Curriculum Book

and

Assessment and Evaluation Scheme

based on

Outcome Based Education (OBE)

and

Choice-Based Credit System (CBCS)

in

Master of Pharmacy

Pharmaceutics (MPH)

2 Year Master Program

Revised as on 01 August 2023
Applicable w.e.f. Academic Session 2023-24

AKS University

Satna 485001, Madhya Pradesh, India

Faculty of Pharmaceutical Science & Technology
Rajiv Gandhi Institute of Pharmacy

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FORWARDING

I am delighted to observe the updated curriculum of the Rajiv Gandhi institute of Pharmacy, for Master Program, which seamlessly integrates the most recent trends and corporate affairs in the field of Pharmaceutical industry and adheres to the guidelines set forth by PCI and UGC. The revised curriculum also thoughtfully incorporates the directives of NEP-2020.

The alignment of course outcomes (COs), Programme Outcome (POs) and Programme specific outcomes (PSOs) has been intricately executed, aligning perfectly with the requisites of NEP-2020 and NAAC standards. I hold the belief that this revised syllabus will significantly enhance the skills and employability of our students.

With immense satisfaction, I hereby present the revised curriculum for the M. Pharmacy program for implementation in the upcoming session.

Er. Anant Kumar Soni
Pro Chancellor & Chairman

AKS University, Satna

Date: 01 Aug 2023

FROM THE DESK OF THE VICE-CHANCELLOR

AKS University is currently undergoing a process store vamp its curriculum into an outcome-based approach, with the aim of enhancing the teaching and learning process. The foundation of quality of quality education lies in the implementation of a curriculum that aligns with both societal and industrial needs, focusing on relevant outcomes. This entails dedicated and inspired

Faculty members, as well as impactful industry internships

Hence, it is of utmost importance to begin this endeavor by crafting an outcome-based curriculum in collaboration with academia and industry experts. This curriculum design should be informed by the latest technological advancements, market demands, the guidelines outlined in the National Education Policy (NEP) of 2020, and sustainable goals.

I'm delighted to learn that the revised curriculum has been meticulously crafted by the Rajiv Gandhi Institute of Pharmacy, in consultation with an array of experts from the industry, research institutes, and academia. This curriculum effectively integrates the principles outlined in the NEP-2020 guidelines, as well as sustainable goals. It also adeptly incorporates the latest advancements in the field of business management.

Furthermore, the curriculum takes into account the specific needs of the Indian Industries, focusing on the creation of effective and efficient managers as well as entrepreneurs. This curriculum will not only imparts knowledge but also encourages student's independent thinking for potential enhancements in the area of Pharmaceutical science.

The curriculum goes beyond theoretical learning and embraces practical applications. To enhance students' skills, the curriculum integrates industrial visits, and On-Job Training experiences, research projects. This well- rounded approach ensures that students receive a comprehensive education, fostering their skill development and preparing them for success in the field of Pharmaceutical Science.

I am confident that the updated curriculum for Rajiv Gandhi Institute of Pharmacy will not only enhance students' managerial skills but also contribute significantly to their employability. During the process of revising the curriculum, I am pleased to observe that the Rajiv Gandhi Institute of Pharmacy has diligently adhered to the guidelines provided by the PCI& UGC. Additionally, they have maintained a total credit requirement of 100 for the M. Pharmacy program.

It's worth noting that curriculum revision is an ongoing and dynamic process, designed to address the continuous evolution of managerial and technological advancements and both local and global concerns. This ensures that the curriculum remains responsive and attuned to the changing landscape of education and industry.

AKS University warmly invites input and suggestions from industry experts and technocrats and Alumni students to enhance the curriculum and make it more student-centric. Your valuable insights will greatly contribute to shaping an education that best serves the needs and aspirations of our students.

PROFESSOR B.A. CHOPADE

01 Aug 2023 *Vice-Chancellor*

PREFACE

As part of our commitment to ongoing enhancement, the Department of Rajiv Gandhi Institute of Pharmacy consistently reviews and updates its M. Pharmacy program curriculum every three years. Through this process, we ensure that the curriculum remains aligned with the latest managerial developments, as well as local and global industrial and social demands.

During this procedure, the existing curriculum for the M. Pharmacy Program undergoes evaluation by a panel of industry specialists, and academicians. Following meticulous scrutiny, the revised curriculum has been formulated and is set to be implemented starting from August 01, 2023. This implementation is contingent upon the endorsement of the curriculum by the University's Board of Studies and Governing Body.

This curriculum closely adheres to the PCI model syllabus distributed in 2016. It seamlessly integrates the guidelines set forth by the Ministry of Higher Education, Government of India, through NEP- 2020, as well as the principles of Sustainable Development Goals. In order to foster the holistic skill development of students, a range of practical activities, including Industrial Visits, Project planning and execution, Report Writing, Seminars, and Industrial On-Job Training, have been incorporated. Furthermore, in alignment with AICTE's directives, the total credit allocation for the M Pharmacy program is capped at 100 credits.

The Master of Pharmacy program typically follows a credit-based system where each subject is assigned a certain number of credits. These credits reflect the workload and importance of the subject in the curriculum. The credit system is designed to ensure that students receive a balanced education that covers all the necessary areas of pharmaceutical science and practice.

Theory Courses these include lectures and tutorials on subjects like Pharmaceutics, Pharmaceutical Chemistry etc. Each theory course may carry 4 credits. Practical Courses: Laboratory sessions where students apply their theoretical knowledge. Practical courses usually carry fewer credits than theory courses, often around 6 credits. Core Subjects: Subjects that are fundamental to the field may have higher credit values. The importance of these subjects in the pharmaceutical industry cannot be overstated. They provide the foundational knowledge and skills necessary for various roles within the industry, such as:

Research and Development: Understanding the principles of drug action, formulation, and analysis is crucial for developing new medications. Quality Control and Assurance: Knowledge of analytical techniques and standards is essential for ensuring the safety and efficacy of pharmaceutical products.

Regulatory Affairs: Familiarity with pharmaceutical laws and regulations is important for compliance in the industry. Sales and Marketing: A strong grasp of pharmacology and therapeutics helps in effectively promoting pharmaceutical products. The total number of credits required to earn a M. Pharm may vary by institution but is typically around 100 credits.

In terms of career prospects, M. Pharm Post graduates can find opportunities in: Pharmaceutical Companies: In roles such as product development, production, quality control, and marketing. Regulatory Bodies: As drug inspectors or regulatory affairs specialists. Research Institutes: Engaging in cutting-edge research to develop new drugs and therapies. Healthcare Settings: As pharmacists in hospitals, clinics, and community pharmacies.

The subjects studied in the M. Pharm program are directly linked to the practical needs of the pharmaceutical industry, ensuring that graduates are well-prepared for Pharmaceutical industry extractions.

For each course, a thorough mapping of Course Outcomes, Program Outcomes, and Program Specific Outcomes has been undertaken. As the course syllabus is being meticulously developed, various elements such as session outcomes, laboratory instruction, classroom instruction, self-learning activities, assignments, and mini projects are meticulously outlined.

We hold the belief that this dynamic curriculum will undoubtedly enhance independent thinking, skills, and overall employ ability of the students.

PROFESSOR (Dr.) GP Richhariya
Dean (I/c)
Rajiv Gandhi Institute of Pharmacy
Faculty of Pharmaceutical Science & Technology
AKS University, Satna
01-August-2023

INTRODUCTION

Rajiv Gandhi Institute of Pharmacy was established in 2006, with the aim of providing quality education in pharmaceutical sciences. The college started with, Bachelor in Pharmacy 2006. The institution became a constituent unit of AKS University Satna, in 2012 and later on other some another courses were add like D. Pharm (2015), M. Pharm (2020), the Ph. D Programme (2021). All courses at the institute are recognized by the Pharmacy Council of India (PCI). The institute has a strong alumni association with over 1100 active members, who are placed globally at various positions in Pharma Marketing, Industrial, Regulatory and Entrepreneurial services.

VISION

To be established as globally recognized academic &research excellence to sustain theneeds of pharmacy profession and the society.

MISSION

M1: To promote & trained as per global requirement of social and pharmaceutical needs in pharmaceutical education and research through prescribed training programmes like B. Pharm., M. Pharm. and PhD with professional pharmaceutical education and effective competency.

M2: Achieve academic excellence in Pharmaceutical science through the innovative teaching learning process.

M3: To establish recognized research center for needs of pharmacy profession and the society.

M4: To Promote Skills through experimental knowledge as per global requirement of social and pharmaceutical industry.

Program Educational Objectives (PEOs)

PEO 1. Knowledge & Learning: To impart sound pharmaceutical knowledge, scientific principles to make them ever-ready for producing quality, safety and effective pharmaceutical formulations.

PEO 2. Expertise: To develop creative thinking, innovative strategies to overcome therapeutic challenges with customized medicines time to time for society.

PEO 3. Leadership: To produce skilled pharmaceutical professionals, leaders, policy makers and entrepreneurs for building healthy nation.

PEO 4. Employment & Entrepreneur: Enable graduate to succeed in technical or professional careers in various pharmaceutical industry/institute or health care system.

PEO 5. Professional Practice: Enable graduate to practice profession and adapt in a globe of constantly developing trends.

Program outcomes (POs)

1. **Scientific knowledge:** To apply the scientific and technological principles to design, develop effective pharmaceutical dosage forms and drug delivery systems for better therapeutic results.
2. **Technological applications:** To utilize technical knowledge and identify any factors affecting the quality of pharmaceutical production.
3. **Modern tool usage:** Learn, select, apply appropriate methods, procedures, resources, and modern pharmacy-related computing tools with an understanding of the limitations.
4. **Entrepreneurship:** To understand the basics of establishing and management of pharmaceutical enterprise.
5. **Practical skills:** To gain practical expertise in formulating and evaluating various novel drug release systems for minor ailments to major diseases.
6. **Applied science:** To employ contemporary scientific knowledge viz., pharmacology, biotechnology for designing disease-centric pharmaceuticals.
7. **Computational and statistical methodologies:** Applying and utilizing the statistical tools with the aid of computer software to optimize the formulations.
8. **Pharmaceutical ethics:** To respect personal values and apply ethical principles in professional and social contexts. Demonstrate behavior that recognizes cultural, personal variability in values, communication and lifestyles. Use ethical frameworks; apply ethical principles while making decisions and take responsibility for the outcomes associated with the decisions.
9. **Environment and sustainability:** To understand, protect and cooperate environmental concerns for sustaining biodiversity.
10. **Life-long learning:** To develop the habit of updating knowledge from time to time to meet industrial demands and social needs for having a fruitful career.

Program Specific outcomes (PSOs)

The Post Graduate shall be able to:

PSO 1. Formulation strategies: To impart practical knowledge, expertise to develop, design disease-centric formulations, targeting approaches using current, advanced scientific principles for better patient care and compliance.

PSO 2. Emerging science: To introduce knowledge about emerging cutting-edge technologies and their application in pharmaceutical field with better formulations for effective treatments.

PSO 3. Computational literacy: To demonstrate the use of artificial intelligence, computer programs or software applications useful in screening formulations, interpretation of experimental data and their validation.

PSO 4. Pharmaceutical regulations: To understand the objectives, roles, functions of various pharmaceutical regulatory bodies governing quality, safety and efficacy of pharmaceuticals from manufacturing to patient door.

Consistence/Mapping of PEOs with Mission of Department

PEO	M1	M2	M3	M4
PEO1	2	3	3	2
PEO2	3	3	2	2
PEO3	3	2	3	3
PEO4	2	2	3	2
PEO5	3	2	2	3

Correlation Indices: 1–Low, 2–Medium, 3–High

GENERAL COURSE STRUCTURE & THEME

1. Definition of Credit:

1 Hr. Lecture (L) per week	1Credit
1 Hr. Tutorial (T) per week	1Credit
2 Hours Practical (P) per week	1Credit

2. Range of Credits:

In the light of the fact that a typical Model Two-year Postgraduate master program in Pharmacy has about 100 credits, the total number of credits proposed for the two year Master of Pharmacy is kept as 100 considering NEP-20 and NAAC guideline.

3. Structure of PG Program in Pharmacy:

The structure of PG Program in Pharmacy shall have essentially the following categories of courses with the breakup of credits as given:

COMPONENTS OF CURRICULUM

(Program curriculum grouping based on course components)

Sr.No	CourseComponent	% of total number of Credits of the Program	Total number of Credits
1	Pharmacy Core Course (PCC)	52	52
2	Research Methodology and Biostatistics (RM)	4	4
3	Journal club (JC)	2	2
4	Discussion/Presentation(Proposal Presentation) (PP)	2	2
5	Research Work (RW)	30	30
6	Discussion/Final Presentation (FP)	3	3
7	Co-curricular Activities (CCA) (Attending Conference, Scientific Presentations and Other Scholarly Activities)	7	7
TOTAL		**100%**	**100**

GENERAL COURSE STRUCTURE AND CREDIT DISTRIBUTION
Curriculum of Master of Pharmacy

SEMESTER-I		SEMESTER-II	
Course Title	**Credit**	**Course Title**	**Credit**
Modern Pharmaceutical Analytical Techniques	4:0:0=4	Molecular Pharmaceutics (Nano Tech and Targeted DDS)	4:0:0=4
Drug Delivery System	4:0:0=4	Advanced Biopharmaceutics & Pharmacokinetics	4:0:0=4
Modern Pharmaceutics	4:0:0=4	Computer Aided Drug Delivery System	4:0:0=4
Regulatory Affair	4:0:0=4	Cosmetic and Cosmeceuticals	4:0:0=4
Pharmaceutics Practical I	6:0:0=6	Pharmaceutics Practical II	6:0:0=6
Seminar/Assignment	4:0:0=4	Seminar/Assignment	4:0:0=4
TOTAL CREDIT	**26**	**TOTAL CREDIT**	**26**
SEMESTER-III		**SEMESTER-IV**	
Course Title	**Credit**	**Course Title**	**Credit**
Research Methodology and Biostatistics*	4:0:0=4	Journal Club	1:0:0=1
Journal club	1:0:0=1	Research Work	16:0:0=16
Discussion / Presentation (Proposal Presentation)	2:0:0=2	Discussion/Final Presentation	3:0:0=3
Research Work	14:0:0=14		
TOTAL CREDIT	**21**	**TOTAL CREDIT**	**20**
Co-curricular Activities (Attending Conference, Scientific Presentations and Other Scholarly Activities)			**7**

TotalCredit:100

GENERAL COURSE STRUCTURE AND CREDIT DISTRIBUTION

Program/Course credit structure As per the philosophy of Credit Based Semester System, certain quantum of academic work viz. theory classes, tutorial hours, practical classes, etc. are measured in terms of credits. On satisfactory completion of the courses, a candidate earns credits. The amount of credit associated with a course is dependent upon the number of hours of instruction per week in that course. Similarly, the credit associated with any of the other academic, co/extra-curricular activities is dependent upon the quantum of work expected to be put in for each of these activities per week.

A Credit assignment

Theory and Laboratory courses are broadly classified as Theory and Practical. Theory courses consist of lecture (L) and /or tutorial (T) hours, and Practical (P) courses consist of hours spent in the laboratory. Credits (C) for a course is dependent on the numberof hours of instruction per week in that course, and is obtained by using a multiplier of one (1) for lecture and tutorial hours, and for practical (laboratory) hours. Thus, for example, a theory course having three lectures and one tutorial per week throughout the semester carries a credit of 4. Similarly, a practical having 12 laboratory hours per week throughout semester carries a credit of 6.

Maximum credit requirements the maximum credit points required for award of a M. Pharm. is 100. These credits are divided into theory courses, Tutorials, Practical, and Project over the duration of forth semesters. The credits are distributed semester-wise as shown in Table. Courses generally progress in sequences, building competencies and their positioning indicates certain academic maturity on the part of the learners. Learners are expected to follow the semester-wise schedule of courses given in the syllabus.

Semester wise credits distribution
Table-

Semester	Credit Points
I	26
II	26
III	21
IV	20
Co-curricular Activities (Attending Conference, Scientific Presentations and Other Scholarly Activities)	Minimum=02 Maximum=07*
Total Credit Points	Minimum=95 Maximum=100*
*Credit Points for Co-curricular Activities	

Course code and definition:

L **T** **P** **C**	Lecture Tutorial Practical Credit
PCC	Pharmacy Core Course
RM	Research Methodology and Biostatistics
JC	Journal club
PP	Discussion/Presentation (Proposal Presentation)
RW	Research Work
FP	Discussion/Final Presentation
CCA	Co-curricular Activities (Attending Conference, Scientific Presentations and Other Scholarly Activities)

COURSE LEVEL CODING SCHEME

Three-digit number (odd numbers are for the odd semester courses and even numbers are for even semester courses) used as suffix with the Course Code for identifying the level of the course.

MPH 101T, MPH 102T ---for first semester
MPH 201T, MPH 202T ---for second semester
MRM 301T---for third semester

CATEGORY-WISE COURSES

Pharmacy Core Course (PCC)

1. Number of Pharmacy Core Course (PCC): 12, Credits: 52

Sr. No	Code No	Subject	Semester	Credits
1	PCC	Modern Pharmaceutical Analytical Techniques	I	4
2	PCC	Drug Delivery System	I	4
3	PCC	Modern Pharmaceutics	I	4
4	PCC	Regulatory Affair	I	4
5	PCC	Pharmaceutics Practical I	I	6
6	PCC	Seminar/Assignment	I	4
7	PCC	Molecular Pharmaceutics (Nano Tech and Targeted DDS)	II	4
8	PCC	Advanced Biopharmaceutics & Pharmacokinetics	II	4
9	PCC	Computer Aided Drug Delivery System	II	4
10	PCC	Cosmetic and Cosmeceuticals	II	4
11	PCC	Pharmaceutics Practical II	II	6
12	PCC	Seminar/Assignment	II	4
Total Credits				**52**

2. Number of Research Methodology and Biostatistics (RM): 01,Credits: 4

Sr. No	Code No	Subject	Semester	Credits
1	RM	Research Methodology and Biostatistics	III	4
Total Credits				**4**

3. Number of Journal club (JC): 02,Credits: 2

Sr. No	Code No	Subject	Semester	Credits
1	JC	Journal club	III	1
2	JC	Journal club	IV	1
Total Credits				**2**

4. Number of Discussion/Presentation (Proposal Presentation) (PP): 01,Credits: 2

Sr. No	Code No	Subject	Semester	Credits
1	PP	Discussion/Presentation (Proposal Presentation)	III	2
Total Credits				**2**

5. Number of Research Work (RW): 02,Credits: 30

Sr. No	Code No	Subject	Semester	Credits
1	RW	Research Work	III	14
2	RW	Research Work	IV	16
Total Credits				**30**

6. Number of Discussion/Final Presentation (FP): 02,Credits: 30

Sr. No	Code No	Subject	Semester	Credits
1	FP	Discussion/Final Presentation	IV	3

Total Credits	3

7. Number of Co-curricular Activities (CCA): 01,Credits: 7

Sr. No	Code No	Subject	Semester	Credits
1	CCA	Co-curricular Activities (Attending Conference, Scientific Presentations and Other Scholarly Activities)	-	7
Total Credits				**7**

INDUCTION PROGRAM

Induction program for students to be offered right at the start of the first year. It is mandatory. AKS University has designed an induction program for 1st year student, details are below:

1. Physical activity
2. Creative Arts
3. Universal Human Values
4. Literary
5. Proficiency Modules
6. Lectures by Eminent speakers
7. Visits to local Areas
8. Familiarization to Dept./Branch & Innovations

MANDATORY VISITS/WORKSHOP/EXPERT LECTURES

1. It is mandatory to arrange one industrial visit every semester for the students.
2. It is mandatory to organize at least one expert lecture per semester for each branch by expert resource persons from industry.

EVALUATION SCHEME

1. **For Theory Courses:**
    - The weightage of Internal assessment is 25% and;
    - End Semester Exam is 75%. The student has to obtain at least 50% marks individually both in internal assessment and end semester Exams to pass.
2. **For Practical Courses:**
    - The weightage of Internal assessment is 33.33% and;
    - End Semester Exam is 66.66%. The student has to obtain at least 50% marks individually both in internal assessment and end semester exams to pass.
3. **For Presentation/Journal Club/Seminar etc.:** Evaluation is based on work done, quality of report, performance in viva-voce, presentation etc.

