabus

SEMESTER-2							
Sl. No.	**Type**	**Course No.**	**Course Name**	**L**	**T**	**P**	**Credits**
THEORY							
1		MQA201T	Hazards and Safety Management - Theory	4	0	0	4
2		MQA202T	Pharmaceutical Validation - Theory	4	0	0	4
3		MQA203T	Audits and Regulatory Compliance - Theory	4	0	0	4
4		MQA204T	Pharmaceutical Manufacturing Technology - Theory	4	0	0	4
PRACTICAL							
5		MQA205P	Pharmaceutical Quality Assurance II - Practical	0	0	12	6
SESSIONAL							
6		MQA206S	Seminar / Assignment	0	0	7	4
MANDATORY CREDIT COURSE							
7	MC	MSD2861	Seminar and Group Discussion	0	0	0	1
8	MC	MSD2862	Skill X and Other activities (MOOCs courses)	0	0	0	1
TOTAL				**16**	**7**	**12**	**26**

Course Code	MPH201T			
Course Title	Molecular Pharmaceutics (Nano Technology and Targeted DDS)-Theory			
Category				
LTP & Credits	L	T	P	Credits
	4	0	0	4
Total Contact Hours	60			
Pre-requisites	None			

Scope:

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

Course Objective:

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

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

Course Content:

UNIT I: **[12L]**

Targeted Drug Delivery Systems:

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

UNIT II: **[12L]**

Targeting Methods: introduction preparation and evaluation. Nano Particles &

Liposomes: Types, preparation and evaluation

UNIT III: **[12L]**

Micro Capsules /Micro Spheres:

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

UNIT IV: **[12L]**

Pulmonary Drug Delivery Systems:

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

UNIT V: **[12L]**

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.

Recommended Books (Latest Editions):

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, Vallabh Prakashan, New Delhi, First edition 2002.
3. N.K. Jain, Controlled and Novel Drug Delivery, CBS Publishers & Distributors, New Delhi, First edition 1997 (reprint in 2001).

CO-PO Mapping:

CO	Program Outcome										
	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11
MPH201T.1	3	3	1	-	-	2	-	1	-	2	3
MPH201T.2	2	3	2	2	1	3	-	1	-	1	2
MPH201T.3	3	2	1	2	-	2	-	2	-	-	2
MPH201T.4	2	3	2	1	1	2	1	1	-	2	2
MPH201T.5	3	3	2	2	1	3	-	-	-	1	1

Course Code	MPH202T			
Course Title	Advanced Biopharmaceutics and Pharmacokinetics			
Category				
LTP & Credits	L	T	P	Credits
	4	0	0	4
Total Contact Hours	60			
Pre-requisites	None			

Scope:

This course is designed to impart knowledge andskills 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.

Course Objective:

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

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

Course Content:

UNIT I: **[12L]**

Drug Absorption from the Gastrointestinal Tract:

Gastrointestinal tract, mechanism of drug absorption, Factors affecting drug absorption, pH–partition theory of drug absorption. Formulation and physicochemical factors: Dissolution rate, Dissolution process, Noyes–Whitney equation and drug dissolution, Factors affecting the dissolution rate.

Gastrointestinal absorption: role of the dosage form: Solution (elixir, syrup and solution) as a dosage form, Suspension as a dosage form, Capsule as a dosage form, Tablet as a dosage form, Dissolution methods, Formulation and processing factors, Correlation of in vivo data with in vitro dissolution data. Transport model: Permeability Solubility Charge State and the pH Partition Hypothesis, Properties of the Gastrointestinal Tract (GIT), pH Microclimate Intracellular pH Environment, Tight Junction Complex.

UNIT II: **[12L]**

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 inthedesign of a drug product.

UNIT III: **[12L]**

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: **[12L]**

Drug Product Performance, In Vivo: Bioavailability and Bioequivalence: drug product performance, purpose of bioavailability studies, relative andabsolute 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: **[12L]**

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), Genetherapies.