Semester	Lecture	Practical	Seminar/Assignment	Journal Club	Discussion/Presentation (Proposal Presentation)	Research Work	Discussion/Final Presentation	Total Hours	No of Hours Per Sem.	Total Credit
Semester– I	16	12	7	-	-	-	-	35	35 x15=525	26
Semester– II	16	12	7	-	-	-	-	35	35 x15=525	26
Semester– III	4	-	-	1	2	28	-	35	35 x15=525	21
Semester– IV	-	-	-	1	-	31	3	35	35 x15=525	20
Co-curricular Activities (Attending Conference, Scientific Presentations and Other Scholarly Activities)									-	7
Total	**36**	**24**	**14**	**2**	**2**	**59**	**3**	**140**	**2100**	**100**

SEMESTR WISE COURSE STRUCTURE

Table-I: Course of study for M. Pharm. (Pharmaceutics) semester I

Course Code	Course	Credit Hours	Credit Points	Hrs./wk	Marks
MPH101T	Modern Pharmaceutical Analytical Techniques	4	4	4	100
MPH102T	Drug Delivery System	4	4	4	100
MPH103T	Modern Pharmaceutics	4	4	4	100
MPH104T	Regulatory Affair	4	4	4	100
MPH105P	Pharmaceutics Practical I	12	6	12	150
--	Seminar/Assignment	7	4	7	100
Total		35	26	35	650

Table-II: Course of study for M. Pharm. (Pharmaceutics) semester II

Course Code	Course	Credit Hours	Credit Points	Hrs./wk	Marks
MPH201T	Molecular Pharmaceutics (Nano Tech and Targeted DDS)	4	4	4	100
MPH202T	Advanced Biopharmaceutics & Pharmacokinetics	4	4	4	100
MPH203T	Computer Aided Drug Delivery System	4	4	4	100
MPH204T	Cosmetic and Cosmeceuticals	4	4	4	100
MPH205P	Pharmaceutics Practical II	12	6	12	150
--	Seminar/Assignment	7	4	7	100
Total		35	26	35	650

Table-III: Course of study for M. Pharm. (Pharmaceutics) semester III

Course Code	Course	Credit Hours	Credit Points
MRM 301T	Research Methodology and Biostatistics*	4	4
--	Journal club	1	1
--	Discussion / Presentation (Proposal Presentation)	2	2
--	Research Work	28	14
Total		35	21

* Non University Exam

Table-IV: Course of study for M. Pharm. (Pharmaceutics) semester IV

Course Code	Course	Credit Hours	Credit Points
--	Journal Club	1	1
--	Research Work	31	16
--	Discussion/Final Presentation	3	3
Total		35	20

A K S University

Faculty of Pharmaceutical Science & Technology
Rajiv Gandhi Institute of Pharmacy
Curriculum of M. Pharmacy (Pharmaceutics-MPH) Program
(Revised as on 01 August 2023)

Semester-I

Course Code: MPH 101T

Course Title: Modern Pharmaceutical Analytical Techniques

Pre-requisite: 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.

Rationale/Objectives: After completion of course student is able to know

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

Course Outcomes:

CO-MPH 101T-1: To understand the working, principles & applications of various analytical instruments like UV-Visible spectroscopy, IR spectroscopy, Spectroflourimetry and Flame emission spectroscopy and Atomic absorption spectroscopy.

CO-MPH 101T-2: To know the various basic working, principles & applications of NMR spectroscopy.

CO-MPH 101T-3: To know the various basic working, principles & applications of Mass Spectroscopy.

CO-MPH 101T-4: To understand about the Chromatography: principle, apparatus and instrumentation.

CO-MPH 101T-5: To understand the Electrophoresis principle, Instrumentation, Working & conditions & their applications.

CO-MPH 101T-6: To understand about the Immunological assay.

Scheme of Studies

Course code	Title of the course	Program Name	Total Number of contact hours/Week					Credit
			Class room Instruction (A) Lecture	Practical (P)	SW	SL	Total Hours (H)	
MPH 101T	Modern Pharmaceutical Analytical Techniques Theory	M. Pharmacy	4	-	1	1	6	4

Legend: CI: Class room Instruction (Includes different instructional strategies i.e. Lecture (L) and Tutorial (T) and others

LI: Laboratory Instruction (Includes Practical performances in laboratory workshop, field or other locations using different instructional strategies)

SW: Sessional Work **(**includes assignment**,** seminar, and mini project etc.)

SL: Self Learning, Credits

Note: SW& SL has to be planned and performed under the continuous guidance and feedback of teacher to ensure outcome of Learning.

Theory Assessment

Course Code	Course	Internal Assessment (A)				End Semester Exams (B)		Total Marks (A+B)
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
MPH 101T	Modern Pharmaceutical Analytical Techniques	10	15	1 Hr	25	75	3Hrs.	100

Guidelines for the allotment of marks for attendance

Percentage of Attendance	Theory	Practical
95–100	8	10
90–94	6	7.5
85–89	4	5
80–84	2	2.5
Less than 80	0	0

Course-Curriculum Detailing:

This course syllabus illustrates the expected learning achievements, both at the course and session levels, which students are anticipated to accomplish through various modes of instruction including Classroom Instruction (CI), Laboratory Instruction (LI), Sessional Work (SW), and Self Learning (SL). As the course progresses, students should showcase their mastery of Session Outcomes (SOs), culminating in the overall achievement of Course Outcomes (COs) upon the course's conclusion.

Unit I

CO-MPH 101T-1: To understand the working, principle & applications of various analytical instruments like UV-Visible spectroscopy. IR spectroscopy, Spectroflourimetry and Flame emission spectroscopy and Atomic absorption spectroscopy.

Item	Approx Hrs
Lecture	11
Practical (P)	0
SW	1
SL	2
Total	14

Session Outcomes (SOs)	Laboratory Instruction (LI)	Class room Instruction (CI)	Self Learning (SL)
Theory **SO1.1:** UV-Visible spectroscopy **SO1.2:** IR spectroscopy **SO1.3:** Spectroflourimetry **SO1.4:** Flame emission spectroscopy and Atomic absorption spectroscopy	**NA**	**1.1:** UV-Visible spectroscopy Introduction, Theory **1.2:** Laws, Instrumentation associated with UV-Visible spectroscopy **1.3:** Choice of solvents and solvent effect and applications of UV-Visible spectroscopy, Difference/ Derivative spectroscopy **1.4:** IR spectroscopy. Theory, of IR spectroscopy & Modes of Molecular vibrations **1.5:** Instrumentation of Dispersive and Fourier - Transform IR Spectrometer **1.6:** Factors affecting vibrational frequencies and applications of IR spectroscopy **1.7:** Data Interpretation of IR Spectrometer **1.8:** Spectroflourimetry: Theory of Fluorescence, Factors effecting fluorescence and Quenchers **1.9:** Flame emission spectroscopy and Atomic absorption spectroscopy **1.10:** Principle, Instrumentation, Interferences and applications. **1.11:** Instrumentation and applications of fluorescence spectrophotometer	**1.1:** Advanced models of UV Spectroscopy **1.2:** UV Spectroscopic applications

Suggested Assignments: 1. Describe the UV- spectroscopy and IR spectroscopy.

Unit II

CO- MPH 101T-2: To know the various basic working, principle & applications of NMR spectroscopy.

Item	Approx Hrs
Lecture	11
Practical (P)	0
SW	1
SL	1
Total	13

Session Outcomes(SOs)	Laboratory Instruction (LI)	Class room Instruction (CI)	Self Learning (SL)
Theory **SO2.1:** NMR spectroscopy	**NA**	**2.1:** Introduction of NMR spectroscopy **2.2:** Role of Quantum numbers in NMR **2.3:** Principle and Instrumentation, of NMR **2.4:** Solvent requirement in NMR, Relaxation process **2.5:** NMR signals in various compounds **2.6:** Chemical shift, Coupling constant **2.7:** Nuclear magnetic double resonance **2.8**: Brief outline of principles of FT-NMR and 13C NMR **2.9**: Applications of NMR spectroscopy **2.10** Factors influencing chemical shift **2.11:** Spin-Spin coupling	**2.1:** Advanced technology in NMR.

Suggested Assignments: 1. Brief outline of principles of FT-NMR and 13C NMR.

Unit III

CO-MPH 101T-3: To know the various basic working, principles & applications of Mass Spectroscopy.

Item	Approx Hrs
Lecture	11
Practical (P)	0
SW	1
SL	1
Total	13

Session Outcomes (SOs)	Laboratory Instruction (LI)	Class room Instruction (CI)	Self Learning (SL)
Theory **SO3.1:** Mass Spectroscopy	**NA**	**3.1:** Principle &Theories of Mass Spectroscopy **3.2:** Instrumentation of Mass Spectroscopy **3.3:** Different types of ionization like electron impact **3.4:** Chemical, field, FAB and MALDI **3.5:** APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight **3.6:** Mass fragmentation and its rules **3.7:** Meta stable ions **3.8:** Isotopic peaks **3.9:** APPI Analyzers of Quadrupole **3.10:** Applications of Mass spectroscopy **3.11:** Importance of Applications of Mass spectroscopy	**3.1:** Latest features & models of Mass spectroscopy

Suggested Assignments: 1. Write down the Mass fragmentation and its rules.

Unit IV

CO-MPH 101T-4: To understand about the Chromatography: Principle, apparatus and Instrumentation.

Item	Approx Hrs
Lecture	11
Practical (P)	0
SW	1
SL	1
Total	13

Session Outcomes (SOs)	Laboratory Instruction (LI)	Class room Instruction (CI)	Self Learning (SL)
Theory **SO4.1:** Chromatography	**NA**	**4.1:** Principles of chromatography **4.2:** Principle, apparatus, instrumentation of Paper chromatography **4.3:** Parameters & factors affecting resolution **4.4:** Applications of Paper chromatography **4.5:** Principle, apparatus, instrumentation of Thin Layer chromatography **4.6:** Principle, apparatus, instrumentation of Paper chromatography Parameters & factors affecting resolution **4.7:** Ion exchange chromatography: Principle, apparatus, instrumentation **4.8:** Column chromatography Principle, apparatus, instrumentation & applications **4.9:** Gas Chromatography Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution **4.10:** Gas Chromatography Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution **4.11:** High Performance Liquid& Affinity chromatography Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution and applications	**4.1:** Latest features & models of Chromatographic techniques

Suggested Assignments:

1. Principle, apparatus, instrumentation, chromatographic parameters of chromatographic techniques.

Unit V

CO-MPH 101T-5: To understand the Electrophoresis Principle, Instrumentation, Working & conditions & their applications.

Item	Approx Hrs
Lecture	11
Practical (P)	0
SW	1
SL	1
Total	13

Session Outcomes (SOs)	Laboratory Instruction (LI)	Class room Instruction (CI)	Self Learning (SL)
Theory **SO5.1:** Electrophoresis	**NA**	**5.1:** Principle, Instrumentation, Working conditions of Paper electrophoresis **5.2:** Factors affecting separation and applications of Paper electrophoresis **5.3:** Principle, Instrumentation, Working conditions of Gel electrophoresis **5.4:** Factors affecting separation and applications of Gel electrophoresis **5.5:** Principle, Instrumentation, Working conditions of Gel electrophoresis **5.6:** Factors affecting separation and applications of Capillary electrophoresis **5.7:** Principle, Instrumentation, Working conditions of Capillary Moving boundary electrophoresis **5.8:** Factors affecting separation and applications of Zone electrophoresis **5.9:** Principle, Instrumentation, Working conditions of Isoelectric focusing **5.10:** Principle, Instrumentation, Working conditions of Isoelectric focusing. **5.11:** 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	**5.1:** Reporting form of UK, Japan, USA

Suggested Assignments:

1. Paper electrophoresis
2. Gel electrophoresis
3. Capillary electrophoresis
4. Zone electrophoresis
5. Moving boundary electrophoresis
6. Isoelectric focusing.

Unit VI

CO-MPH 101T-6: To understand about the Immunological assays.

Item	Approx Hrs
Lecture	05
Practical (P)	0
SW	1
SL	1
Total	07

Session Outcomes (SOs)	Laboratory Instruction (LI)	Class room Instruction (CI)	Self Learning (SL)
Theory **SO6.1:** Immunological Assays.	**NA**	**6.1:** introduction of Immunological assays. **6.2:** basic concept of immunolisation. **6.3:** RIA (Radio immuno assay). **6.4:** briefly explain ELISA test. **6.5:** Bioluminescence assays	**6.1:** ELISA test.

Suggested Assignments: 1. Explain in detail about RIA (Radio immuno assay) and ELISA test.

Brief of Hours suggested for the Course Outcome

Course Outcomes	Class Lecture (CL)	Laboratory Instructions (LI)	Sessional Work (SW)	Self Learning (SL)	Total Hour (CL+SW+ SL+LI)
CO-MPH 101T-1: To understand the working, Principals& applications of various analytical instruments like UV-Visible spectroscopy. IR spectroscopy, Spectroflourimetry and Flame emission spectroscopy and Atomic absorption spectroscopy.	11	0	1	2	14
CO-MPH 101T-2: To know the various basic working, Principals& applications of NMR spectroscopy.	11	0	1	1	13
CO-MPH 101T-3: To know the various basic working, Principals& applications of Mass Spectroscopy	11	0	1	1	13
CO-MPH 101T-4: To understand about the Chromatography: Principle, apparatus, instrumentation.	11	0	1	1	13
CO-MPH 101T-5: To understand the Electrophoresis Principle, Instrumentation, Working& conditions & their applications**.**	11	0	1	1	13
CO-MPH 101T-6: To understand about the Immunological assay.	05	0	1	1	07
Total Hours	**60**	**0**	**6**	**7**	**73**

Suggestion for End Semester Assessment

Suggested Specification Table (For ESA)

Course Outcome	Unit Titles	Marks Distribution			Total Marks
		A	C	E	
CO-MPH 101T-1:	To understand the working, Principals& applications of various analytical instruments like UV-Visible spectroscopy. IR spectroscopy, Spectroflourimetry and Flame emission spectroscopy and Atomic absorption spectroscopy.	08	06	01	15
CO-MPH 101T-2:	To know the various basic working, Principals& applications of NMR spectroscopy	12	07	01	20
CO-MPH 101T-3:	To know the various basic working, Principals& applications of Mass Spectroscopy	08	06	02	16
CO-MPH 101T-4:	To understand about the Chromatography: Principle, apparatus, instrumentation	10	02	03	15
CO-MPH 101T-5:	To understand the Electrophoresis Principle, Instrumentation, Working& conditions & their applications.	10	07	03	20
CO-MPH 101T-6:	To understand about the Immunological assay.	10	02	02	14
Total		**58**	**30**	**12**	**100**

Legend: A: Analyze, C: create, E: Evaluate

The end of semester assessment for Modern Pharmaceutical Analytical Techniques will be held with written examination of 75 marks.

Note. Detailed Assessment rubric need to be prepared by the course wise teachers for above tasks. Teachers can also design different tasks as per requirement, for end semester assessment.

Suggested Instructional/Implementation Strategies:

1. Improved Lecture
2. Tutorial
3. Case Method
4. Group Discussion
5. Role Play
6. Demonstration
7. ICT Based Teaching Learning(Video Demonstration/Tutorials CBT, Blog, Face book, Twitter, Whats app, Mobile, Online sources)
8. Brainstorming

Suggested Learning Resources:

S. No.	Title	Author	Publisher	Edition & Year
1	Spectrometric Identification of Organic compounds	Robert M Silverstein	John Wiley & Sons	Sixth edition, 2004
2	Principles of Instrumental Analysis Doglas A Skoog	F. James Holler, Timothy A. Nieman	Cengate india private limlted	7th edition, 2020
3	Instrumental methods of analysis	Willards	CBS publishers	7th edition, 2023
4	Practical Pharmaceutical Chemistry	Beckett and Stenlake, Vol II,	CBS Publishers	4th edition, New Delhi, 2023
5	Organic Spectroscopy	William Kemp	ELBS	3rd edition, 2022
6	Quantitative Analysis of Drugs in Pharmaceutical formulation	P D Sethi	CBS Publishers	4rd Edition, New Delhi, 2022
7	Pharmaceutical Analysis-Modern methods Part B	J W Munson, Volume-11	CRC Press	2ND edition 2012

Curriculum Development Team:

1. **Prof. S.P. Gupta,** Director, Rajiv Gandhi Institute of Pharmacy, AKS University
2. **Ms. Neha Goel,** Associate Professor, Rajiv Gandhi Institute of Pharmacy, AKS University
3. **Mrs. Neelam Singh,** Assistant Professor, Rajiv Gandhi Institute of Pharmacy, AKS University

Course Outcome & Program Outcome Mapping

Course Outcome	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PSO1	PSO2	PSO3	PSO4
	Scientific Knowledge	Technological Application	Modern tool usage	Entrepreneur ship	Practical Skill	Applied Science	Computational and Statistical methodologies	Pharmaceutical Ethics	Environment and sustainability	Life-long learning	Formulation strategies	Emerging science	Computational literacy	Pharmaceutical regulations
CO-MPH 101T-1: UV-Visible Spectroscopy	3	2	3	1	3	2	1	3	2	3	2	3	2	1
CO-MPH 102T-1: NMR Spectroscopy	2	2	3	2	1	3	2	2	1	3	3	2	2	3
CO-MPH 103T-1: Mass Spectroscopy	1	2	1	3	3	2	3	3	2	2	1	2	1	2
CO-MPH 104T-1: Chromatography	2	1	3	2	2	3	2	2	2	3	2	3	2	1
CO-MPH 105T-1: Electrophoresis	3	2	2	1	3	2	3	3	1	2	3	1	2	3
CO-MPH 106T-1: Immunological assay	2	1	3	2	1	3	1	3	2	3	1	2	1	2

Legend: 1- Low, 2-Medium, 3-High

Course Curriculum Mapping

POs & PSOs No.	COs No. & Title	SOs No.	Class Room Instructions	Laboratory Instructions	Self learning
POs:1,2,3,4,5,6,7,8,9,10 PSOs:1,2,3,4	**CO-MPH 101T-1:** To understand the working, Principals& applications of various analytical instruments like UV-Visible spectroscopy. IR spectroscopy, Spectroflourimetry and Flame emission spectroscopy and Atomic absorption spectroscopy.	SO1.1 SO1.2 SO1.3 SO1.4	1.1,1.2,1.3,1.4,1.5,1.6,1.7,1.8,1.9,1.10,1.11	-	SL-1.1 SL-1.2
POs:1,2,3,4,5,6,7,8,9,10 PSOs:1,2,3,4	**CO-MPH 101T-2:** To know the various basic working, Principals& applications of NMR spectroscopy	SO2.1	2.1,2.2,2.3,2.4,2.5,2.6,2.7,2.8,2.9,2.10,2.11	-	SL-2.1
POs:1,2,3,4,5,6,7,8,9,10 PSOs:1,2,3,4	**CO-MPH 101T -3:** To know the various basic working, Principals& applications of Mass Spectroscopy	SO3.1	3.1,3.2,3.3,3.4,3.5,3.6,3.7,3.8,3.9,3.10,3.11	-	SL-3.1
POs:1,2,3,4,5,6,7,8,9,10 PSOs:1,2,3,4	**CO-MPH 101T-4:** To understand about the Chromatography: Principle, apparatus, instrumentation	SO4.1	4.1,4.2,4.3,4.4,4.5,4.6,4.7,4.8,4.9,4.10,4.11	-	SL-4.1
POs:1,2,3,4,5,6,7,8,9,10 PSOs:1,2,3,4	**CO-MPH 101T-5:** To understand the Electrophoresis Principle, Instrumentation, Working& conditions & their applications	SO5.1	5.1,5.2,5.3,5.4,5.5,5.6,5.7,5.8,5.9,5.10,5.11	-	SL-5.1
POs:1,2,3,4,5,6,7,8,9,10 PSOs:1,2,3,4	**CO-MPH 101T-6:** To understand about the Immunological assay	SO6.1	6.1,6.2,6.3,6.4,6.5	-	SL-6.1

Semester-I

Course Code: MPH 102T

Course Title: Drug Delivery System

Pre-requisite: Student should have basic knowledge on the area of advances in novel Regulatory affairs

Rationale/Objectives: Upon completion of the course, student shall be able to understand

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

Course Out comes:

CO-MPH 102T-1: To understand about the sustained release and controlled release formulation.

CO-MPH 102T-2: To understand about the Rate Controlled Drug Delivery Systems.

CO-MPH 102T-3: To understand about the Gastro-Retentive Drug Delivery Systems.

CO-MPH 102T-4: Understand about the Occular Drug Delivery Systems.

CO-MPH 102T-5: Understand about the Transdermal Drug Delivery Systems.

CO-MPH 102T-6: To understand about the Protein and Peptide Delivery.

CO-MPH 102T-7: To understand about the Vaccine delivery systems.

Scheme of Studies

Course code	Title of the course	Program Name	Total Number of contact hours/Week					Credit
			Class room Instruction (A)	Practical (P)	SW	SL	Total Hours (H)	
			Lecture					
MPH 102T	Drug Delivery System	M. Pharmacy	4	-	1	1	6	4

Legend: CI: Class room Instruction (Includes different instructional strategies i.e. Lecture (L) and Tutorial (T) and others
LI: Laboratory Instruction (Includes Practical performances in laboratory workshop, field or other locations using different instructional strategies)
SW: Sessional Work (includes assignment**,** seminar, and mini project etc)
SL: Self Learning, Credits
Note: SW& SL has to be planned and performed under the continuous guidance and feedback of teacher to ensure outcome of Learning

Theory Assessment

Course Code	Course	Internal Assessment (A)				End Semester Exams (B)		Total Marks (A+B)
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
MPH 102T	Drug Delivery System	10	15	1 Hr	25	75	3 Hrs	100

Guidelines for the allotment of marks for attendance

Percentage of Attendance	Theory	Practical
95–100	8	10
90–94	6	7.5
85–89	4	5
80–84	2	2.5
Less than 80	0	0

Course-Curriculum Detailing:
This course syllabus illustrates the expected learning achievements, both at the course and session levels, which students are anticipated to accomplish through various modes of instruction including Classroom Instruction (CI), Laboratory Instruction (LI), Sessional Work (SW), and Self Learning (SL). As the course progresses, students should showcase their mastery of Session Outcomes (SOs), culminating in the overall achievement of Course Outcomes (COs) upon the course's conclusion.

Unit I

CO-MPH 102T-1: To understand about the Sustained Release (SR) and Controlled Release (CR) formulation.

Item	Approx Hrs
Lecture	10
Practical (P)	0
SW	1
SL	2
Total	13

Session Outcomes (SOs)	Laboratory Instruction (LI)	Class room Instruction (CI)	Self Learning (SL)
Theory **SO1.1:** Sustained Release(SR) and Controlled Release (CR) formulations: Introduction & basic concepts, advantages/ disadvantages, factors influencing, Physicochemical & biological approaches for SR/CR formulation **SO1.2:** Mechanism of Drug Delivery from SR/CR formulation **SO1.3:** Polymers: introduction, definition, classification, properties and application Dosage Forms for Personalized Medicine **SO1.4:** Introduction, Definition, Pharmacogenetics, Categories of Patients for Personalized Medicines **SO1.5:** Customized drug delivery systems, Bioelectronics' Medicines, 3D printing of pharmaceuticals, Telepharmacy	**NA**	**1.1:** Introduction & basic concepts of Sustained Release (SR) and Controlled Release (CR) formulations **1.2:** Advantages/disadvantages of Sustained Release (SR) and Controlled Release (CR) formulations **1.3:** Factors influencing of the Sustained Release (SR) and Controlled Release (CR) formulations **1.4:** Physicochemical & biological approaches for SR/CR formulation **1.5:** Mechanism of Drug Delivery from SR/CR formulation **1.6:** Introduction, definition and classification of Polymers **1.7:** Properties and application Dosage Forms for Personalized Medicine **1.8:** Introduction, Definition, Pharmacogenetics, Categories of Patients for Personalized Medicines **1.9:** Introduction of the Customized drug delivery system and Bioelectronics' Medicines **1.10:** 3-D printing of pharmaceuticals and Telepharmacy	**1.1:** To learn about Sustained Release(SR) and Controlled Release (CR) formulations **1.2:** To learn about Polymers

Suggested Assignments:

1. Explain 3D printing of pharmaceuticals and Telepharmacy.

Unit II

CO-MPH 102T-2: To understand about the Rate Controlled Drug Delivery Systems.

Item	Approx Hrs
Lecture	10
Practical (P)	0
SW	1
SL	2
Total	13

Session Outcomes (SOs)	Laboratory Instruction (LI)	Class room Instruction (CI)	Self Learning (SL)
Theory **SO2.1:** Rate Controlled Drug Delivery Systems **SO2.2:** Principles & Fundamentals of Modulated Drug Delivery Systems **SO2.3:** Types and Activation of Modulated Drug Delivery Systems **SO2.4:** Mechanically activated, pH activated, Enzyme activated, and Osmotic activated Drug Delivery Systems **SO2.5:** Feedback regulated Drug Delivery Systems; Principles & Fundamentals	**NA**	**2.1:** Analyzed the rate of Controlled Drug Delivery Systems **2.2:** Principles of Modulated Drug Delivery Systems **2.3:** Fundamentals of Controlled Drug Delivery Systems **2.4:** Types of Modulated Drug Delivery Systems **2.5:** Activation of Modulated Drug Delivery Systems **2.6:** Mechanically activated, pH activated, Enzyme activated **2.7:** Osmotic activated Drug Delivery Systems **2.8:** Principles & Fundamentals Controlled Drug Delivery System **2.9:** Feedback of the regulated Drug Delivery Systems **2.10:** Controlled Drug Delivery Systems	**2.1:** To interpret Modulated Drug Delivery Systems **2.2:** To learn about the ph activated and enzyme activated of drug delivery systems

Suggested Assignments:

1. Given Feedback regulated Drug Delivery Systems.

Unit III

CO-MPH 102T-3: To understand about the Occular Drug Delivery Systems.

Item	Approx Hrs
Lecture	10
Practical (P)	0
SW	2
SL	2
Total	14

Session Outcomes (SOs)	Laboratory Instruction (LI)	Class room Instruction (CI)	Self Learning (SL)
Theory **SO3.1** Gastro-Retentive Drug Delivery Systems: Principle, concepts, advantages and disadvantages, Modulation of GI transit time approaches to extend GI transit **SO3.2** Buccal Drug Delivery Systems: Principle of muco-adhesion, advantages and disadvantages, Mechanism of drug permeation, Methods of formulation and its evaluations	**NA**	**3.1:** Introduction about Gastro-Retentive Drug Delivery Systems **3.2:** Principle of Gastro-Retentive Drug Delivery Systems **3.3:** Concepts of Gastro-Retentive Drug Delivery Systems **3.4:** Advantages and disadvantages of Modulation of GI transit time **3.5:** Discuss the various Approaches to extend GI transit time **3.6:** Discuss in Buccal Drug Delivery Systems **3.7:** Given the Principle of muco-adhesion drugs **3.8:** Explain the advantages and disadvantages of Buccal Drug Delivery Systems **3.9:** Mechanism of drug permeation. **3.10:** Methods of Formulation of Buccal Drug Delivery Systems **3.11:** Evaluations of muco-adhesive drugs	**3.1:** To learn about the Gastro-Retentive Drug Delivery Systems **3.2:** analyses of the Buccal Drug Delivery Systems

Suggested Assignments:

1. Write the classification of Gastro-Retentive Drug Delivery Systems.
2. Give note on formulation of the mucoadhesive drugs.

Unit IV

CO-MPH 102T-4: To understand about the Occular Drug Delivery Systems.

Item	Approx Hrs
Lecture	06
Practical (P)	0
SW	1
SL	1
Total	08

Session Outcomes (SOs)	Laboratory Instruction (LI)	Class room Instruction (CI)	Self Learning (SL)
Theory **SO4.1:** Occular Drug Delivery Systems **SO4.2:** Barriers of drug permeation, Methods to overcome barriers	NA	**4.1:** To brief introduction of human eyes **4.2:** discuss in detail about internal and external part of ocular system **4.3:** explain about ocular drug delivery system (ODDS) **4.4:** To evaluate the potential (efficacy) activity of ocular drug delivery system **4.5:** given the factor affecting of formulation of ocular drug **4.6:** Methods to overcome barriers ocular drug delivery system	**4.1:** To learn about eyes and Occular Drug Delivery Systems

Suggested Assignments:

1. Preparation of ophthalmic formulation

Unit V

CO-MPH 102T-5: To understand about the Transdermal Drug Delivery Systems.

Item	Approx Hrs
Lecture	10
Practical (P)	0
SW	1
SL	1
Total	12

Session Outcomes (SOs)	Laboratory Instruction (LI)	Class room Instruction (CI)	Self Learning (SL)
Theory **SO5.1:** Transdermal Drug Delivery Systems Structure of skin and Barrier, Penetration enhancers **SO5.2:** Transdermal Drug Delivery Systems, Formulation and evaluation	**NA**	**5.1:** To brief introduction of human skin structure **5.2:** Given introduction Transdermal Drug Delivery Systems **5.3:** Explain various route of administration of TDDS **5.4:** Classification of Transdermal Drug Delivery Systems **5.5:** Affecting of barrier of route of administration **5.6:** Explain the Penetration enhancers techniques **5.7:** Preparation of Transdermal Drug Delivery Systems **5.8:** Factor affecting of Transdermal dosage form **5.9:** Types of Transdermal patches dosage form **5.10:** Evaluation of Transdermal Drug Delivery Systems	**5.1:** To learn about Transdermal Drug Delivery Systems

Suggested Assignments:-

1. Preparation of Transdermal Dosage form.

Unit VI

CO-MPH 102T-6: To understand about the Protein and Peptide Delivery.

Item	Approx Hrs
Lecture	08
Practical (P)	0
SW	1
SL	2
Total	11

Session Outcomes (SOs)	Laboratory Instruction (LI)	Class room Instruction(CI)	Self Learning (SL)
Theory **SO6.1:** Protein and Peptide Delivery **SO6.2:** Barriers for protein delivery **SO6.3:** Formulation and Evaluation of delivery systems of proteins and Other macromolecules	**NA**	**6.1:** To brief introduction of Protein and other Biomolecules **6.2:** Given detail is Peptide Delivery system **6.3:** Affecting of Barriers for protein delivery **6.4:** Formulation of Protein and Peptide Delivery system **6.5:** Formulations of various macromolecules drugs **6.6:** Given the various route of administration of Protein and Peptide Delivery **6.7:** Evaluation of peptide delivery system **6.8:** Evaluation of Other macromolecules	**6.1:** To learn about the Protein and Peptide drug Delivery system **6.2:** To understand about the various barriers of dosage form

Suggested Assignments:

1. Preparation of Protein and Peptide drug delivery system.

Unit VII

CO-MPH 102T-7: To understand about the Vaccine delivery systems.

Item	Approx Hrs
Lecture	06
Practical (P)	0
SW	1
SL	1
Total	08

Session Outcomes (SOs)	Laboratory Instruction (LI)	Class room Instruction (CI)	Self Learning (SL)
Theory **SO7.1:** Vaccine drug delivery systems. **SO7.2:** Vaccines, uptake of antigens, single shot vaccines, mucosal and Transdermal delivery of vaccines	**NA**	**7.1:** To brief introduction of Vaccine drug delivery systems **7.2:** Types of vaccines **7.3:** Uptake of antigen **7.4:** Shot vaccines **7.5:** Mucosal and Transdermal delivery of vaccines **7.6:** Given detail about various age of human being.	**7.1:** To understand about the vaccine

Suggested Assignments:

1. Write a note on- How to store is vaccine.

Brief of Hours suggested for the Course Outcome

Course Out comes	Class Lecture (CL)	Laboratory Instructions (LI)	Sessional Work (SW)	Self Learning (SL)	Total Hour (CL+SW+ SL+LI)
CO-MPH 102T-1: To understand about the Sustained Release (SR) and Controlled Release (CR) formulations	10	0	1	2	13
CO-MPH 102T-2: To understand about the Rate Controlled Drug Delivery Systems	10	0	1	2	13
CO-MPH 102T-3: To understand about the Gastro-Retentive Drug Delivery Systems	10	0	2	2	14
CO-MPH 102T-4: To understand about the Occular Drug Delivery Systems	06	0	1	1	08
CO-MPH 102T-5: To understand about the Transdermal Drug Delivery Systems	10	0	1	1	12
CO-MPH 102T-6: To understand about the Protein and Peptide Delivery	08	0	1	2	11
CO-MPH 102T-7: To understand about the Vaccine delivery system	06	0	1	1	08
Total Hours	**60**	**0**	**08**	**11**	**79**

Suggestion for End Semester Assessment

Suggested Specification Table (For ESA)

Course Outcome	Unit Titles	Marks Distribution			Total Marks
		A	C	E	
CO-MPH 102T-1:	To understand about the Sustained Release (SR) and Controlled Release (CR) formulations	08	06	01	15
CO-MPH 102T-2:	To understand about the Rate Controlled Drug Delivery Systems	12	07	01	20
CO-MPH 102T-3:	To understand about the Gastro-Retentive Drug Delivery Systems	02	06	02	10
CO-MPH 102T-4:	To understand about the Occular Drug Delivery Systems	10	02	03	15
CO-MPH 102T-5:	To understand about the Transdermal Drug Delivery Systems	05	07	03	15
CO-MPH 102T-6:	To understand about the Protein and Peptide Delivery	05	03	03	11
CO-MPH 102T-7:	To understand about the Vaccine delivery systems	04	05	05	14
Total		**46**	**36**	**18**	**100**

Legend: A: Analyze, C: Create, E: Evaluate

The end of semester assessment for Drug Delivery Systems will be held with written examination of 75 marks.
Note. Detailed Assessment rubric need to be prepared by the course wise teachers for above tasks.
Teachers can also design different tasks as per requirement, for end semester assessment.

Suggested Instructional/Implementation Strategies:

1. Improved Lecture
2. Tutorial
3. Case Method
4. Group Discussion
5. Role Play
6. Demonstration
7. ICT Based Teaching Learning(Video Demonstration/Tutorials CBT, Blog,Face book, Twitter, Whats app, Mobile, Online sources)
8. Brainstorming

Suggested Learning Resources:

S. No.	Title	Author	Publisher	Edition & Year
1	Novel Drug Delivery Systems	Y W. Chien Marcel Dekker	Marcel Dekker New York,	2nd edition, revised and expanded 2022
2	Controlled Drug Delivery Systems	Robinson, J. R., Lee V. H. L	Marcel Dekker New York,	2nd edition,2021
3	Encyclopedia of controlled delivery	John Wiley and Sons.	WileyInter science Publication	2nd edition,2009
4	Controlled and Novel Drug Delivery	N.K. Jain	CBS Publishers & Distributors , New Delhi,	First edition 1997 (reprint in 2001)
5	Controlled Drug Delivery - concepts and advances	S.P. Vyas and R.K.Khar,	Vallabh Prakashan, New Delhi	First edition 2002

Journals

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

Curriculum Development Team:

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2. **Ms. Neha Goel,** Associate Professor, Rajiv Gandhi Institute of Pharmacy, AKS University
3. **Mrs. Neelam Singh,** Assistant Professor, Rajiv Gandhi Institute of Pharmacy, AKS University

Course Outcome & Program Outcome Mapping

Course Outcome	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PSO1	PSO2	PSO3	PSO4
	Scientific Knowledge	Technological Application	Modern tool usage	Entrepreneur ship	Practical Skill	Applied Science	Computational and Statistical methodologies	Pharmaceutical Ethics	Environment and sustainability	Life-long learning	Formulation strategies	Emerging science	Computational literacy	Pharmaceutical regulations
CO-MPH 102T-1: Sustained release and controlled release formulation	3	2	3	1	3	2	1	3	2	3	3	2	1	2
CO-MPH 102T-2: Controlled Drug Delivery Systems	2	2	3	2	1	3	2	2	1	3	2	3	2	1
CO-MPH 102T-3: Gastro-Retentive Drug Delivery Systems	1	2	1	3	3	2	3	3	2	2	2	1	3	3
CO-MPH 102T-4: Occular Drug Delivery Systems	2	1	3	2	2	3	2	2	2	3	3	2	1	2
CO-MPH 102T-5: Transdermal Drug Delivery Systems	3	2	2	1	3	2	3	3	1	2	1	2	2	3
CO-MPH 102T-6: Protein and Peptide Delivery	2	1	3	2	1	3	1	3	2	3	3	2	1	2
CO-MPH 102T-7: Vaccine delivery systems	1	3	2	3	2	2	3	2	3	1	2	3	2	1

Legend: 1- Low, 2-Medium, 3-High

Course Curriculum Mapping

POs & PSOs No.	COs No. & Title	SOs No.	Class Room Instructions	Laboratory Instructions	Self learning
Pos:1,2,3,4,5,6,7,8,9,10 PSOs:1,2,3,4	**CO-MPH 102T-1:** To understand about the Sustained Release (SR) and Controlled Release (CR) formulations	SO1.1 SO1.2 SO1.3 SO1.4 SO1.5	1.1,1.2,1.3,1.4,1.5,1.6 ,1.7,1.8,1.9,1.10	-	SL-1.1 SL-1.2
Pos:1,2,3,4,5,6,7,8,9,10 PSOs:1,2,3,4	**CO-MPH 102T-2:** Tounderstand about the Rate Controlled Drug Delivery Systems	SO2.1 SO2.2 SO2.3 SO2.4 SO2.5	2.1,2.2,2.3,2.4,2.5,2.6 ,2.7,2.8,2.9,2.10	-	SL-2.1 SL-2.2
Pos:1,2,3,4,5,6,7,8,9,10 PSOs:1,2,3,4	**CO-MPH 102T -3:** To understand about the Gastro-Retentive Drug Delivery Systems	SO3.1 SO3.2	3.1,3.2,3.3,3.4,3.5,3.6 ,3.7,3.8,3.9,3.10,3.11	-	SL-3.1 SL-3.2
Pos:1,2,3,4,5,6,7,8,9,10 PSOs:1,2,3,4	**CO-MPH 102T-4:** To understand about the Occular Drug Delivery Systems	SO4.1 SO4.2	4.1,4.2,4.3,4.4,4.5,4.6 ,4.7	-	SL-4.1
Pos:1,2,3,4,5,6,7,8,9,10 PSOs:1,2,3,4	**CO-MPH 102T-5:** To understand about the Transdermal Drug Delivery Systems	SO5.1 SO5.2	5.1,5.2,5.3,5.4,5.5,5.6 ,5.7,5.8,5.9,5.10	-	SL-5.1
Pos:1,2,3,4,5,6,7,8,9,10 PSOs:1,2,3,4	**CO-MPH 102T-6:** To understand about the Protein and Peptide Delivery	SO6.1 SO6.2 SO6.3	6.1,6.2,6.3,6.4,6.5,6.6 ,6.7,6.8	-	SL-6.1 SL-6.2
Pos:1,2,3,4,5,6,7,8,9,10 PSOs:1,2,3,4	**CO-MPH 102T-7:** To understand about the Vaccine delivery systems	SO7.1 SO7.2	7.1,7.2,7.3,7.4,7.5,7.6	-	SL-7.1

A K S University

Faculty of Pharmaceutical Science & Technology
Rajiv Gandhi Institute of Pharmacy
Curriculum of M. Pharmacy (Pharmaceutics-MPH) Program
(Revised as on 01 August 2023)

Semester-I

Course Code: MPH 103T

Course Title: Modern Pharmaceutics

Pre-requisite: Student should have basic knowledge of modern pharmaceutics and skills required to learn various aspects and concepts at pharmaceutical industries.

Rationale/Objective s:

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

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

Course Outcomes:

CO-MPH 103T-1: To understand about the Preformation concept of pharmaceutical products.
CO-MPH 103T-2: To understand about the validation and calibration of master plan, ICH & WHO guidelines of equipment and dosage form.
CO-MPH 103T-3: To understand about the c-GMP & Industrial Management for layout of buildings, services, equipments and their Production.
CO-MPH 103T-4: To understand the Compression and compaction of tablets.
CO-MPH 103T-5: To understand about the consolidation parameters like Diffusion, Dissolution and Pharmacokinetic parameters of pharmaceutical products.

Scheme of Studies

Course code	Title of the course	Program Name	Total Number of contact hours/Week					Credit
			Classroom Instruction (A)	Practical (P)	SW	SL	Total Hours (H)	
			Lecture					
MPH 103T	Modern Pharmaceutics	M. Pharmacy	4	0	1	1	6	4

Legend: CI: Classroom Instruction (Includes different instructional strategies i.e. Lecture (L) and Tutorial (T) and other

LI: Laboratory Instruction (Includes Practical performances in laboratory workshop, field or other locations usingdifferent instructional strategies)

SW**:** Sessional Work (includes assignment, seminar, mini project etc.)

SL: Self Learning, Credits

Note: SW & SL has to be planned and performed under the continuous guidance and feedback of teacher to ensure outcomeof Learning

Theory Assessment

Course Code	Course	Internal Assessment (A)				End Semester Exams (B)		Total Marks (A+B)
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
MPH 103T	Modern Pharmaceutics	10	15	1 Hr	25	75	3 Hrs	100

Guidelines for the allotment of marks for attendance

Percentage of Attendance	Theory	Practical
95–100	8	10
90–94	6	7.5
85–89	4	5
80–84	2	2.5
Less than 80	0	0

Course-Curriculum Detailing:

This course syllabus illustrates the expected learning achievements, both at the course and session levels, which students are anticipated to accomplish through various modes of instruction including Classroom Instruction (CI), Laboratory Instruction (LI), Sessional Work (SW), and Self Learning (SL). As the course progresses, students should showcase their mastery of Session Outcomes (SOs), culminating in the overall achievement of Course Outcomes (COs) upon the course's conclusion.