Recommended Books (Latest Editions):

1. Biopharmaceutics and Clinical Pharmacokinetics by Milo Gibaldi, 4th edition,Philadelphia, Lea and Febiger, 1991
2. Biopharmaceutics and Pharmacokinetics, A. Treatise, D .M. Brahmankar and Sunil B Jaiswal, Vallab Prakashan, Pitampura, Delhi
3. Applied Biopharmaceutics and Pharmacokinetics by Shargel. Land 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 Malcolm Rowland and Thom N. Tozer, Lea andFebiger, Philadelphia, 1995

8. Dissolution, Bioavailability and Bioequivalence, Abdou. H.M, Mack Publishing Company, Pennsylvania 1989

9. Biopharmaceutics and Clinical Pharmacokinetics, An Introduction, 4th edition, revised and expanded 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 Pharmaceutics, 1st edition, Sunil S Jambhekarand Philip J Breen, Pharmaceutical Press, RPS Publishing, 2009.

13. Absorption and Drug Development- Solubility, Permeability, and Charge State, Alex Avdeef, John Wiley & Sons,Inc,2003.

CO-PO Mapping:

CO	Program Outcome										
	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11
MPH202T.1	3	2	2	-	-	-	1	-	-	-	3
MPH202T.2	3	3	3	3	-	1	-	-	-	-	3
MPH202T.3	3	2	3	3	-	2	1	-	2	-	3
MPH202T.4	3	3	3	3	-	2	1	-	2	-	3
MPH202T.5	3	3	3	3	-	3	1	-	2	-	3

Course Code	MPH203T			
Course Title	Computer Aided Drug Delivery System			
Category				
LTP & Credits	L	T	P	Credits
	4	0	0	4
Total Contact Hours	60			
Pre-requisites	None			

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.

Course Objective:

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

1. History of Computers in Pharmaceutical Research and Development
2. Computational Modeling of Drug Disposition
3. Computers in Preclinical Development
4. Optimization Techniques in Pharmaceutical Formulation
5. Computers in Market Analysis
6. Computers in Clinical Development
7. Artificial Intelligence (AI) and Robotics
8. Computational fluid dynamics(CFD)

Course Content:

UNIT I: **[12L]**

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: **[12L]**

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: **[12L]**

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 RD, The Ethics of Computing in Pharmaceutical Research, Computers in Market analysis.

UNIT IV: **[12L]**

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: **[12L]**

Artificial Intelligence (AI), Robotics and Computational fluid dynamics:

General overview, Pharmaceutical Automation, Pharmaceutical applications, Advantages and Disadvantages. Current Challenges and Future Directions.

Recommended Books (Latest Editions):

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.

CO-PO Mapping:

CO	Program Outcome (PO)										
	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11
MPH203T.1	3	-	-	1	-	1	1	2	1	-	3
MPH203T.2	2	1	3	2	2	1	1	2	-	-	2
MPH203T.3	2	3	3	2	3	3	2	3	2	-	1
MPH203T.4	1	2	2	2	3	3	2	3	2	-	1
MPH203T.5	1	1	2	1	1	2	-	2	1	-	2
MPH203T.6	1	2	3	3	1	3	2	3	1	-	1

Course Code	MPT204T			
Course Title	Cosmetics and Cosmeceuticals			
Category				
LTP & Credits	L	T	P	Credits
	4	0	0	4
Total Contact Hours	60			
Pre-requisites	None			

Scope:

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

Course Objective:

Upon completion of the course the students shall be able to:

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

Course Content:

UNIT I: **[12L]**

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: **[12L]**

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.