Unit I

CO-MPH 103T-1: To understand about the Pre-formulation concept of pharmaceutical products.

Item	Approx Hrs
Lecture	20
Practical (P)	0
SW	2
SL	2
Total	24

Session Outcomes (SOs)	Laboratory Instruction (LI)	Class room Instruction (CI)	Self Learning (SL)
Theory **SO1.1:**Pre-formulation Concepts – Drug Excipients interactions - different methods, kinetics of stability, Stability testing **SO1.2:** Theories of dispersion and pharmaceutical Dispersion (Emulsion and Suspension, SMEDDS) **SO1.3:** preparation and stability Large and small volume parental – physiological and formulation consideration, Manufacturing and evaluation **SO1.**4: Optimization techniques in Pharmaceutical Formulation Concept and parameters of optimization **SO1.5:** Optimization techniques in pharmaceutical formulation and processing **SO1.6:** Statistical design, Response surface method, Contour designs, Factorial designs and application in formulation	**NA**	**1.1:** To brief introduction of Pre-formulation Concepts **1.2:** Drug Excipients interactions. **1.3:** Different methods of drug Excipients **1.4:** Kinetics of stability and Stability testing of drug-Excipients **1.5:** Theories of pharmaceutical Dispersion system (Emulsion) **1.6:** Theories of pharmaceutical Dispersion system (Suspension) **1.7:** Theories of pharmaceutical Dispersion system SMEDDS (self micro emulsifying drug delivery system) **1.8:** Preparation and stability of Large volume parenteral **1.9:** Preparation and stability of small volume parental **1.10:** Physiological and formulation consideration of large volume parenteral **1.11:** Physiological and formulation consideration of small volume parenteral **1.12:** Manufacturing procedure and evaluation parameter of small volume parenteral **1.13:** Manufacturing procedure and evaluation parameter of large volume parenteral **1.14:** Optimization techniques in Pharmaceutical Formulation **1.15:** Concept and parameters of optimization technique **1.16:** Optimization techniques in pharmaceutical formulation **1.17:** Optimization techniques in pharmaceutical processing **1.18:** Explain Statistical design and Response surface method **1.19:** Explain Contour designs and Factorial designs **1.20:** Application in pharmaceutical formulation.	**1.1:** Theories of dispersion and pharmaceutical Dispersion (Emulsion and Suspension, SMEDDS). **1.2:** Optimization techniques in Pharmaceutical Formulation.

Suggested Assignments:

1. Concept and parameters of optimization techniques in pharmaceutical formulation.
2. Preformulation Concepts of Drug Excipients interactions.

Unit II

CO-MPH 103T-2: Tounderstand about the validation and calibration of master plan, ICH & WHO guidelines of equipment and dosage form.

Item	Approx Hrs
Lecture	10
Practical (P)	0
SW	1
SL	2
Total	13

Session Outcomes (SOs)	Laboratory Instruction (LI)	Class room Instruction (CI)	Self Learning (SL)
Theory **SO2.1:** Introduction to Pharmaceutical Validation **SO2.2:** Scope & merits of Validation, Validation and calibration of Master plan **SO2.3:** ICH & WHO guidelines for calibration and validation of equipments **SO2.4:** Validation of specific dosage form and Types of validation **SO2.5:** Government regulation, Manufacturing Process Model, URS, DQ, IQ, OQ & P.Q. of facilities	**NA**	**2.1:** To brief introduction pharmaceutical Validation **2.2:** Scope & merits of Validation **2.3:** Validation and calibration of Master plan **2.4:** ICH & WHO guidelines for calibration and validation of equipments **2.5:** Validation of specific dosage form **2.6:** Types of validation **2.7:** Manufacturing Process Model- URS and DQ **2.8:** Manufacturing Process Model- IQ and OQ **2.9:** Manufacturing Process Model- P.Q. **2.10:** Manufacturing Process Model of facilities	**2.1:** Validation and calibration of Master plan **2.2:** ICH & WHO guidelines for calibration and validation of equipments

Suggested Assignments:

1. Define and types of validation and calibration. Write about Validation of specific dosage form.

Unit III

CO-MPH 103T-3: To understand about the cGMP & Industrial Management for layout of buildings, services, equipments and their Production.

Item	Approx Hrs
Lecture	10
Practical (P)	0
SW	2
SL	2
Total	13

Session Outcomes (SOs)	Laboratory Instruction (LI)	Class room Instruction (CI)	Self Learning (SL)
Theory **SO3.1** Explain cGMP & Industrial Management **SO3.2** Concept of Total Quality Management (TQM)	**NA**	**3.1:** To brief introduction of cGMP **3.2:** Objectives and policies of current good manufacturing practices **3.3:** Layout of buildings, and services of equipments and their maintenance **3.4:** Explain Production management and organization and material management **3.5:** Discuss handling and transportation **3.6:** Inventory management and control **3.7:** Production and planning control **3.8:** Sales forecasting, budget and cost control **3.9:** Industrial and personal relationship **3.10:** Concept of Total Quality Management	**3.1:** layout of buildings, services, equipments and their maintenance production Management **3.2:** inventory management and control production and planning control

Suggested Assignments:

1. Discuss in detail about cGMP and industrial management**.**
2. Explain the industrial and personal relationship of current good manufacturing practices.

Unit IV

CO-MPH 103T-4: To understand the Compression and compaction of tablets.

Item	Approx Hrs
Lecture	10
Practical (P)	0
SW	2
SL	2
Total	14

Session Outcomes (SOs)	Laboratory Instruction (LI)	Class room Instruction (CI)	Self Learning (SL)
Theory **SO4.1:** Compression and compaction of solid dosage form	**NA**	**4.1:** Introduction of Compression and compaction **4.2:** Explain Compression of tablets. **4.3:** Discuss the Compaction of tablets **4.5:** Physics of tablet compression **4.6:** Discuss the compression of solid dosage form **4.7:** Consolidation parameter of pharmaceutical product **4.8:** Effect of friction of drug **4.9:** Distribution of Forces Compaction profiles **4.10:** Solubility of pharmaceutical product	**4.1:** Compression and compaction of tablets **4.2:** Solubility parameter of tablets

Suggested Assignments:

1. Explain the consolidation parameter of pharmaceutical product.
2. Solubility parameter of pharmaceutical product.

Unit V

CO-MPH 103T-5: To understand about the consolidation parameters like Diffusion, Dissolution and Pharmacokinetic parameters of pharmaceutical products.

Item	Approx Hrs
Lecture	10
Practical (P)	0
SW	1
SL	2
Total	13

Session Outcomes (SOs)	Laboratory Instruction (LI)	Class room Instruction (CI)	Self Learning (SL)
Theory **SO5.1:** Study of consolidation parameters **SO5.2:** explain these are test like- chi square test, students T-test, ANOVA test	**NA**	**5.1:** To brief introduction of consolidation parameters **5.2:** Explain Diffusion parameters **5.3:** Discuss Dissolution parameters and Pharmacokinetic parameters **5.4:** To brief Heckel plots **5.5:** Explain Similarity factors – f2 and f1 **5.6:** Discuss Higuchi and Pappas plot **5.7:** Linearity Concept of significance **5.8:** Standard deviation **5.9:** Chi square test **5.10:** Students T-test and ANOVA test	**5.1:** Explain Similarity factors – f2 and f1 **5.2:** Chi square test, students T-test

Suggested Assignments:-

1. Explain Chi square test, students T-test & ANOVA test.

Brief of Hours suggested for the Course Outcome

Course Out comes	Class Lecture (Cl)	(LI)	Sessional Work (SW)	Self Learning (SL)	Total Hour (Cl+SW+ Sl+LI)
CO-MPH 103T-1: To understand about the Preformation concept of pharmaceutical products.	20	0	2	2	24
CO-MPH 103T-2: To understand about the validation and calibration of master plan, ICH & WHO guidelines of equipment and dosage form.	10	0	1	2	13
CO-MPH 103T-3: To understand about the c-GMP & Industrial Management for layout of buildings, services, equipments and their Production.	10	0	2	2	14
CO-MPH 103T-4: To understand the Compression and compaction of tablets.	10	0	2	2	14
CO-MPH 103T-5: To understand about the consolidation parameters like Diffusion, Dissolution and Pharmacokinetic parameters of pharmaceutical products.	10	0	1	2	13
Total Hours	**60**	**0**	**08**	**10**	**78**

Suggestion for End Semester Assessment

Suggested Specification Table (For ESA)

Course Outcome	Unit Titles	Marks Distribution			Total Marks
		A	C	E	
CO-MPH 103T-1:	To understand about the Preformation concept of pharmaceutical products.	08	07	03	18
CO-MPH 103T-2:	To understand about the validation and calibration of master plan, ICH & WHO guidelines of equipment and dosage form.	12	07	03	22
CO-MPH 103T-3:	To understand about the c-GMP & Industrial Management for layout of buildings, services, equipments and their Production.	12	07	03	22
CO-MPH 103T-4:	To understand the Compression and compaction of tablets.	10	07	03	20
CO-MPH 103T-5:	To understand about the consolidation parameters like Diffusion, Dissolution and Pharmacokinetic parameters of pharmaceutical products.	08	07	03	18
Total		**50**	**35**	**15**	**100**

Legend: A: Analyze, C: create, E: Evaluate

The end of semester assessment for Modern Pharmaceutics will be held with written examination of 75 marks.
Note. Detailed Assessment rubric need to be prepared by the course wise teachers for above tasks.
Teachers can also design different tasks as per requirement, for end semester assessment.

Suggested Instructional/Implementation Strategies:

1. Improved Lecture
2. Tutorial
3. Case Method
4. Group Discussion
5. Role Play
6. Demonstration
7. ICT Based Teaching Learning(Video Demonstration/Tutorials CBT, Blog,Face book, Twitter, Whats app, Mobile, Online sources)
8. Brainstorming

Suggested Learning Resources:

S. No.	Title	Author	Publisher	Edition &Year
1	Theory and Practice of Industrial Pharmacy	Lachmann and Libermann	CBS	Edition -2009
2	Pharmaceutical dosage forms: Tablets	Leon Lachmann.	CBS	2020 Vol. 1-3
3	Pharmaceutical Dosage forms: Disperse systems	Leon Lachmann.	Marcel Dekker Inc	26 aug 2020 Vol, 1-2;
4	Pharmaceutical Dosage forms: Parenteral medications	Leon Lachmann.	Published April 1, 1993 by CRC Press	2018 Vol. 1-2
5	Modern Pharmaceutics	Gillbert and S. Banker	PharmaMed Press / BSP Books.	1 January 2023
6	Pharmaceutical Sciences	Remington's	Elsevier exclusive	23rd edition 2021
7	Advances in Pharmaceutical Sciences	H.S. Bean & A.H. Beckett.	Amidon and Roy	Vol. 1-5 13 June 2022.
8	Physical Pharmacy	Alfred martin	Lippincott Williams and wilkins	8th edition 2023
9	Good manufacturing practices for Pharmaceuticals- A plan for total quality control	Sidney H. Willig	WHO	22 March 2023
10	Drug formulation manual	D.P.S. Kohli and D.H.Shah	Eastern publishers, New Delh	1 January 2023

Curriculum Development Team:

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Course Outcome & Program Outcome Mapping

Course Outcome	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PSO1	PSO2	PSO3	PSO4
	Scientific Knowledge	Technological Application	Modern tool usage	Entrepreneur ship	Practical Skill	Applied Science	Computational and Statistical methodologies	Pharmaceutical Ethics	Environment and sustainability	Life-long learning	Formulation strategies	Emerging science	Computational literacy	Pharmaceutical regulations
CO-MPH 103T-1: Preformation concept of pharmaceutical products	3	2	3	1	3	2	1	3	2	3	3	2	1	2
CO-MPH 103T-2: ICH & WHO guidelines	2	2	3	2	1	3	2	2	1	3	2	3	2	1
CO-MPH 103T-3: c-GMP & Industrial Management	1	2	1	3	3	2	3	3	2	2	2	1	3	3
CO-MPH 103T-4: Compression and compaction of tablets	2	1	3	2	2	3	2	2	2	3	3	2	1	2
CO-MPH 103T-5: Diffusion & Dissolution	3	2	2	1	3	2	3	3	1	2	1	2	2	3

Legend: 1- Low, 2-Medium, 3-High

Course Curriculum Mapping

POs & PSOs No.	COs No. & Title	SOs No.	Class Room Instructions	Laboratory Instructions	Self learning
POs:1,2,3,4,5,6,7,8,9,10 PSOs:1,2,3,4	**CO-MPH 103T-1:** To understand about the Preformation concept of pharmaceutical products	SO1.1 SO1.2 SO1.3 SO1.4 SO1.5 SO1.6	1.1,1.2,1.3,1.4,1.5,1.6,1.7,1.8,1.9,1.10,1.11,1.12,1.13,1.14,1.15,1.16,1.17,1.18,1.19,1.20	-	SL-1.1 SL-1.2
POs:1,2,3,4,5,6,7,8,9,10 PSOs:1,2,3,4	**CO-MPH 103T-2:** To understand about the validation and calibration of master plan, ICH & WHO guidelines of equipment and dosage form	SO2.1 SO2.2 SO2.3 SO2.4 SO2.5	2.1,2.2,2.3,2.4,2.5,2.6,2.7,2.8,2.9,2.10	-	SL-2.1 SL2.2
POs:1,2,3,4,5,6,7,8,9,10 PSOs:1,2,3,4	**CO-MPH 103T -3:** To understand about the c-GMP & Industrial Management for layout of buildings, services, equipments and their Production	SO3.1 SO3.2	3.1,3.2,3.3,3.4,3.5,3.6,3.7,3.8,3.9,3.10	-	SL-3.1 SL-3.2
POs:1,2,3,4,5,6,7,8,9,10 PSOs:1,2,3,4	**CO-MPH 103T-4:** To understand the Compression and compaction of tablets	SO4.1	4.1,4.2,4.3,4.4,4.5,4.6,4.7,4.8,4.9,4.10	-	SL-4.1 SL-4.2
POs:1,2,3,4,5,6,7,8,9,10 PSOs:1,2,3,4	**CO-MPH 103T-5:** To understand about the consolidation parameters like Diffusion, Dissolution and Pharmacokinetic parameters of pharmaceutical products	SO5.1 SO5.2	5.1,5.2,5.3,5.4,5.5,5.6,5.7,5.8,5.9,5.10	-	SL-5.1 SL-5.2

Semester-I

Course Code: MPH 104T

Course Title: Regulatory Affair

Pre-requisite: Student should have basic a knowledge and skills required to learn the concept of generic drug and their development, various regulatory filings in different countries, different phases of clinical trials and submitting regulatory documents: filing process of IND, NDA and ANDA.

Rationale/Objective s:

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

- To know the chemistry, manufacturing controls and their regulatory importance.
- To learn the documentation requirements for Regulatory affairs.
- To learn the importance and objectives.

Course Out comes:

CO-MPH 104T-1: To understand about the Concepts of innovator and generic drugs and drug development process Regulatory guidance's and guidelines for filing and approval process.

CO-MPH 104T-2: To understand about the Submission of global documents in CTD/ e CTD formats and Post approval regulatory requirements for actives and drug products.

CO-MPH 104T-3: To understand about the Preparation of Dossiers and their submission to regulatory agencies in different countries.

CO-MPH 104T-4: To understand about the Pharmacovigilance and process of monitoring in clinical trials.

Scheme of Studies

Course code	Title of the course	Program Name	Total Number of contact hours/Week					Credit
			Classroom Instruction (A)	Practical (P)	SW	SL	Total Hours (H)	
			Lecture					
MPH 104T	Regulatory Affairs	M. Pharmacy	4	0	1	1	6	4

Legend: CI: Classroom Instruction (Includes different instructional strategies i.e. Lecture (L) and Tutorial (T) and other

LI: Laboratory Instruction (Includes Practical performances in laboratory workshop, field or other locations usingdifferent instructional strategies)

SW: Sessional Work (includes assignment, seminar, mini project etc.)

SL: Self Learning, Credits

Note: SW & SL has to be planned and performed under the continuous guidance and feedback of teacher to ensure outcomeof Learning

Theory Assessment

Course Code	Course	Internal Assessment (A)				End Semester Exams (B)		Total Marks (A+B)
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
MPH 104T	Regulatory Affairs	10	15	1 Hr	25	75	3 Hrs	100

Guidelines for the allotment of marks for attendance

Percentage of Attendance	Theory	Practical
95–100	8	10
90–94	6	7.5
85–89	4	5
80–84	2	2.5
Less than 80	0	0

Course-Curriculum Detailing:

This course syllabus illustrates the expected learning achievements, both at the course and session levels, which students are anticipated to accomplish through various modes of instruction including Classroom Instruction (CI), Laboratory Instruction (LI), Sessional Work (SW), and Self Learning (SL). As the course progresses, students should showcase their mastery of Session Outcomes (SOs), culminating in the overall achievement of Course Outcomes (COs) upon the course's conclusion.

Unit I

CO-MPH 104T-1: To understand about the concepts of innovator and generic drugs and drug development process regulatory guidance's and guidelines for filing and approval process.

Item	Approx Hrs
Lecture	12
Practical (P)	0
SW	1
SL	3
Total	16

Session Outcomes (SOs)	Laboratory Instruction (LI)	Class room Instruction (CI)	Self Learning (SL)
Theory **SO1.1:** Documentation in Pharmaceutical industry: Master formula record, DMF (Drug Master File), distribution records. Generic drugs product development **SO1.2:** Introduction to Hatch- Waxman act and amendments, CFR (code of federal regulation), drug product performance **SO1.3:** 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 **SO1.4:** Regulatory requirement for product approval: API, biologics, novel, therapies obtaining NDA, ANDA for generic drugs ways and means of US registration for foreign drugs	**NA**	**1.1:** To brief introduction of Documentation in Pharmaceutical industry **1.2:** Master formula record, DMF (Drug Master File) and distribution records **1.3:** Generic drugs product development **1.4:** Introduction to the Hatch- Waxman act and amendments **1.5:** CFR (code of federal regulation) and drug product performance **1.6:** In-vitro, ANDA regulatory approval process and NDA approval process **1.7:** BE and drug product assessment. **1.8:** In –vivo, scale up process approval changes **1.9:** Post marketing surveillance and Outsourcing BA and BE to CRO **1.10:** Regulatory requirement for product approval- API and biologics **1.11:** Regulatory requirement for product approval and novel **1.12:** Therapies obtaining NDA, ANDA for generic drugs ways and means of US registration for foreign drugs	**1.1:** To learn about Master formula record (MFR) and drug master file (DMF) **1.2:** To learn about CFR (code of federal regulation) and drug product performance **1.3:** To learn about BA and BE to CRO

Suggested Assignments:

1. To create post marketing surveillance, outsourcing BA and BE to CRO.

Unit II

CO-MPH 104T-2: To understand about the Submission of global documents in CTD/ e CTD formats and Post approval regulatory requirements for actives and drug products.

Item	Approx Hrs
Lecture	12
Practical (P)	0
SW	1
SL	3
Total:	16

Session Outcomes (SOs)	Laboratory Instruction (LI)	Class room Instruction (CI)	Self Learning (SL)
Theory **SO2.1:** CMC, post approval regulatory affairs. Regulation for combination products and medical devices **SO2.2:** CTD and E-CTD format, industry and FDA liaison **SO2.3:** ICH - Guidelines of ICH-Q, S E, M. Regulatory requirements of EU, MHRA, TGA and ROW countries	**NA**	**2.1:** To brief introduction chemistry, manufacturing and control (CMC) **2.2:** Post approval regulatory affair. **2.3:** Regulation for combination products **2.4:** Regulation for combination medical devices **2.5:** Common technical document (CTD) and electrical common technical document (E-CTD) format **2.6:** Industry and FDA liaison **2.7:** ICH - Guidelines of regulatory affairs **2.8:** ICH- guideline for Q series QSEM **2.9:** Regulatory requirements of EU countries **2.10:** Regulatory requirements of MHRA countries **2.11:** Regulatory requirements of TGA countries **2.12:** Regulatory requirements of ROW countries	**2.1:** To learn about ICH - Guidelines of ICH- QSEM **2.2:** To learn about CTD and E-CTD format in pharma industry **2.3:** To learn about MHRA countries

Suggested Assignments:

1. Given regulation for combination products and medical devices.

Unit III

CO- MPH 104T-3: To understand about the preparation of dossiers and their submission to regulatory agencies in different countries.

Item	Approx Hrs
Lecture	12
Practical (P)	0
SW	1
SL	4
Total	17

Session Outcomes (SOs)	Laboratory Instruction (LI)	Class room Instruction (CI)	Self Learning (SL)
Theory **SO3.1:** Non clinical drug development: Global submission of IND, NDA, ANDA **SO3.2:** Investigation of medicinal products dossier, dossier (IMPD) and investigator brochure (IB)	**NA**	**3.1:** To brief introduction of Non clinical drug development **3.2:** Importance of Non clinical drug development **3.3:** Advantage and disadvantage of Non clinical drug development **3.4:** Give the introduction of Global submission of IND, NDA, and ANDA **3.5:** Importance of Global submission of IND, NDA and ANDA **3.6:** Advantage and disadvantage of Global submission of IND, NDA, ANDA **3.7:** Global submission of IND **3.8:** Global submission of NDA **3.9:** Global submission of ANDA **3.10:** Investigation of medicinal products dossier **3.11:** Investigation dossier (IMPD) **3.12:** Investigator brochure (IB)	**3.1:** To learn about the Investigation medicinal product dossier (IMPD) **3.2:** To learn about the Investigator brochure (IB) **3.3:** To learn about the ANDA **3.4:** To learn about the Non clinical drug development

Suggested Assignments:

1. Write the notes on Non clinical drug development

Unit IV

CO-MPH 104T-4: To understand about the Pharmacovigilance and process of monitoring in clinical trials.

Item	Approx Hrs
Lecture	12
Practical (P)	0
SW	1
SL	4
Total	17

Session Outcomes (SOs)	Laboratory Instruction (LI)	Class room Instruction (CI)	Self Learning (SL)
Theory **SO4.1:** Clinical trials: Developing clinical trial protocols **SO4.2:** Institutional review board/ independent ethics committee Formulation and working procedures **SO4.3:** Informed Consent process and procedures **SO4.4:** HIPAA- new, requirement to clinical study process, Pharmacovigilence safety monitoring in clinical trials	**NA**	**4.1:** To give the introduction of clinical trials **4.2:** Importance of clinical trials **4.3:** Discuss in detail Developing clinical trial protocols **4.4:** General discussions about Institutional review board **4.5:** Independent ethics committee **4.6:** Describe Formulation and working procedures **4.7:** Informed Consent process and procedures **4.8:** Give the information of HIPAA- new **4.9:** General Requirement to clinical study process **4.10:** Discuss in detail about pharmacovigilance safety **4.11:** Pharmacovigilance safety monitoring in clinical trials **4.12:** Discuss in detail in clinical study process	**4.1:** To learn about the Developing clinical trial protocols **4.2:** To learn about the formulation and working procedures **4.3:** To learn about the safety monitoring in clinical trials **4.4:** To learn about the clinical study

Suggested Assignments:

1. To evaluate Formulation and working procedures of clinical studies.

Brief of Hours suggested for the Course Outcome

Course Out comes	Class Lecture (Cl)	(LI)	Sessional Work (SW)	Self Learning (Sl)	Total Hour (Cl+SW+ Sl+LI)
CO-MPH 104T-1: To understand about the Concepts of innovator and generic drugs and drug development process Regulatory guidance's and guidelines for filing and approval process.	12	0	1	3	16
CO-MPH 104T-2: To understand about the Submission of global documents in CTD/ e CTD formats and Post approval regulatory requirements for actives and drug products.	12	0	1	3	16
CO-MPH 104T-3: To understand about the Preparation of Dossiers and their submission to regulatory agencies in different countries.	12	0	1	4	17
CO-MPH 104T-4: To understand about the Pharmacovigilence and process of monitoring in clinical trials.	12	0	1	4	17
Total Hours	**48**	**0**	**4**	**14**	**66**

Suggestion for End Semester Assessment

Suggested Specification Table (For ESA)

Course Outcome	Unit Titles	Marks Distribution			Total Marks
		A	C	E	
CO-MPH 104T-1:	To understand about the Concepts of innovator and generic drugs and drug development process Regulatory guidance's and guidelines for filing and approval process.	15	06	07	28
CO-MPH 104T-2:	To understand about the Submission of global documents in CTD/ e CTD formats and Post approval regulatory requirements for actives and drug products.	12	07	05	24
CO-MPH 104T-3:	To understand about the Preparation of Dossiers and their submission to regulatory agencies in different countries.	15	06	03	24
CO-MPH 104T-4:	To understand about the Pharmacovigilence and process of monitoring in clinical trials.	10	08	06	24
Total		**52**	**27**	**21**	**100**

Legend: A: Analyze, C: Create, E: Evaluate

The end of semester assessment for Regulatory Affair will be held with written examination of 75 marks.
Note. Detailed Assessment rubric need to be prepared by the course wise teachers for above tasks.
Teachers can also design different tasks as per requirement, for end semester assessment.

Suggested Instructional/Implementation Strategies:

1. Improved Lecture
2. Tutorial
3. Case Method
4. Group Discussion
5. Role Play
6. Demonstration
7. ICT Based Teaching Learning(Video Demonstration/Tutorials CBT, Blog,Face book, Twitter, Whats app, Mobile, Online sources)
8. Brainstorming

Suggested Learning Resources:

S. No.	Title	Author	Publisher	Edition & Year
1.	Generic Drug Product Development and Solid Oral Dosage forms	Leon Shargel and Isader Kaufer,	Publisher by Marcel Dekker series,	Vol.143 2ed Vol 212 (2020)
2.	The Pharmaceutical Regulatory Process, (Drugs and the Pharmaceutical Science)	Ira R. Berry and Robert P.Martin	Publisher by Informa Health care Publishers	2nd **Edition** - 2 December 2008 - Vol.185
3.	New Drug Approval Process: Accelerating Global Registrations	Richard A Guarino, MD	Publisher By Accelerating Global Registrations	7th edition Year: 2017.
4.	Guidebook for drug regulatory submissions / Sandy Weinberg	Weinberg, Sandy	Publisher By John Wiley & Sons.Inc	2009. Edition
5.	FDA regulatory affairs: a guide for prescription drugs, medical devices, and biologics	DOUGLAS J. PISANO	Publisher By Douglas J. Pisano, David Mantus.	11 Jan 2024
6.	Clinical Trials and Human Research: A Practical Guide to Regulatory Compliance	Rodney K. Adams	Published by Jossey-Bass	1st Edition (2023).

Journals

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

Curriculum Development Team:

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Course Outcome & Program Outcome Mapping

Course Outcome	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PSO1	PSO2	PSO3	PSO4
	Scientific Knowledge	Technological Application	Modern tool usage	Entrepreneurship	Practical Skill	Applied Science	Computational and Statistical methodologies	Pharmaceutical Ethics	Environment and sustainability	Life-long learning	Formulation strategies	Emerging science	Computational literacy	Pharmaceutical regulations
CO-MPH 104T-1: Generic drugs and drug development process Regulatory guidance's	2	1	3	2	3	2	1	3	2	3	3	2	1	2
CO-MPH 104T-2: Global documents in CTD/ e CTD formats	3	2	3	2	1	3	2	1	1	3	2	3	2	1
CO-MPH 104T-3: Preparation of Dossiers	3	2	1	3	3	2	3	3	3	2	2	1	3	3
CO-MPH 104T-4: Pharmacovigilance and process of monitoring	1	1	3	2	2	3	2	2	2	3	3	2	1	2

Legend: 1- Low, 2-Medium, 3-High

Course Curriculum Mapping

POs & PSOs No.	COs No. & Title	SOs No.	Class Room Instructions	Laboratory Instructions	Self learning
POs:1,2,3,4,5,6,7,8,9,10 PSOs:1,2,3,4	**CO-MPH 104T-1:** To understand about the concepts of innovator and generic drugs and drug development process Regulatory guidance's and guidelines for filing and approval process	SO1.1 SO1.2 SO1.3 SO1.4	1.1,1.2,1.3,1.4,1.5,1.6,1.7 ,1.8,1.9,1.10,1.11,1.12	-	SL-1.1 SL-1.2 SL-1.3
POs:1,2,3,4,5,6,7,8,9,10 PSOs:1,2,3,4	**CO-MPH 104T-2:** To understand about the submission of global documents in CTD/ e CTD formats and Post approval regulatory requirements for actives and drug products	SO2.1 SO2.2 SO2.3	2.1,2.2,2.3,2.4,2.5,2.6,2.7 ,2.8,2.9,2.10,2.11,2.12	-	SL-2.1 SL-2.2 SL-2.3
POs:1,2,3,4,5,6,7,8,9,10 PSOs:1,2,3,4	**CO-MPH 104T-3**: To understand about the Preparation of Dossiers and their submission to regulatory agencies in different countries	SO3.1 SO3.2	3.1,3.2,3.3,3.4,3.5,3.6,3.7 ,3.8,3.9,3.10,3.11,3.12	-	SL-3.1 SL-3.2 SL-3.3 SL-3.4
POs:1,2,3,4,5,6,7,8,9,10 PSOs:1,2,3,4	**CO-MPH 104T-4:** To understand about the Pharmacovigilence and process of monitoring in clinical trials	SO4.1 SO4.2 SO4.3 SO4.4	4.1,4.2,4.3,4.4,4.5,4.6,4.7 ,4.8,4.9,4.10,4.11,4.12	-	SL-4.1 SL-4.2 SL-4.3 SL-4.4

A K S University

Faculty of Pharmaceutical Science & Technology
Rajiv Gandhi Institute of Pharmacy
Curriculum of M. Pharmacy (Pharmaceutics-MPH) Program
(Revised as on 01 August 2023)

Semester-I

Course Code: MPH 105P
Course Title: Pharmaceutics Practical - I

Practical Assessment

Course Code	Course	Internal Assessment (A)				End Semester Exams (B)		Total Marks (A+B)
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
MPH 105P	Pharmaceutics Practical - I	20	30	6 Hrs	50	100	6 Hrs	150

S. No.	List of Practicals
1.	Analysis of pharmacopoeial compounds and their formulations by UV Vis spectrophotometer.
2.	Simultaneous estimation of multi component containing formulations by UV spectrophotometry.
3.	Experiments based on HPLC.
4.	Experiments based on Gas Chromatography.
5.	Estimation of riboflavin/quinine sulphate by fluorimetry.
6.	Estimation of sodium/potassium by flame photometry.
7.	To perform In-vitro dissolution profile of CR/ SR marketed formulation.
8.	Formulation and evaluation of sustained release matrix tablets.
9.	Formulation and evaluation osmotically controlled DDS.
10.	Preparation and evaluation of Floating DDS- hydro dynamically balanced DDS
11.	Formulation and evaluation of Muco adhesive tablets.
12.	Formulation and evaluation of trans dermal patches.
13.	To carry out preformulation studies of tablets.
14.	To study the effect of compressional force on tablets disintegration time.
15.	To study Micromeritic properties of powders and granulation.
16.	To study the effect of particle size on dissolution of a tablet.
17.	To study the effect of binders on dissolution of a tablet.
18.	To plot Heckal plot, Higuchi and peppas plot and determine similarity factors.

A K S University

Faculty of Pharmaceutical Science & Technology
Rajiv Gandhi Institute of Pharmacy
Curriculum of M. Pharmacy (Pharmaceutics-MPH) Program
(Revised as on 01 August 2023)
Semester-II

Course Code: MPH 201T
Course Title: Molecular Pharmaceutics (Nano Technology & Targeted DDS) (NTDS)

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

Rationale/Objectives: Upon completion of this course it is expected that students will be able to understand

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

Course Outcomes:

CO-MPH 201T-1: To understand the target Drug Delivery System.

CO-MPH 201T-2: To understand targeting method.

CO-MPH 201T-3: To understand the micro capsule /micro sphere.

CO-MPH 201T-4: To understand the pulmonary Drug Delivery System.

CO-MPH 201T-5: To understand nucleic acid based therapeutic delivery system.

Scheme of Studies

Course code	Title of the course	Program Name	Total Number of contact hours/Week					Credit
			Class room Instruction (A)	Practical (P)	SW	SL	Total Hours	
			Lecture				(H)	
MPH 201T	Molecular Pharmaceutics (Nano Technology & Targeted DDS) (NTDS)	M. Pharmacy	4	-	1	1	6	4

Legend: CI: Classroom Instruction (Includes different instructional strategies i.e. Lecture (L) and Tutorial (T) and other
LI: Laboratory Instruction (Includes Practical performances in laboratory workshop, field or other locations using different instructional strategies)
SW: Sessional Work (includes assignment, seminar, mini project etc.)
SL: Self Learning, Credits
Note: SW & SL has to be planned and performed under the continuous guidance and feedback of teacher to ensure outcome of Learning

Theory Assessment

Course Code	Course	Internal Assessment (A)				End Semester Exams (B)		Total Marks (A+B)
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
MPH 201T	Molecular Pharmaceutics (Nano Technology & Targeted DDS) (NTDS)	10	15	1 Hr	25	75	3Hrs.	100

Guidelines for the allotment of marks for attendance

Percentage of Attendance	Theory	Practical
95–100	8	10
90–94	6	7.5
85–89	4	5
80–84	2	2.5
Less than 80	0	0

Course-Curriculum Detailing:

This course syllabus illustrates the expected learning achievements, both at the course and session levels, which students are anticipated to accomplish through various modes of instruction including Classroom Instruction (CI), Laboratory Instruction (LI), Sessional Work (SW), and Self Learning (SL). As the course progresses, students should showcase their mastery of Session Outcomes (SOs), culminating in the overall achievement of Course Outcomes (COs) upon the course's conclusion.

Unit I

CO-MPH 201T-1: To understand the Target Drug Delivery System.

Item	Approx Hrs
Lecture	12
Practical (P)	0
SW	4
SL	4
Total	20

Session Outcomes (SOs)	Laboratory Instruction (LI)	Classroom Instruction (CI)	Self Learning (SL)
Theory **SO1.1:** Targeted Drug Delivery Systems: Concepts, Events **SO1.2:** Biological process involved in drug targeting	**NA**	**1.1:** Introduction to TDDS **1.2:** Objectives of TDDS **1.3:** Ideal characteristics of TDDS **1.4:** Advantages of TDDS **1.5:** Disadvantages of TDDS **1.6:** Concepts of TDDS **1.7:** Types of TDDS **1.8:** Strategies of drug targeting **1.9:** Targeted Drug Delivery Systems events **1.10:** Biological process involved in drug targeting **1.11:** Tumor targeting **1.12:** Brain specific delivery	**1.1:** Study of Targeted Drug Delivery Systems **1.2:** Concepts, Events and biological process involved in drug targeting **1.3:** Tumor targeting. **1.4:** Brain specific delivery

Suggested Assignments:

1. Explain targeted Drug Delivery Systems
2. Given targeted Drug Delivery Systems events.
3. Discuss about biological process involved in drug targeting.
4. Write brain specific delivery.

Unit II

CO-MPH 201T-2: To understand targeting method.

Item	Approx Hrs
Lecture	12
Practical (P)	0
SW	4
SL	4
Total	20

Session Outcomes (SOs)	Laboratory Instruction (LI)	Classroom Instruction (CI)	Self Learning (SL)
Theory **SO2.1:** Targeting Methods	**NA**	**2.1:** Targeting Methods **2.2:** Targeting Methods: Introduction **2.3:** Targeting Methods: Preparation **2.4:** Targeting Methods: Evaluation **2.5:** Nano Particle **2.6:** Liposome **2.7:** Liposomes: Types **2.8:** Liposomes: preparation **2.9:** Liposomes: evaluation **2.10:** Strategies of drug targeting **2.11:** Ideal Properties of Nano particles **2.12:** Advantages & disadvantages of Nano particles	**2.1:** Study of Targeting Methods: introduction **2.2:** Nano Particle **2.3:** Liposome **2.4:** Liposomes: preparation

Suggested Assignments:

1. Explain targeting Methods: introduction.
2. Given targeting Methods: Preparation.
3. Write nano particle.
4. Given types & evaluation of liposomes.

Unit III

CO-MPH 201T-3: To understand the micro capsule /micro sphere.

Item	Approx Hrs
Lecture	12
Practical (P)	0
SW	1
SL	1
Total	14

Session Outcomes (SOs)	Laboratory Instruction (LI)	Classroom Instruction (CI)	Self Learning (SL)
Theory **SO3.1:** Micro Capsules	**NA**	**3.1:** Micro Capsules **3.2:** Micro Spheres **3.3:** Micro Capsules: Types, preparation **3.4:** Micro Capsules: evaluation **3.5:** Micro Spheres: Types **3.6:** Micro Spheres: preparation, evaluation **3.7:** Monoclonal Antibodies **3.8:** Monoclonal Antibodies **3.9:** Monoclonal Antibodies **3.10:** Applications, preparation **3.11:**Applications of Niosomes, Aquasomes **3.12:** Applications of Phytosomes, Electrosomes	**3.1:** Study of Monoclonal Antibodies

Suggested Assignments:

1. Explain Micro Capsules / Micro Spheres: Types, preparation and evaluation.

Unit IV

CO-MPH 201T-4: To understand the pulmonary drug delivery system.

Item	Approx Hrs
Lecture	12
Practical (P)	0
SW	3
SL	3
Total	18

Session Outcomes (SOs)	Laboratory Instruction (LI)	Classroom Instruction (CI)	Self Learning (SL)
Theory **SO4.1:** Pulmonary Drug Delivery Systems **SO4.2:** Aerosols, propellents, Containers Types. **SO4.3:** Preparation and evaluation, Intra Nasal Route Delivery	**NA**	**4.1:** Pulmonary Drug Delivery Systems **4.2:** Advantages & disadvantages of PDDS **4.3:** Applications of PDDS **4.4:** Aerosols **4.5:** Propellants **4.6:** Containers Types **4.7:** Preparation **4.8:** Evaluation **4.9:** Intra Nasal Route Delivery systems **4.10:** Intra Nasal Route Delivery systems: Types **4.11:** Intra Nasal Route Delivery systems: preparation **4.12:** Intra Nasal Route Delivery systems: evaluation	**4.1:** Study of pulmonary drug delivery systems **4.1:** Study of Intra Nasal Route Delivery systems; Types, preparation and evaluation **4.3:** Study of Containers Types, preparation

Suggested Assignments:

1. Explain Pulmonary Drug Delivery Systems.
2. Discuss about aerosols.
3. Write intra Nasal Route Delivery systems; Types, preparation and evaluation.

Unit V

CO-MPH 201T-5: To understand nucleic acid based therapeutic delivery system.

Item	Approx Hrs
Lecture	12
Practical (P)	0
SW	3
SL	3
Total	18

Session Outcomes (SOs)	Laboratory Instruction (LI)	Classroom Instruction (CI)	Self Learning (SL)
Theory **SO5.1:** Nucleic acid based therapeutic delivery system	**NA**	**5.1:** Nucleic acid based therapeutic delivery system **5.2:** Differentiations of types of gene therapy **5.3:** Gene therapy **5.4:** Introduction (ex-vivo & in-vivo gene therapy) **5.5:** Types of somatic cell gene therapy **5.6:** Potential target diseases for gene therapy (inherited disorder and cancer). **5.7:** Gene expression systems (viral and non-viral gene transfer) **5.8:** Liposomal gene delivery systems. **5.9:** Bio-distribution and Pharmacokinetics **5.10:** Knowledge of therapeutic antisense **5.11:** Molecules as drugs of future **5.12:** Aptamers as drugs of future	**5.1:** Study of Nucleic acid based therapeutic delivery system **5.2:** Study of Gene therapy, introduction (ex-vivo & in-vivo gene therapy) **5.3:** Study of Gene expression systems (viral and non-viral gene)

Suggested Assignments:

1. Explain Potential target diseases for gene therapy (inherited disorder and cancer).
2. Discuss about Gene expression systems (viral and non-viral gene transfer).
3. Write Liposomal gene delivery systems. Bio-distribution and Pharmacokinetics.

Brief of Hours suggested for the Course Outcome

Course Outcomes	Class Lecture (Cl)	(LI)	Sessional Work (SW)	Self Learning (Sl)	Total Hour (Cl+SW+ Sl+LI)
CO-MPH 201T-1: To understand the target Drug Delivery System.	12	0	4	4	20
CO-MPH 201T-2: To understand targeting method.	12	0	4	4	20
CO-MPH 201T-3: To understand the micro capsule /micro sphere.	12	0	1	1	14
CO-MPH 201T-4: To understand the pulmonary Drug Delivery System	12	0	3	3	18
CO-MPH 201T-5: To understand nucleic acid based therapeutic delivery system.	12	0	3	3	18
Total Hours	**60**	**0**	**15**	**15**	**90**

Suggestion for End Semester Assessment

Suggested Specification Table (For ESA)

Course Outcome	Unit Title	Marks Distribution			Total Marks
		A	C	E	
CO-MPH 201T-1:	To understand the target Drug Delivery System	08	06	01	15
CO-MPH 201T-2:	To understand targeting method	12	07	01	20
CO-MPH 201T-3:	To understand the micro capsule/micro sphere	08	06	02	16
CO-MPH 201T-4:	To understand the pulmonary Drug Delivery System	10	02	03	15
CO-MPH 201T-5:	To understand nucleic acid based therapeutic delivery system	20	09	05	34
Total		**58**	**30**	**12**	**100**

Legend: A: Analyze, C: Create, E: Evaluate

The end of semester assessment for Molecular Pharmaceutics (Nano Technology & Targeted DDS) (NTDS) will be held with written examination of 75 marks.