UNIT III: **[12L]**

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: **[12L]**

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: **[12L]**

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

Recommended Books (Latest Editions):

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. 3 rd edition"
5. Cosmetic and Toiletries recent suppliers catalogue"
6. CTFA directory"

CO-PO Mapping:

CO	Program Outcome										
	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11
MPH204T.1	3	-	3	-	-	-	-	-	-	-	-
MPH204T.2	3	-	-	-	-	-	-	-	-	-	3
MPH204T.3	-	-	-	-	-	-	3	-	-	-	3
MPH204T.4	-	-	-	-	-	-	3	-	-	-	-
MPH204T.5	3	-	-	-	-	-	-	-	3	-	-

Course Code	MPH205P			
Course Title	Pharmaceutics Practical-II (Practical)			
Category				
LTP & Credits	L	T	P	Credits
	0	0	12	6
Total Contact Hours	180			
Pre-requisites	None			

Course Objective:

Upon completion of the course the students shall be able to:

1. Understand the formulation and evaluation of novel drug delivery systems
2. Understand preparation of various cosmetics and cosmeceuticals and know about the use of various key ingredients to develop cosmetics and cosmeceuticals.
3. Understand the use computers in Preclinical and Clinical Development.
4. Understand various optimization techniques in Pharmaceutical Formulation.
3. Understand basic concepts in biopharmaceutics and pharmacokinetics process.
4. Understand the use raw data and derive the pharmacokinetic models and parameters the best describes the process of drug absorption, distribution, metabolism and elimination

Suggestive List of Experiments:

1. To study the effect of temperature change , non solvent addition, incompatible polymer addition in microcapsules preparation **[2 day(s)]**