Note. Detailed Assessment rubric need to be prepared by the course wise teachers for above tasks.
Teachers can also design different tasks as per requirement, for end semester assessment.

Suggested Instructional/Implementation Strategies:

1. Improved Lecture
2. Tutorial
3. Case Method
4. Group Discussion
5. Role Play
6. Demonstration
7. ICTBasedTeachingLearning(Video Demonstration/TutorialsCBT,Blog,Facebook,Twitter,Whatsapp,Mobile, Onlinesources)
8. Brainstorming

Suggested Learning Resources:

S. No.	Title	Author	Publisher	Edition & Year
1	Novel Drug Delivery Systems	Y W. Chien	revised and expanded, Marcel Dekker, Inc., New York,	2nd edition/1992.
2	Controlled Drug Delivery	S.P.Vyas and R.K.Khar,	Ballabh PrakashanNew Delhi,	First edition 2002.
3	Controlled and Novel Drug Delivery	N.K. Jain	CBS Publishers & Distributors, NewDelhi,	First edition 1997 (reprint in 2001).

Curriculum Development Team:

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Course Outcome & Program Outcome Mapping

Course Outcome	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PSO1	PSO2	PSO3	PSO4
	Scientific Knowledge	Technological Application	Modern tool usage	Entrepreneur ship	Practical Skill	Applied Science	Computational and Statistical methodologies	Pharmaceutical Ethics	Environment and sustainability	Life-long learning	Formulation strategies	Emerging science	Computational literacy	Pharmaceutical regulations
CO-MPH 201T-1: Target Drug Delivery System	3	2	3	1	3	2	1	3	2	3	3	2	3	1
CO-MPH 201T-2: Targeting method	2	2	3	2	1	3	2	2	1	3	2	3	2	2
CO-MPH 201T-3: Micro capsule/Micro sphere	1	2	1	3	3	2	3	3	2	2	2	3	3	1
CO-MPH 201T-4: Pulmonary Drug Delivery System	2	1	3	2	2	3	2	2	2	3	1	2	3	2
CO-MPH 201T-5: Nucleic acid based therapeutic delivery system	3	2	2	1	3	2	3	3	1	2	2	2	3	3

Legend: 1- Low, 2-Medium, 3-High

Course Curriculum Mapping

POs & PSOs No.	COs No. & Title	SOs No.	Class Room Instructions	Laboratory Instructions	Self learning
POs:1,2,3,4,5,6,7,8,9,10 PSOs:1,2,3,4	**CO-MPH 201T-1:** To understand the target Drug Delivery System.	SO1.1 SO1.2	1.1,1.2,1.3,1.4,1.5,1.6	_	SL-1.1 SL-1.2 SL-1.3 SL-1.4
POs:1,2,3,4,5,6,7,8,9,10 PSOs:1,2,3,4	**CO-MPH 201T-2:** To understand targeting method.	SO-2.1	2.1,2.2,2.3,2.4,2.5,2.6, 2.7,2.8,2.9	--	SL-2.1 SL-2.2 SL-2.3 SL-2.4
POs:1,2,3,4,5,6,7,8,9,10 PSOs:1,2,3,4	**CO-MPH 201T-3:** To understand the micro capsule /micro sphere.	SO-3.1	3.1,3.2,3.3,3.4,3.5,3.6, 3.7,3.8,3.9,3.10,3.11,3 .12	--	SL-3.1
POs:1,2,3,4,5,6,7,8,9,10 PSOs:1,2,3,4	**CO-MPH 201T-4:** To understand the pulmonary Drug Delivery System.	SO-4.1 SO-4.2 SO-4.3	4.1,4.2,4.3,4.4,4.5,4.6, 4.7,4.8,4.9,4.10	--	SL-4.1 SL-4.2 SL-4.3
POs:1,2,3,4,5,6,7,8,9,10 PSOs:1,2,3,4	**CO-MPH 201T-5:** To understand nucleic acid based therapeutic delivery system.	SO-5.1	5.1,5.2,5.3,5.4,5.5,5.6, 5.7,5.8,5.9,5.10	--	SL-5.1 SL-5.2 SL-5.3

A K S University

Faculty of Pharmaceutical Science & Technology
Rajiv Gandhi Institute of Pharmacy
Curriculum of M. Pharmacy (Pharmaceutics-MPH) Program
(Revised as on 01 August 2023)
Semester-II

Course Code: MPH 202T

Course Title: Advanced Biopharmaceutics & Pharmacokinetics

Pre-requisite: This course is designed to impart knowledge on the area of advances in Novel drug delivery systems.

Rationale/Objectives: Upon completion of this course it is expected that students will be able understand,

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

Course Outcomes:

CO-MPH 202T-1: The basic concepts in biopharmaceutics and pharmacokinetics.

CO-MPH 202T-2: The use raw data and derive the pharmacokinetic models and parameters the best describe the process of drug absorption, distribution, metabolism and elimination.

CO-MPH 202T-3: The critical evaluation of biopharmaceutic studies involving drug product equivalency.

CO-MPH 202T-4: The design and evaluation of dosage regimens of the drugs using pharmacokinetic and biopharmaceutic parameters.

CO-MPH 202T-5: The potential clinical pharmacokinetic problems and application of basics of pharmacokinetic.

Scheme of Studies

Course code	Title of the course	Program Name	Total Number of contact hours/Week					Credit
			Class room Instruction (A) Lecture	Practical (P)	SW	SL	Total Hours (H)	
MPH 202T	Advanced Biopharmaceutics & Pharmacokinetics	M. Pharmacy	4	-	1	1	6	4

Legend: CI: Class room Instruction (Includes different instructional strategies i.e. Lecture (L) and Tutorial (T) and others

LI: Laboratory Instruction (Includes Practical performances in laboratory workshop, field or other locations using different instructional strategies)

SW: Sessional Work **(**includes assignment**,** seminar, and mini project etc.)

SL: Self Learning, Credits

Note: SW& SL has to be planned and performed under the continuous guidance and feedback of teacher to ensure outcome of Learning

Theory Assessmen

Course Code	Course	Internal Assessment (A)				End Semester Exams (B)		Total Marks (A+B)
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
MPH 202T	Advanced Biopharmaceutics & Pharmacokinetics	10	15	1 Hr	25	75	3Hrs.	100

Guidelines for the allotment of marks for attendance

Percentage of Attendance	Theory	Practical
95–100	8	10
90–94	6	7.5
85–89	4	5
80–84	2	2.5
Less than 80	0	0

Course-Curriculum Detailing:

This course syllabus illustrates the expected learning achievements, both at the course and session levels, which students are anticipated to accomplish through various modes of instruction including Classroom Instruction (CI), Laboratory Instruction (LI), Sessional Work (SW), and Self Learning (SL). As the course progresses, students should showcase their mastery of Session Outcomes (SOs), culminating in the overall achievement of Course Outcomes (COs) upon the course's conclusion.

Unit I

CO-MPH 202T-1: The basic concepts in biopharmaceutics and pharmacokinetics.

Item	Approx Hrs
Lecture	12
Practical (P)	0
SW	2
SL	4
Total	18

Session Outcomes (SOs)	Laboratory Instruction (LI)	Classroom Instruction (CI)	Self Learning (SL)
Theory **SO1.1:** Drug absorption from the Gastrointestinal Tract **SO1.2:** Formulation and physicochemical factors **SO1.3:** Gastrointestinal Absorption **SO1.4:** Transport model	**NA**	**1.1:** Gastrointestinal tract, Mechanism of drug absorption **1.2:** Factors affecting drug absorption pH– partition theory of drug absorption. **1.3:** Dissolution rate **1.4:** Dissolution process, Noyes–Whitney equation and drug dissolution **1.5:** Role of the dosage form: Solution (elixir, syrup and solution) as a dosage form, Suspension as a dosage form **1.6:** Capsule as a dosage form, Tablet as a dosage form, Dissolution methods **1.7:** Formulation and processing factors **1.8:** Correlation of in vivo data with in vitro dissolution data **1.9:** Transport model **1.10:** Permeability-Solubility-Charge State and the pH Partition Hypothesis **1.11:** Properties of the Gastrointestinal Tract (GIT), pH Microclimate Intracellular pH Environment **1.12:** Tight-Junction Complex	**1.1:** Study of drug absorption from the Gastrointestinal Tract **1.2:** Study of formulation and physicochemical factors **1.3:** Study of Gastrointestinal Absorption **1.4:** Study of Transport model

Suggested Assignments:

1. Explain drug absorption from the gastrointestinal tract.
2. Discuss about role of dosage form.

Unit II

CO-MPH 202T-2: The use raw data and derive the pharmacokinetic models and parameters the best describe the process of drug absorption, distribution, metabolism and elimination.

Item	Approx Hrs
Lecture	12
Practical (P)	0
SW	2
SL	2
Total	16

Session Outcomes (SOs)	Laboratory Instruction (LI)	Classroom Instruction (CI)	Self Learning (SL)
Theory **SO2.1:** Biopharmaceutic considerations in drug product design and In Vitro Drug Product Performance	**NA**	**2.1:** Introduction of Biopharmaceutics **2.2:** Scope of Biopharmaceutics **2.3:** Biopharmaceutic factors affecting drug bioavailability **2.4:** Rate-limiting steps in drug absorption **2.5:** Physicochemical nature of the drug formulation **2.6:** Factors affecting drug product performance **2.7:** In vitro. dissolution and drug release testing **2.8:** Compendial methods of dissolution **2.9:** Alternative methods of dissolution testing **2.10:** Meeting dissolution requirements **2.11:** Problems of variable control in dissolution testing **2.12:** Performance of drug products	**2.1:** Study of Biopharmaceutic considerations in drug product design and In Vitro Drug Product Performance Introduction **2.2:** Biopharmaceutic factors affecting drug bioavailability, rate-limiting steps in drug absorption

Suggested Assignments:

1. Explain In vitro dissolution and drug release testing.
2. Explain dissolution requirements of biopharmaceutic considerations in drug product design.

Unit III

CO-MPH 202T-3: The critical evaluation of biopharmaceutic studies involving drug product equivalency.

Item	Approx Hrs
Lecture	12
Practical (P)	0
SW	2
SL	2
Total	16

Session Outcomes (SOs)	Laboratory Instruction (LI)	Classroom Instruction (CI)	Self Learning (SL)
Theory **SO3.1:** Pharmacokinetics **SO3.2:** Drug interactions	**NA**	**3.1:** Basic considerations, pharmacokinetic models **3.2:** compartment modeling: one compartment model- IV bolus **3.3:** IV infusion, extra-vascular **3.4:** Multi compartment model **3.5:** Two compartment - model in brief, non-linear **3.6:** Pharmacokinetics: cause of non-linearity **3.7:** Michaelis - Menten equation, estimation of K_{max} and V_{max} **3.8:** Drug interactions: introduction **3.9:** The effect of protein- binding interactions **3.10:** The effect of tissue-binding interactions **3.11:** Cytochrome p450-based drug interactions **3.12:** Drug interactions linked to transporters	**3.1:** Study of Pharmacokinetics **3.2:** Study of Drug interactions

Suggested Assignments:

1. Define Pharmacokinetics.
2. Given note on Drug interactions.

Unit IV

CO-MPH 202T-4: The design and evaluation of dosage regimens of the drugs using pharmacokinetic and biopharmaceutic parameters.

Item	Approx Hrs
Lecture	12
Practical (P)	0
SW	2
SL	1
Total	15

Session Outcomes (SOs)	Laboratory Instruction (LI)	Classroom Instruction (CI)	Self Learning (SL)
Theory **SO4.1:** Drug Product Performance, InVivo: Bioavailability and Bioequivalence	**NA**	**4.1:** Drug product performance **4.2:** Purpose of bioavailability studies **4.3:** Relative and absolute availability **4.4:** Methods for assessing bioavailability, bioequivalence studies **4.5:** Design and evaluation of bioequivalence studies **4.6:** Study designs **4.7:** Crossover study designs, evaluation of the data **4.8:** Bioequivalence example, study submission and drug review process **4.9:** Biopharmaceutics classification system, methods **4.10:** Permeability: In-vitro, in-situ and In-vivo methods generic biologics (biosimilar drug products) **4.11:** Clinical significance of bioequivalence studies **4.12:** Special concerns in bioavailability and bioequivalence studies, generic substitution	**4.1:** Study of Drug Product Performance, InVivo Bioavailability and Bioequivalence

Suggested Assignments:

1. Explain biopharmaceutics classification system (BCS) & its methods.
2. Discuss about clinical significance of bioequivalence studies.

Unit V

CO-MPH 202T-5: The potential clinical pharmacokinetic problems and application of basics of pharmacokinetic.

Item	Approx Hrs
Lecture	12
Practical (P)	0
SW	1
SL	1
Total	17

Session Outcomes (SOs)	Laboratory Instruction (LI)	Classroom Instruction (CI)	Self Learning (SL)
Theory **SO5.1:** Applications of Pharmacokinetics	**NA**	**5.1:** Modified-Release Drug Products **5.2:** Targeted Drug Delivery Systems **5.3:** Biotechnological Products **5.4:** Introduction to Pharmacokinetics **5.5:** Introduction to pharmacodynamic **5.6:** Drug interactions **5.7:** Pharmacokinetics and pharmacodynamics of biotechnology drugs **5.8:** Introduction, Proteins and peptides **5.9:** Monoclonal antibodies **5.10:** Oligonucleotides **5.11:** Vaccines (immunotherapy) **5.12:** Gene therapies	**5.1:** Study of Introduction to Pharmacokinetics, pharmacodynamic & drug interactions

Suggested Assignments:

1. Explain application of pharmacokinetics.

Brief of Hours suggested for the Course Outcome

Course Outcomes	Class Lecture (Cl)	(LI)	Sessional Work (SW)	Self Learning (Sl)	Total Hour (Cl+SW+ Sl+LI)
CO-MPH 202T-1: The basic concepts in biopharmaceutics and pharmacokinetics.	12	0	2	4	18
CO-MPH 202T-2: The use raw data and derive the pharmacokinetic models and parameters the best describe the process of drug absorption, distribution, metabolism and elimination.	12	0	2	2	16
CO-MPH 202T-3: The critical evaluation of biopharmaceutic studies involving drug product equivalency.	12	0	2	2	16
CO-MPH 202T-4: The design and evaluation of dosage regimens of the drugs using pharmacokinetic and biopharmaceutic parameters.	12	0	2	1	15
CO-MPH 202T-5: The potential clinical pharmacokinetic problems and application of basics of pharmacokinetic.	12	0	1	1	14
Total Hours	**60**	**0**	**9**	**10**	**79**

Suggestion for End Semester Assessment

Suggested Specification Table (For ESA)

Course Outcome	Unit Title	Marks Distribution			Total Marks
		A	C	E	
CO-MPH 202T-1:	The basic concepts in biopharmaceutics and pharmacokinetics.	08	06	01	15
CO-MPH 202T-2:	The use raw data and derive the pharmacokinetic models and parameters the best describe the process of drug absorption, distribution, metabolism and elimination.	12	07	01	20
CO-MPH 202T-3:	The critical evaluation of biopharmaceutic studies involving drug product equivalency.	08	06	02	16
CO-MPH 202T-4:	The design and evaluation of dosage regimens of the drugs using pharmacokinetic and biopharmaceutic parameters.	12	02	03	17
CO-MPH 202T-5:	The potential clinical pharmacokinetic problems and application of basics of pharmacokinetic.	20	09	03	32
Total		**60**	**30**	**10**	**100**

Legend: A: Analyze, C: Create, E: Evaluate

The end of semester assessment for Advanced Biopharmaceutics & Pharmacokinetics will be held with written examination of 75 marks.

Note. Detailed Assessment rubric need to be prepared by the course wise teachers for above tasks. Teachers can also design different tasks as per requirement, for end semester assessment.

Suggested Instructional/Implementation Strategies:

1. Improved Lecture
2. Tutorial
3. CaseMethod
4. GroupDiscussion
5. RolePlay
6. Demonstration
7. ICTBasedTeachingLearning(VideoDemonstration/TutorialsCBT,Blog, Facebook,Twitter,Whatsapp,Mobile,Onlinesources)
8. Brainstorming

Suggested Learning Resources:

S. No.	Title	Author	Publisher	Edition & Year
1	Biopharmaceutics and Clinical Pharmacokinetics.	Milo Gibald	Philadelphia : Lea & Febiger	4th volume, 2020
2	Biopharmaceutics and Pharmacokinetics,	DM Brahmankar & Sunil B.Jaiswal	vallabh prakashan	3rd edi,2019
3	Applied Biopharmaceutics & Pharmacokinetics,	Leon Shargel, Andrew B.C.	Yu McGraw-Hill Education	Seventh Edition, Aug 28**,** 2015
4	Textbook of Biopharmaceutics and Pharmacokinetics.	Dr.Shaik Harun Rasheed	As Per the Latest Syllabus of Pharmacy Council of India (PCI)	2020 Edition,1 January 2020
5	Handbook of Basic Pharmacokinetics	Milo Gibaldi and D. Perrier	Marcel Dekker Inc.,New York	7th Edition Published: January 2009
6	Clinical Pharmacokinetics, Concepts and Applications	Malcolm Rowland, Thomas N. Tozer	Lippincott Williams and Wilkins	4th edition (5 February 2010)
7	Dissolution, Bioavailability and Bioequivalence,	Hamed M. Abdou.	Mack Publishing Company: Easton, PA,	1989

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Course Outcome & Program Outcome Mapping

Course Outcome	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PSO1	PSO2	PSO3	PSO4
	Scientific Knowledge	Technological Application	Modern tool usage	Entrepreneur ship	Practical Skill	Applied Science	Computational and Statistical methodologies	Pharmaceutical Ethics	Environment and sustainability	Life-long learning	Formulation strategies	Emerging science	Computational literacy	Pharmaceutical regulations
CO-MPH 202T-1: Biopharmaceutics and pharmacokinetics	3	2	3	1	3	2	1	3	2	3	3	2	3	1
CO-MPH 202T-2: Pharmacokinetic models	2	2	3	2	1	3	2	2	1	3	2	3	2	2
CO-MPH 202T-3: Evaluation of biopharmaceutic studies	1	2	1	3	3	2	3	3	2	2	2	3	3	1
CO-MPH 202T-4: Evaluation of dosage regimens	2	1	3	2	2	3	2	2	2	3	1	2	3	2
CO-MPH 202T-5: Clinical Pharmacokinetic	3	2	2	1	3	2	3	3	1	2	2	2	3	3

Legend: 1- Low, 2-Medium, 3-High

Course Curriculum Mapping

POs & PSOs No.	Cos No. & Title	SOs No.	Class Room Instructions	Laboratory Instructions	Self learning
POs:1,2,3,4,5,6,7,8,9,10 PSOs:1,2,3,4	**CO-MPH 202T-1:** The basic concepts in biopharmaceutics and pharmacokinetics.	SO1.1 SO1.2 SO1.3 SO1.4	1.1,1.2,1.3,1.4,1.5,1.6,1.7,1.8,1.9,1.10,1.11,1.12	--	SL-1.1 SL-1.2 SL-1.3 SL-1.4
POs:1,2,3,4,5,6,7,8,9,10 PSOs:1,2,3,4	**CO-MPH 202T-2:** The use raw data and derive the pharmacokinetic models and parameters the best describe the process of drug absorption, distribution, metabolism and elimination.	SO2.1	2.1,2.2,2.3,2.4,2.5,2.6,2.7,2.8,2.9	--	SL-2.1 SL-2.2
POs:1,2,3,4,5,6,7,8,9,10 PSOs:1,2,3,4	**CO-MPH 202T-3:** The critical evaluation of biopharmaceutic studies involving drug product equivalency.	SO3.1 SO3.2	3.1,3.2,3.3,3.4,3.5,3.6,3.7,3.8,3.9,3.10,3.11	--	SL-3.1 SL-3.2
POs:1,2,3,4,5,6,7,8,9,10 PSOs:1,2,3,4	**CO-MPH 202T-4:** The design and evaluation of dosage regimens of the drugs using pharmacokinetic and biopharmaceutic parameters.	SO4.1	4.1,4.2,4.3,4.4,4.5,4.6,4.7,4.8,4.9,4.10,4.11,4.12	--	SL-4.1
POs:1,2,3,4,5,6,7,8,9,10 PSOs:1,2,3,4	**CO-MPH 202T-5:** The potential clinical pharmacokinetic problems and application of basics of pharmacokinetic.	SO5.1	5.1,5.2,5.3,5.4,5.5,5.6,5.7,5.8,5.9,5.10,5.11,5.12	--	SL-5.1

A K S University

Faculty of Pharmaceutical Science & Technology
Rajiv Gandhi Institute of Pharmacy
Curriculum of M. Pharmacy (Pharmaceutics-MPH) Program
(Revised as on 01 August 2023)
Semester-II

Course Code: MPH 203T
Course Title: Computer Aided Drug Delivery System

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

Rationale/Objectives: Upon completion of this course it is expected that students will be able to understand

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

Course Outcomes:

CO-MPH 203T-1: History of Computers in Pharmaceutical Research and Development and Computational Modeling of Drug Disposition.
CO-MPH 203T-2: Computers in Preclinical Development.
CO-MPH 203T-3: Optimization Techniques in Pharmaceutical Formulation Computers in Market Analysis.
CO-MPH 203T-4: Computers in Clinical Development Artificial Intelligence (AI) and Robotics.
CO-MPH 203T-5: Computational fluid dynamics (CFD).