   ⋮

2. Preparation and evaluation of Alginate beads **[2 day(s)]**

   ⋮

3. Formulation and evaluation of gelatin /albumin microspheres **[2 day(s)]**

   ⋮

4. Formulation and evaluation of liposomes/niosomes **[2 day(s)]**

   ⋮

5. Formulation and evaluation of spherules **[2 day(s)]**

   ⋮

6. Improvement of dissolution characteristics of slightly soluble drug by Solid dispersion technique. **[2 day(s)]**

   ⋮

7. Comparison of dissolution of two different marketed products /brands **[1 day(s)]**

⋮

8. Protein binding studies of a highly protein bound drug poorly protein bound drug **[1 day(s)]**

⋮

9. Bioavailability studies of Paracetamol in animals. **[2 day(s)]**

⋮

10. Pharmacokinetic and IVIVC data analysis by Winnoline R software **[1 day(s)]**

⋮

11. In vitro cell studies for permeability and metabolism **[2 day(s)]**

⋮

12. DoE Using Design Expert® Software **[1 day(s)]**

⋮

13. Formulation data analysis Using Design Expert® Software **[1 day(s)]**

⋮

14. Quality-by-Design in Pharmaceutical Development **[1 day(s)]**

⋮

15. Computer Simulations in Pharmacokinetics and Pharmacodynamics **[1 day(s)]**

⋮

16. Computational Modeling Of Drug Disposition **[1 day(s)]**

⋮

17. To develop Clinical Data Collection manual **[2 day(s)]**

⋮

18. To carry out Sensitivity Analysis, and Population Modeling. **[1 day(s)]**

⋮

19. Development and evaluation of Creams **[1 day(s)]**

⋮

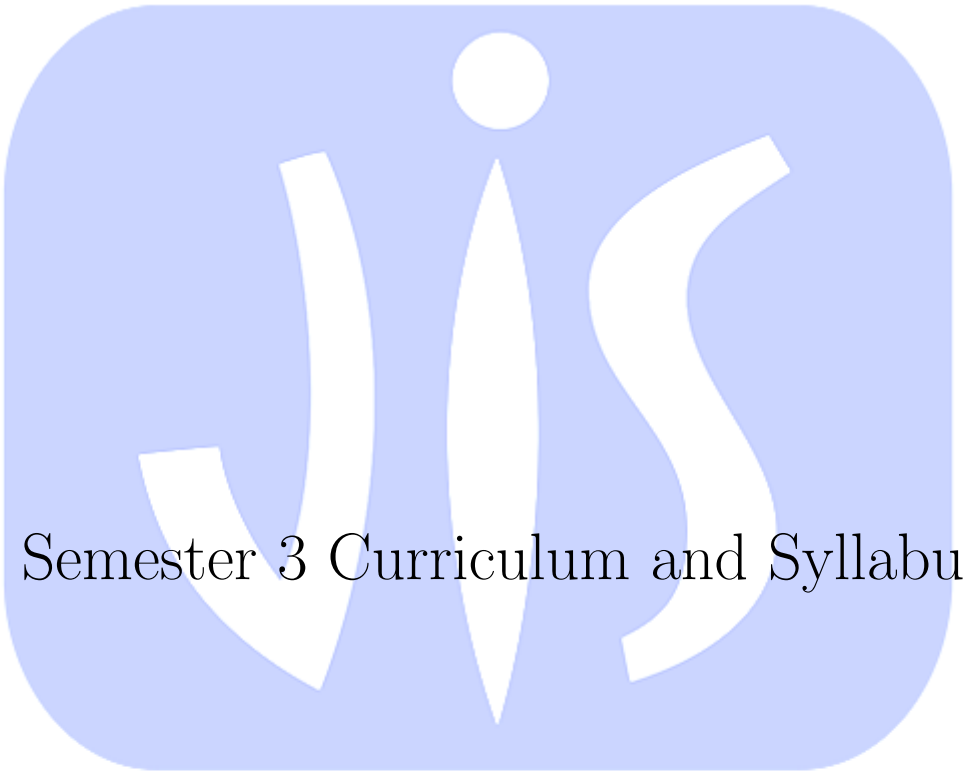
20. Development and evaluation of Shampoo and Toothpaste base **[1 day(s)]**

⋮

21. To incorporate herbal and chemical actives to develop products **[1 day(s)]**

CO-PO Mapping:

	Program Outcome										
CO	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11
MPH205P.1	3	2	2	1	2	3	1	2	-	1	2
MPH205P.2	2	3	3	1	2	3	1	2	1	-	2
MPH205P.3	1	2	3	2	2	3	1	2	1	-	2
MPH205P.4	2	3	3	2	2	3	1	2	-	-	2
MPH205P.5	2	1	1	2	2	-	1	1	-	-	3
MPH205P.6	2	2	3	2	3	3	1	2	2	-	1



Semester 3 Curriculum and Syllabus

UNIVERSITY

SEMESTER-3							
Sl. No.	**Type**	**Course No.**	**Course Name**	**L**	**T**	**P**	**Credits**
THEORY							
1		MRM301T	Research Methodology and Biostatistics – Theory*	4	0	0	4
SESSIONAL							
2		MRM302S	Journal Club	0	1	0	1
3		MRM303S	Discussion / Presentation (Proposal Presentation)	0	2	0	2
4		MRM304S	Research Work	0	0	28	14
MANDATORY CREDIT COURSE							
5	MC	MSD3861	Seminar and Group Discussion	0	0	0	1
6	MC	MSD3862	Skill X and Other activities (MOOCs courses)	0	0	0	1
TOTAL				**4**	**3**	**28**	**21**

Course Code	MRM301T			
Course Title	RESEARCH METHODOLOGY AND BIOSTATISTICS			
Category				
LTP & Credits	L	T	P	Credits
	4	0	0	4
Total Contact Hours	60			
Pre-requisites	None			

Scope:

The course describes the basic methodology to carry out the dissertation work..

Course Objective:

After completion of course student is able to know:

1. Evaluate the various statistical techniques to solve statistical problems
2. Evaluate research methodology
3. Analyze statistical techniques in solving the problems
4. Analyze the operation of M.S. Excel and other Microsoft applications
5. Analyze the operation of SPSS and other statistical software

Course Content:

UNIT I: **[12L]**

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: **[12L]**

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: **[12L]**

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: **[10L]**

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.