Scheme of Studies

Course code	Title of the course	Program Name	Total Number of contact hours/Week					Credit
			Class room Instruction (A)	Practical (P)	SW	SL	Total Hours (H)	
			Lecture					
MPH 203T	Computer Aided Drug Delivery System	M. Pharmacy	4	-	1	1	6	4

Legend: CI: Class room Instruction (Includes different instructional strategies i.e. Lecture (L) and Tutorial (T) and others,

LI: Laboratory Instruction (Includes Practical performances in laboratory workshop, field or other locations using different instructional strategies)

SW: Sessional Work **(**includes assignment**,** seminar, and mini project etc.),

SL: Self Learning, Credits.

Note: SW& SL has to be planned and performed under the continuous guidance and feedback of teacher to ensure outcome of Learning

Theory Assessment

Course Code	Course	Internal Assessment (A)				End Semester Exams (B)		Total Marks (A+B)
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
MPH 203T	Computer Aided Drug Delivery System	10	15	1 Hr	25	75	3Hrs.	100

Guidelines for the allotment of marks for attendance

Percentage of Attendance	Theory	Practical
95–100	8	10
90–94	6	7.5
85–89	4	5
80–84	2	2.5
Less than 80	0	0

Course-Curriculum Detailing:

This course syllabus illustrates the expected learning achievements, both at the course and session levels, which students are anticipated to accomplish through various modes of instruction including Classroom Instruction (CI), Laboratory Instruction (LI), Sessional Work (SW), and Self Learning (SL). As the course progresses, students should showcase their mastery of Session Outcomes (SOs), culminating in the overall achievement of Course Outcomes (COs) upon the course's conclusion.

Unit I

CO-MPH 203T-1: History of Computers in Pharmaceutical Research and Development and Computational Modeling of Drug Disposition.

Item	Approx Hrs
Lecture	12
Practical (P)	0
SW	2
SL	2
Total	16

Session Outcomes (SOs)	Laboratory Instruction (LI)	Classroom Instruction (CI)	Self Learning (SL)
Theory **SO1.1:** Computers in Pharmaceutical Research and Development **SO1.2:** Quality-by-Design In Pharmaceutical Development	**NA**	**1.1:** A General Overview: History of Computers in Pharmaceutical Research and Development **1.2:** Statistical modeling in Pharmaceutical research and development **1.3:** Descriptive versus Mechanistic Modeling **1.4:** Statistical Parameters **1.5:** Estimation **1.6:** Confidence Regions **1.7:** Nonlinearity at the Optimum, Sensitivity Analysis **1.8:** Optimal Design, Population Modeling **1.9:** Quality-by-Design In Pharmaceutical Development: Introduction **1.10:** ICH Q8 guideline **1.11:** Regulatory and industry views on QbD **1.12:** Scientifically based QbD - examples of applications	**1.1:** Study of Computers in Pharmaceutical Research and Development **1.2:** Descriptive versus Mechanistic Modeling

Suggested Assignments:

1. Explain statistical modeling in pharmaceutical research and development.
2. Write descriptive versus mechanistic Modeling.

Unit II
CO-MPH 203T-2: Computers in Preclinical Development.

Item	Approx Hrs
Lecture	12
Practical (P)	0
SW	2
SL	2
Total	16

Session Outcomes (SOs)	Laboratory Instruction (LI)	Classroom Instruction (CI)	Self Learning (SL)
Theory **SO2.1:** Computational Modeling Of Drug Disposition: Introduction, Modeling Techniques	**NA**	**2.1:** Drug Absorption **2.2:** Solubility **2.3:** Intestinal Permeation **2.4:** Drug Distribution **2.5:** Drug Excretion **2.6:** Active Transport **2.7:** P-gp **2.8:** BCRP **2.9:** Nucleoside Transporters **2.10:** hPEPT1 **2.11:** ASBT, OCT, OATP **2.12:** BBB-Choline Transporter	**2.1:** Study of Active Transport; P-gp, BCRP, Nucleoside Transporters. **2.2:** hPEPT1, ASBT, OCT, OATP, BBB-Choline Transporter.

Suggested Assignments:

1. Explain Drug Absorption, Solubility, Intestinal Permeation, and Drug Distribution.
2. Write the following terms-hPEPT1, ASBT, OCT, OATP, BBB-Choline Transporter.

Unit III

CO-MPH 203T-3: Optimization Techniques in Pharmaceutical Formulation Computers in Market Analysis.

Item	Approx Hrs
Lecture	12
Practical (P)	0
SW	2
SL	3
Total	17

Session Outcomes (SOs)	Laboratory Instruction (LI)	Classroom Instruction (CI)	Self Learning (SL)
Theory **SO3.1:** Computer-aided formulation development	**NA**	**3.1:** Computer-aided formulation development **3.2:** Concept of optimization **3.3:** Optimization parameters **3.4:** Factorial design, **3.5:** Optimization technology **3.6:** Screening design **3.7:** Computers in Pharmaceutical Formulation **3.8:** Development of pharmaceutical emulsions **3.9:** Micro emulsion drug carriers Legal Protection of Innovative Uses of Computers in R&D **3.10:** The Ethics of Computing in Pharmaceutical Research **3.11:** Computers in Market analysis **3.12:** Computer-aided drug development with different technoques	**3.1:** Study of Computer-aided formulation development **3.2:** Factorial design, Optimization technology & Screening design **3.3:** Computers in Market analysis

Suggested Assignments:

1. Write note on factorial design, optimization technology & screening design.
2. Give note on computers in market analysis.

Unit IV

CO-MPH 203T-4: Computers in Clinical Development Artificial Intelligence (AI) and Robotics.

Item	Approx Hrs
Lecture	12
Practical (P)	0
SW	2
SL	2
Total	16

Session Outcomes (SOs)	Laboratory Instruction (LI)	Classroom Instruction (CI)	Self Learning (SL)
Theory **SO4.1:** Computer-aided biopharmaceutical characterization **SO4.2:** Computer Simulations in Pharmacokinetics and Pharmacodynamics: Introduction, Computer Simulation **SO4.3:** Computers in Clinical Development	**NA**	**4.1:** Gastrointestinal absorption simulation **4.2:** Introduction **4.3:** Theoretical background **4.4:** Model construction **4.5:** Parameter sensitivity analysis, Virtual trial, Fed **4.6:** Fasted state, In vitro dissolution and in vitro in vivo correlation, Biowaiver considerations **4.7:** Computer Simulations in Pharmacokinetics and Pharmacodynamics: Introduction **4.8:** Computer Simulation: Whole Organism, Isolated Tissues **4.9:** Organs, Cell, Proteins and Genes **4.10:** Computers in Clinical Development **4.11:** Clinical Data Collection and Management **4.12:** Regulation of Computer Systems	**4.1:** Study of Computer Simulations in Pharmacokinetics and Pharmacodynamics: Introduction, Computer **4.2:** Simulation: Whole Organism, Isolated Tissues, Organs, Cell, Proteins and Genes

Suggested Assignments:

1. Explain gastrointestinal absorption simulation.
2. Write note on computer simulation: whole organism, isolated tissues.

Unit V

CO-MPH 203T-5: Computational fluid dynamics (CFD).

Item	Approx Hrs
Lecture	12
Practical (P)	0
SW	2
SL	3
Total	17

Session Outcomes (SOs)	Laboratory Instruction (LI)	Classroom Instruction (CI)	Self Learning (SL)
Theory **SO5.1:** Artificial Intelligence (AI), Robotics and Computational fluid dynamics	**NA**	**5.1:** Introduction to Artificial Intelligence **5.2:** Brief history of AI **5.3:** Goal & techniques of AI **5.4:** Applications of AI in pharmaceuticals **5.5:** Programming without & with AI in pharmaceuticals **5.6:** General overview **5.7:** Pharmaceutical Automation **5.8:** Pharmaceutical applications **5.9:** Pharmaceutical Advantages **5.10:** Pharmaceutical Disadvantages **5.11:** Current Challenges **5.12:** Future Directions	**5.1:** Study of General overview of Pharmaceutical Automation & Pharmaceutical applications **5.2:** Advantages and Disadvantages **5.3:** Current Challenges and Future Directions

Suggested Assignments:

1. Explain pharmaceutical applications.
2. Write current challenges and future directions.

Brief of Hours suggested for the Course Outcome

Course Outcomes	Class Lecture (Cl)	(LI)	Sessional Work (SW)	Self Learning (Sl)	Total Hour (Cl+SW+ Sl+LI)
CO-MPH 203T-1: History of Computers in Pharmaceutical Research and Development and Computational Modeling of Drug Disposition.	12	0	2	2	16
CO-MPH 203T-2: Computers in Preclinical Development.	12	0	2	2	16
CO-MPH 203T-3: Optimization Techniques in Pharmaceutical Formulation Computers in Market Analysis.	12	0	2	3	17
CO-MPH 203T-4: Computers in Clinical Development Artificial Intelligence (AI) and Robotics.	12	0	2	2	16
CO-MPH 203T-5: Computational fluid dynamics (CFD).	12	0	2	3	17
Total Hours	**60**	**0**	**10**	**12**	**82**

Suggestion for End Semester Assessment

Suggested Specification Table (For ESA)

Course Outcome	Unit Title	Marks Distribution			Total Marks
		A	C	E	
CO-MPH 203T-1:	History of Computers in Pharmaceutical Research and Development and Computational Modeling of Drug Disposition.	08	06	01	15
CO-MPH 203T-2:	Computers in Preclinical Development	12	07	01	20
CO-MPH 203T-3:	Optimization Techniques in Pharmaceutical Formulation Computers in Market Analysis.	08	06	02	16
CO-MPH 203T-4:	Computers in Clinical Development Artificial Intelligence (AI) and Robotics	10	02	03	15
CO-MPH 203T-5:	Computational fluid dynamics (CFD)	20	09	05	34
Total		**58**	**30**	**12**	**100**

Legend: A: Analyze, C: Create, E: Evaluate

The end of semester assessment for Computer Aided Drug Delivery System will be held with written examination of 75 marks.

Note. Detailed Assessment rubric need to be prepared by the course wise teachers for above tasks. Teachers can also design different tasks as per requirement, for end semester assessment.

Suggested Instructional/Implementation Strategies:

1. Improved Lecture
2. Tutorial
3. Case Method
4. Group Discussion
5. Role Play
6. Demonstration
7. ICTBasedTeachingLearning(VideoDemonstration/TutorialsCBT,Blog, Facebook,Twitter,Whatsapp,Mobile,Onlinesources)
8. Brainstorming.

Suggested Learning Resources:

S. No.	Title	Author	Publisher	Edition & Year
1	Computer Applications in Pharmaceutical Research and Development.	John Wiley & Sons	Sean Ekins	2006
2	Computer-Aided Applications in Pharmaceutical Technology.	Jelena Djuris	Woodhead Publishing	1st Edition
3	Encyclopedia of Pharmaceutical Technology.	James Swarbrick, James.	G.Boylan, Marcel Dekker Inc, New York.	Vol 13, 1996.

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Course Outcome & Program Outcome Mapping

Course Outcome	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PSO1	PSO2	PSO3	PSO4
	Scientific Knowledge	Technological Application	Modern tool usage	Entrepreneur ship	Practical Skill	Applied Science	Computational and Statistical methodologies	Pharmaceutical Ethics	Environment and sustainability	Life-long learning	Formulation strategies	Emerging science	Computational literacy	Pharmaceutical regulations
CO-MPH 203T-1: Pharmaceutical Research and Development	3	2	3	1	3	2	1	3	2	3	3	2	3	1
CO-MPH 203T-2: Preclinical Development	2	2	3	2	1	3	2	2	1	3	2	3	2	2
CO-MPH 203T-3: Pharmaceutical Formulation	1	2	1	3	3	2	3	3	2	2	2	3	3	1
CO-MPH 203T-4: Clinical Development	2	1	3	2	2	3	2	2	2	3	1	2	3	2
CO-MPH 203T-5: Computational fluid dynamics	3	2	2	1	3	2	3	3	1	2	2	2	3	3

Legend: 1- Low, 2-Medium, 3-High

Course Curriculum Mapping

POs & PSOs No.	Cos No. & Title	SOs No.	Class Room Instructions	Laboratory Instructions	Self learning
POs:1,2,3,4,5,6,7,8,9,10 PSOs:1,2,3,4	**CO-MPH 203T-1:** History of Computers in Pharmaceutical Research and Development and Computational Modeling of Drug Disposition.	SO1.1 SO1.2	1.1,1.2,1.3,1.4,1.5,1.6,1.7 ,1.8,1.9,1.10,1.11,1.12	_	SL-1.1 SL-1.2
POs:1,2,3,4,5,6,7,8,9,10 PSOs:1,2,3,4	**CO-MPH 203T-2:** Computers in Preclinical Development.	SO2.1	2.1,2.2,2.3,2.4,2.5,2.6,2.7 ,2.8,2.9,2.10,2.11,2.12	--	SL-2.1 SL-2.2
POs:1,2,3,4,5,6,7,8,9,10 PSOs:1,2,3,4	**CO-MPH 203T-3:** Optimization Techniques in Pharmaceutical Formulation Computers in Market Analysis.	SO3.1	3.1,3.2,3.3,3.4,3.5,3.6,3.7 ,3.8	--	SL-3.1 SL-3.2 SL-3.3
POs:1,2,3,4,5,6,7,8,9,10 PSOs:1,2,3,4	**CO-MPH 203T-4:** Computers in Clinical Development Artificial Intelligence (AI) and Robotics.	SO4.1 SO4.2 SO4.3	4.1,4.2,4.3,4.4,4.5,4.6,4.7 ,4.8,4.9,4.10,4.11,4.12	--	SL-4.1 SL-4.2
POs:1,2,3,4,5,6,7,8,9,10 PSOs:1,2,3,4	**CO-MPH 203T-5:** Computational fluid dynamics (CFD).	SO5.1	5.1,5.2,5.3,5.4,5.5,5.6,5.7	--	SL-5.1 SL-5.2 SL-5.3

A K S University

Faculty of Pharmaceutical Science & Technology
Rajiv Gandhi Institute of Pharmacy
Curriculum of M. Pharmacy (Pharmaceutics-MPH) Program
(Revised as on 01 August 2023)
Semester-II

Course Code: MPH 204T
Course Title: Cosmetics and Cosmeceuticals

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

Rationale/Objectives: Upon completion of the course, the students shall be able to understand

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

Course Outcomes:

CO-MPH 204T-1: Key ingredients used in cosmetics and cosmeceuticals.

CO-MPH 204T-2: Key building blocks for various formulations.

CO-MPH 204T-3: Current technologies in the market.

CO-MPH 204T-4: Various key ingredients and basic science to develop cosmetics and cosmeceuticals.

CO-MPH 204T-5: Scientific knowledge to develop cosmetics and cosmeceuticals with desired safety, stability and efficacy.

Scheme of Studies

Course code	Title of the course	Program Name	Total Number of contact hours/Week					Credit
			Classroom Instruction (A) Lecture	Practical (P)	SW	SL	Total Hours (H)	
MPH 204T	Cosmetics and Cosmeceuticals	M. Pharmacy	4	0	1	1	6	4

Legend: CI: Class room Instruction (Includes different instructional strategies i.e. Lecture (L) and Tutorial (T) and others
LI: Laboratory Instruction (Includes Practical performances in laboratory workshop, field or other locations using different instructional strategies)
SW: Sessional Work (includes assignment**,** seminar, and mini project etc.)
SL: Self Learning, Credits
Note: SW & SL has to be planned and performed under the continuous guidance and feedback of teacher to ensure outcome of Learning

Theory Assessment

Course Code	Course	Internal Assessment (A)				End Semester Exams (B)		Total Marks (A+B)
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
MPH 204T	Cosmetics and Cosmeceuticals	10	15	1 Hr	25	75	3 Hrs	100

Guidelines for the allotment of marks for attendance

Percentage of Attendance	Theory	Practical
95–100	8	10
90–94	6	7.5
85–89	4	5
80–84	2	2.5
Less than 80	0	0

Course-Curriculum Detailing:

This course syllabus illustrates the expected learning achievements, both at the course and session levels, which students are anticipated to accomplish through various modes of instruction including Classroom Instruction (CI), Laboratory Instruction (LI), Sessional Work (SW), and Self Learning (SL). As the course progresses, students should showcase their mastery of Session Outcomes (SOs), culminating in the over all achievement of Course Outcomes (COs) upon the course's conclusion.

Unit I

CO-MPH 204T-1: Key ingredients used in cosmetics and cosmeceuticals.

Item	Approx Hrs
Lecture	12
Practical (P)	0
SW	2
SL	2
Total	16

Session Outcomes (SOs)	Laboratory Instruction (LI)	Classroom Instruction (CI)	Self Learning (SL)
Theory **SO1.1:** Cosmetics – Regulatory	**NA**	**1.1:** Introduction to Cosmetics **1.2:** Cosmetics – Regulatory: Definition of cosmetic products as per Indian regulation **1.3:** Indian regulatory requirements for labeling of cosmetics **1.4:** Regulatory provisions relating to import of cosmetics **1.5:** Misbranded and spurious cosmetics **1.6:** Regulatory provisions relating to manufacture of cosmetics **1.7:** Conditions for obtaining license. **1.8:** loan license **1.9:** Offences and penalties **1.10:** Prohibition of manufacture **1.11:** Sale of certain cosmetics **1.12:** loan license, offences and penalties	**1.1:** Study of Cosmetics – Regulatory : Definition of cosmetic products as per Indian regulation **1.2:** Regulatory provisions relating to manufacture of cosmetics

Suggested Assignments:

1. Give note on prohibition of manufacture and sale of certain cosmetics, loan license, offences and penalties.
2. Explain regulatory provisions relating to manufacture of cosmetics.

Unit II
CO-MPH 204T-2: Key building blocks for various formulations.

Item	Approx Hrs
Lecture	12
Practical (P)	0
SW	2
SL	2
Total	16

Session Outcomes (SOs)	Laboratory Instruction (LI)	Classroom Instruction (CI)	Self Learning (SL)
Theory **SO2.1:** Cosmetics – Biological aspects	**NA**	**2.1:** Cosmetics - Biological aspects **2.2:** Structure of skin relating to problems like dry skin **2.3:** Acne **2.4:** Pigmentation & Prickly heat **2.5:** Wrinkles, and body odor **2.6:** Structure of hair and hair growth cycle **2.7:** Common problems associated with oral cavity **2.8:** Cleansing and care needs for face **2.9:** Eye lids, lips **2.10:** Hands, feet **2.11:** Nail, scalp **2.12:** Neck, body and under-arm	**2.1:** Study of Cosmetics- Biological aspects **2.2:** Structure of hair and hair growth cycle. Common problems associated with oral cavity

Suggested Assignments:

1. Explain common problems associated with oral cavity.
2. Explain structure of hair and hair growth cycle. Common problems associated with oral cavity.

Unit III

CO-MPH 204T-3: Current technologies in the market.

Item	Approx Hrs
Lecture	12
Practical (P)	0
SW	2
SL	2
Total	16

Session Outcomes (SOs)	Laboratory Instruction (LI)	Classroom Instruction (CI)	Self Learning (SL)
Theory **SO3.1:** Formulation building blocks	**NA**	**3.1:** Formulation Building blocks: Building blocks for different product formulations of cosmetics/cosmeceuticals **3.2:** Surfactants – Classification and application **3.3:** Emollients **3.4:** Rheological additives **3.5:** Classification and application **3.6:** Antimicrobial used as preservatives **3.7:** Their merits and demerits **3.8:** Factors affecting microbial preservative efficacy **3.9:** Building blocks for formulation of a moisturizing cream **3.10:** Vanishing cream, cold cream, shampoo and toothpaste. Soaps and syndetbars **3.11:** Perfumes; Classification of perfumes. Perfume ingredients listed as allergens in EU regulation **3.12:** Controversial ingredients: Parabens, formaldehyde liberators, dioxane	**3.1:** Study of Building blocks for different product formulations of cosmetics/ cosmeceuticals **3.2:** Emollients, rheological additives

Suggested Assignments:

1. Write the factors affecting microbial preservative efficacy.
2. Give note on emollients & rheological additives.

Unit IV

CO-MPH 204T-4: Various key ingredients and basic science to develop cosmetics and cosmeceuticals.