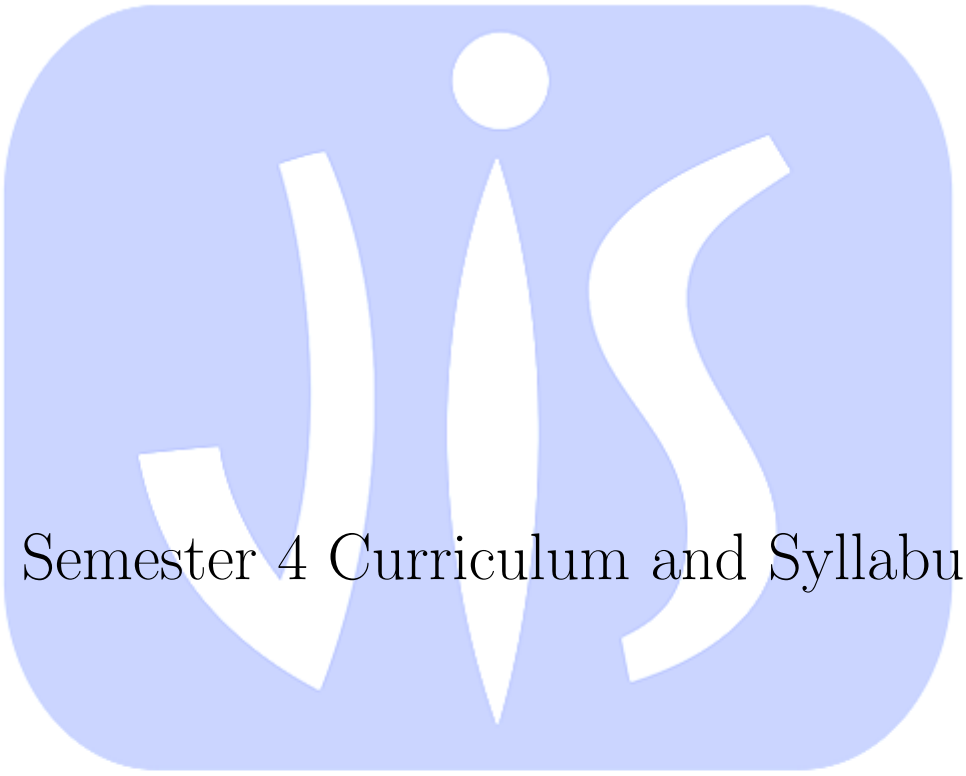
UNIT V: **[10L]**

Declaration of Helsinki:

History, introduction, basic principles for all medical research, and additional principles for medical research combined with medical care.

CO-PO Mapping:

CO	Program Outcome										
	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11
MRM301T.1	1	2	3	-	-	2	-	-	1	-	3
MRM301T.2	-	3	3	-	-	2	-	-	-	-	2
MRM301T.3	-	2	3	3	-	2	-	-	-	-	1
MRM301T.4	-	2	3	3	-	2	-	1	2	-	1
MRM301T.5	-	2	3	3	-	2	-	1	2	-	1



Semester 4 Curriculum and Syllabus

UNIVERSITY

SEMESTER-4							
Sl. No.	**Type**	**Course No.**	**Course Name**	**L**	**T**	**P**	**Credits**
SESSIONAL							
1		MRM401S	Journal Club	0	1	0	1
2		MRM402S	Research Work	0	0	31	16
3		MRM403S	Discussion / Presentation (Final Presentation)	0	3	0	3
MANDATORY CREDIT COURSE							
4	MC	MSD4861	Seminar and Group Discussion	0	0	0	1
5	MC	MSD4862	Skill X and Other activities (MOOCs courses)	0	0	0	1
TOTAL				**0**	**4**	**31**	**20**