Item	Approx Hrs
Lecture	12
Practical (P)	0
SW	2
SL	2
Total	16

Session Outcomes (SOs)	Laboratory Instruction (LI)	Classroom Instruction (CI)	Self Learning (SL)
Theory **SO4.1:** Design of cosmeceuticals products	**NA**	**4.1:** Design of cosmeceuticals products: Sun protection **4.2:** Sunscreens classification **4.3:** Regulatory aspects of cosmeceutical products **4.4:** Addressing dry skin, acne **4.5:** Sun-protection **4.6:** Pigmentation **4.7:** Prickly heat **4.8:** Wrinkles, body odor **4.9:** Dandruff, dental cavities **4.10:** Bleeding gums **4.11:** Mouth odor **4.12:** Sensitive teeth through cosmeceuticals formulations	**4.1:** Study of Design of cosmeceuticals products: Sun protection **4.2:** Sunscreens classification and regulatory aspects

Suggested Assignments:

1. Given short description on sunscreens classification and regulatory aspects.
2. Explain gums, mouth odor and sensitive teeth through cosmeceuticals formulations.

Unit V

CO-MPH 204T-5: Scientific knowledge to develop cosmetics and cosmeceuticals with desired safety, stability and efficacy.

Item	Approx Hrs
Lecture	12
Practical (P)	0
SW	2
SL	2
Total	16

Session Outcomes (SOs)	Laboratory Instruction (LI)	Classroom Instruction (CI)	Self Learning (SL)
Theory **SO5.1:** Herbal cosmetics	**NA**	**5.1:** Introduction to Herbal Cosmetics **5.2:** Types according to site of applications **5.3:** Guidelines for using herbs **5.4:** Herbal ingredients used in Hair care **5.5:** Skin care **5.6:** Oral care **5.7:** Review of guidelines for herbal cosmetics by private bodies like cosmos with respect to preservatives **5.8:** Emollients **5.9:** Foaming agents **5.10:** Emulsifiers and rheology modifiers **5.11:** Challenges in formulating herbal cosmetics **5.12:** Evaluation of finished product	**5.1:** Study of Herbal cosmetics **5.2:** Study of Review of guidelines for herbal cosmetics by private bodies like cosmos with respect to preservatives

Suggested Assignments:

1. Explain emulsifiers and rheology modifiers.
2. Write challenges in formulating herbal cosmetics.

Brief of Hours suggested for the Course Outcome

Course Outcomes	Class Lecture (Cl)	(LI)	Sessional Work (SW)	Self Learning (Sl)	Total Hour (Cl+SW+ Sl+LI)
CO-MPH 204T-1: Key ingredients used in cosmetics and cosmeceuticals.	12	0	2	2	16
CO-MPH 204T-2: Key building blocks for various formulations.	12	0	2	2	16
CO-MPH 204T-3: Current technologies in the market.	12	0	2	2	16
CO-MPH 204T-4: Various key ingredients and basic science to develop cosmetics and cosmeceuticals.	12	0	2	2	16
CO-MPH 204T-5: Scientific knowledge to develop cosmetics and cosmeceuticals with desired Safety, stability, and efficacy.	12	0	2	2	16
Total Hours	**60**	**0**	**10**	**10**	**80**

Suggestion for End Semester Assessment

Suggested Specification Table (For ESA)

Course Outcome	Unit Title	Marks Distribution			Total Marks
		A	C	E	
CO-MPH 204T-1:	Key ingredients used in cosmetics and cosmeceuticals.	08	06	01	15
CO-MPH 204T-2:	Key building blocks for various formulations.	12	07	01	20
CO-MPH 204T-3:	Current technologies in the market.	08	06	02	16
CO-MPH 204T-4:	Various key ingredients and basic science to develop cosmetics and cosmeceuticals.	10	02	03	15
CO-MPH 204T-5:	Scientific knowledge to develop cosmetics and cosmeceuticals with desired Safety, stability, and efficacy.	20	09	05	34
Total		**58**	**30**	**12**	**100**

Legend: A: Analyze, C: Create, E: Evaluate

The end of semester assessment for Cosmetics and Cosmeceuticals will be held with written examination of 75 marks.

Note: Detailed Assessment rubric need to be prepared by the course wise teachers for above tasks. Teachers can also design different tasks as per requirement, for end semester assessment.

Suggested Instructional/Implementation Strategies:

1. Improved Lecture
2. Tutorial
3. Case Method
4. Group Discussion
5. Role Play
6. Demonstration
7. ICTBasedTeachingLearning(VideoDemonstration/TutorialsCBT, Blog,Facebook,Twitter,Whatsapp,Mobile,Onlinesources)
8. Brainstorming.

Suggested Learning Resources:

S. No.	Title	Author	Publisher	Edition & Year
1	Harry's Cosmeticology	Meyer R. Rosen,	Editor-in-Chief President, Interactive Consulting Inc.	Ninth Edition The three-volume Friday, July 5, 2019
2	Poucher'sperfume cosmetics and Soaps	W.A. Poucher.	Join thousands of researchers worldwide that have published their work in one of our 3,000+ Springer Nature journals.	January 2022 was the 10th edition.
3	Handbook of cosmetic science and Technology	A.O.Barel, M.Paye and H.I. Maibach	Boca Raton	3 rd edition 6 December 1984

Curriculum Development Team:

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Course Outcome & Program Outcome Mapping

Course Outcome	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PSO1	PSO2	PSO3	PSO4
	Scientific Knowledge	Technological Application	Modern tool usage	Entrepreneur ship	Practical Skill	Applied Science	Computational and Statistical methodologies	Pharmaceutical Ethics	Environment and sustainability	Life-long learning	Formulation strategies	Emerging science	Computational literacy	Pharmaceutical regulations
CO-MPH 204T-1: Cosmetics and Cosmeceuticals	3	2	3	1	3	2	1	3	2	3	3	2	3	1
CO-MPH 204T-2: Various formulations	2	2	3	2	1	3	2	2	1	3	2	3	2	2
CO-MPH 204T-3: Current technologies	1	2	1	3	3	2	3	3	2	2	2	3	3	1
CO-MPH 204T-4: Ingredients and basic science	2	1	3	2	2	3	2	2	2	3	1	2	3	2
CO-MPH 204T-5: Safety, stability and efficacy	3	2	2	1	3	2	3	3	1	2	2	2	3	3

Legend: 1- Low, 2-Medium, 3-High

Course Curriculum Mapping

POs & PSOs No.	COs No. & Title	SOs No.	Class Room Instructions	Laboratory Instructions	Self learning
POs:1,2,3,4,5,6,7,8,9,10 PSOs:1,2,3,4	**CO-MPH 204T-1:** Key ingredients used in cosmetics and cosmeceuticals.	SO1.1	1.1,1.2,1.3,1.4,1.5,1.6, 1.7,1.8,1.9,1.10	--	SI-1.1 SI-1.2
POs:1,2,3,4,5,6,7,8,9,10 PSOs:1,2,3,4	**CO-MPH 204T-2:** Key building blocks for various formulations.	SO2.1	2.1,2.2,2.3,2.4,2.5,2.6, 2.7,2.8,2.9,2.10,2.11,2 .12,2.13	--	SL-2.1 SL-2.2
POs:1,2,3,4,5,6,7,8,9,10 PSOs:1,2,3,4	**CO-MPH 204T-3:** Current technologies in the market.	SO3.1	3.1,3.2,3.3,3.4,3.5,3.6, 3.7,3.8,3.9,3.10,3.11,3 .12	--	SL-3.1 SL-3.2
POs:1,2,3,4,5,6,7,8,9,10 PSOs:1,2,3,4	**CO-MPH 204T-4:** Various key ingredients and basic science to develop cosmetics and cosmeceuticals.	SO4.1	4.1,4.2,4.3,4.4,4.5,4.6, 4.7,4.8,4.9,4.10,4.11	--	SL-4.1 SL-4.2
POs:1,2,3,4,5,6,7,8,9,10 PSOs:1,2,3,4	**CO-MPH 204T-5:** Scientific knowledge to develop cosmetics and cosmeceuticals with desired Safety, stability, and efficacy.	SO5.1	5.1,5.2,5.3,5.4,5.5,5.6, 5.7,5.8,5.9	--	SL-5.1 SL-5.2

A K S University

Faculty of Pharmaceutical Science & Technology
Rajiv Gandhi Institute of Pharmacy
Curriculum of M. Pharmacy (Pharmaceutics-MPH) Program
(Revised as on 01 August 2023)
Semester-II

Course Code: MPH 205P
Course Title: Pharmaceutics Practical - II

Practical Assessment

Course Code	Course	Internal Assessment (A)				End Semester Exams (B)		Total Marks (A+B)
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
MPH 205P	Pharmaceutics Practical - II	20	30	6 Hrs	50	100	6 Hrs	150

S. No.	List of 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 Solid dispersion technique.
7.	Comparison of dissolution of two different marketed products /brands.
8.	Protein binding studies of a highly protein bound drug & poorly protein bound drug.
9.	Bioavailability studies of Paracetamol in animals.
10.	Pharmacokinetic and IVIVC data analysis by Winnoline^{R} software.
11.	In vitro cell studies for permeability and metabolism.
12.	DoE Using Design Expert® Software.
13.	Formulation data analysis Using Design Expert® Software.
14.	Quality-by-Design in Pharmaceutical Development.
15.	Computer Simulations in Pharmacokinetics and Pharmacodynamics.
16.	Computational Modeling Of Drug Disposition.
17.	To develop Clinical Data Collection manual.
18.	To carry out Sensitivity Analysis, and Population Modeling.
19.	Development and evaluation of Creams.
20.	Development and evaluation of Shampoo and Toothpaste base.
21.	To incorporate herbal and chemical actives to develop products.
22.	To address Dry skin, acne, blemish, Wrinkles, bleeding gums and dandruff.

Course Code: MRM 301T

Course Title: Research Methodology & Biostatistics

Pre-requisite: Awareness of ethical guidelines related to human and animal research is necessary. Students should know how to search for scientific literature using databases like Pub Med, Scopus, or Google Scholar. Students should have Basic Pharmacology Knowledge.

Rationale/Objectives: Research methodology equips students with critical skills needed for scientific inquiry. It empowers them to contribute to the field of pharmacology by conducting rigorous studies.

Career Relevance: Understanding research methods is crucial for future pharmacists, researchers, and academics. It prepares them for evidence-based practice and scholarly work.

Course Outcomes:

CO-MRM 301-1: Understand General Research Methodology.

CO-MRM 301-2: Evaluation of Biostatistics: Definition, application, sample size, importance of sample size, factors influencing sample size, dropouts, (students "t" test, ANOVA, Correlation coefficient, regression), null hypothesis.

CO-MRM 301-3: Analysis of Medical Research: History, values in medical ethics, autonomy, beneficence, non-maleficence, double effect, conflicts between autonomy and beneficence/non-maleficence, euthanasia.

CO-MRM 301-4: Understand **C**PCSEA guidelines for laboratory animal facility.

CO-MRM 301-5: Understand Declaration of Helsinki: History, introduction, basic principles for all medical research, and additional principles for medical research combined with medical care**.**

Scheme of Studies

Course code	**Title of the course**	**Program Name**	**Total Number of contact hours/Week**					**Credit**
			Class room Instruction (A)	**Practical (P)**	**SW**	**SL**	**Total Hours**	
			Lecture				**(H)**	
MRM 101T	Research Methodology & Biostatistics	M. Pharmacy	4	-	1	1	6	4

Legend: CI: Class room Instruction (Includes different instructional strategies i.e. Lecture (L) and Tutorial (T) and others
LI: Laboratory Instruction (Includes Practical performances in laboratory workshop, field or other locations using different instructional strategies)
SW: Sessional Work **(**includes assignment, seminar, and mini project etc.)
SL: Self Learning, Credits
Note: SW& SL has to be planned and performed under the continuous guidance and feedback of teacher to ensure outcome of Learning

Theory Assessment

Course Code	Course	Internal Assessment (A)				End Semester Exams (B)		Total Marks (A+B)
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
MRM 101T	Research Methodology & Biostatistics	10	15	1 Hr	25	75	3Hrs.	100

Guidelines for the allotment of marks for attendance

Percentage of Attendance	Theory	Practical
95–100	8	10
90–94	6	7.5
85–89	4	5
80–84	2	2.5
Less than 80	0	0

Course-Curriculum Detailing:

This course syllabus illustrates the expected learning achievements, both at the course and session levels, which students are anticipated to accomplish through various modes of instruction including Classroom Instruction (CI), Laboratory Instruction (LI), Sessional Work (SW), and Self Learning (SL). As the course progresses, students should showcase their mastery of Session Outcomes (SOs), culminating in the overall achievement of Course Outcomes (COs) upon the course's conclusion.

Unit I

CO-MRM 301-1: Understand General Research Methodology.

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Item	Approx Hrs
Lecture	10
Practical (P)	0
SW	3
SL	3
Total	16

Session Outcomes (SOs)	Laboratory Instruction (LI)	Classroom Instruction (CI)	Self Learning (SL)
Theory **SO1.1:** Understand General Research Methodology: Research, objective, requirements, practical difficulties **SO1.2:** Understand review of literature, study design, types of studies **SO1.3:** To Learn dosage strategies to eliminate errors/bias, controls, randomization **SO1.4:** Understands crossover design, placebo, blinding techniques	**NA**	**1.1:** General Research Methodology: Research **1.2:** Objective, requirements **1.3:** Practical difficulties **1.4:** Review of literature **1.5:** Study design, types of studies **1.6:** Strategies to eliminate **1.7:** Errors/bias, controls **1.8:** Randomization **1.9:** Crossover design **1.10:** Placebo, blinding techniques	**1.1:** Different dosage of animal available in market **1.2:** Different types of dosage and calculation **1.3:** Types of studies

Suggested Assignments:

1. Write different animal species and different dose calculation.
2. What do you know about crossover design?
3. Give note on general research methodology.

Unit II

CO-MRM 301-2: Evaluation of Biostatistics: Definition, application, sample size, importance of sample size, factors influencing sample size.

Item	Approx Hrs
Lecture	09
Practical (P)	0
SW	4
SL	3
Total	16

Session Outcomes (SOs)	Laboratory Instruction (LI)	Classroom Instruction (CI)	Self Learning (SL)
Theory **SO2.1:** To Understand definition, application Sample size, importance of sample size **SO2.2:** Understand Factors influencing sample size, dropouts **SO2.3:** To statistical tests of significance analysis of variance, correlation, chi square test **SO2.4:** To understand Non-parametric tests (wilcoxan rank tests) **SO2.5:** To learn about null hypothesis, P values, degree of freedom, interpretation of P values	**NA**	**2.1:** Definition, applications **2.2:** Sample size, importance of sample size **2.3:** Factors influencing sample size, dropouts **2.4:** Statistical tests of significance **2.5:** Analysis of variance, correlation, chi square test) **2.6:** Non-parametric tests (wilcoxan rank tests) **2.7:** Null hypothesis **2.8:** P values, degree of freedom **2.9:** Interpretation of P values	**2.1:** Read research article **2.2:** Work in different software **2.3:** Importance of sample size

Suggested Assignments:

1. Differentiate null hypothesis and alternate hypothesis.
2. Write type of significance tests.
3. Give note on analysis of variance, correlation, chi square test.
4. Write note on importance of sample size.

Unit III

CO-MRM 301-3: Analysis of Medical Research: History, values in medical ethics, autonomy, beneficence, non-maleficence, double effect, conflicts between autonomy.

Item	Approx Hrs
Lecture	09
Practical (P)	0
SW	4
SL	3
Total	16

Session Outcomes (SOs)	Laboratory Instruction (LI)	Classroom Instruction (CI)	Self Learning (SL)
Theory **SO3.1:** To Understand definition, application Sample size, importance of sample size **SO3.2:** Understand Factors influencing sample size, dropouts **SO3.3:** To statistical tests of significance analysis of variance, correlation, chi square test **SO3.4:** To understand Non-parametric tests (wilcoxan rank tests) **SO3.5:** To learn about Null hypothesis, P values, degree of freedom, interpretation of P values		**3.1:** History, values in medical ethics, conflicts **3.2:** Autonomy, Beneficence **3.3:** Non-maleficence, double effect **3.4:** Conflicts between autonomy and beneficence/non-maleficence **3.5:** Euthanasia, informed consent, confidentiality **3.6:** Criticisms of orthodox medical ethics, importance of communication **3.7:** Control resolution, guidelines, ethics committees, cultural concerns **3.8:** Truth telling, online business practices, conflicts of interest **3.9:** Referral, vendor relationships, fatality	**3.1:** Different examples of conflict of interest **3.2:** Learn about duplicate research **3.3:** Values in medical ethics

Suggested Assignments:

1. Discuss the History, values in medical ethics.
2. Write conflicts between autonomy and beneficence/non-maleficence.
3. Give importance of communication.
4. Write different examples of conflict of interest.

Unit IV

CO-MRM 301-4: Understand CPCSEA guidelines for laboratory animal facility.

Item	Approx Hrs
Lecture	09
Practical (P)	0
SW	4
SL	2
Total	15

Session Outcomes (SOs)	Laboratory Instruction (LI)	Classroom Instruction (CI)	Self Learning (SL)
Theory **SO4.1:** To learn CPCSEA guidelines for laboratory animal facility. **SO4.2:** Understand Quarantine, surveillance, diagnosis, treatment and control of disease, personal hygiene. **SO4.3:** To analyze 5 Euthanasia, physical facilities, environment. **SO4.4:** To Understand SOPs, personnel and training. **SO4.5:** To learn about Transport of lab animals.		**4.1:** Goals, veterinary care **4.2:** Quarantine, surveillance, diagnosis **4.3:** Treatment and control of disease, personal hygiene **4.4:** location of animal facilities to laboratories, anesthesia **4.5:** Euthanasia, physical facilities, environment **4.6:** Animal husbandry, record keeping **4.7:** SOPs **4.8:** Personnel and training **4.9:** Transport of lab animals	**4.1:** Knowledge about animal model **4.2:** Anatomy of different laboratory animals

Suggested Assignments:

1. Note on CPCSEA guidelines for laboratory animal facility.
2. Write different aspect of transport of lab animal.
3. How to learn CPCSEA guidelines for laboratory animal facility.
4. Give note on animal husbandry, record keeping.

Unit V

CO-MPH 301-5: Understand Declaration of Helsinki: Basic principles for all medical research and additional principles for medical research combined with medical care.

Item	Approx Hrs
Lecture	04
Practical (P)	0
SW	4
SL	4
Total	12

Session Outcomes (SOs)	Laboratory Instruction (LI)	Classroom Instruction (CI)	Self Learning (SL)
Theory **SO5.1:** To learn CPCSEA guidelines for laboratory animal facility **SO5.2:** Understand History, introduction, basic principles for all medical research **SO5.3:** To understand Additional principles for medical research combined with medical care		**5.1:** History **5.2:** Introduction **5.3:** Basic principles for all medical research **5.4:** Additional principles for medical research combined with medical care	**5.1:** learn about biostatics **5.2:** learn MS word **5.3:** learn MS office **5.4:** learn MS excel

Suggested Assignments:

1. Write note on basic principles for all medical research.
2. Explain declaration of helsinki.
3. Give note on principles for medical research combined with medical care.
4. How to learn CPCSEA guidelines for laboratory animal facility.

Brief of Hours suggested for the Course Outcome

Course Outcomes	Class Lecture (Cl)	(LI)	Sessional Work (SW)	Self Learning (Sl)	Total Hour (Cl+SW+ Sl+LI)
CO-MRM 301-1: Understand General Research Methodology.	10	0	3	3	16
CO-MRM 301-2: Evaluation of Biostatistics: Definition, application, sample size, importance of sample size.	09	0	4	3	16
CO-MRM 301-3: Analysis of Medical Research: History, values in medical ethics, autonomy, beneficence, non-maleficence, double effect, conflicts between autonomy.	09	0	4	3	16
CO-MRM 301-4: Understand CPCSEA guidelines for laboratory animal facility.	09	0	4	2	15
CO-MRM 301-5: Understand declaration of Helsinki: Basic principles for all medical research and additional principles for medical research combined with medical care.	04	0	4	4	12
Total Hours	**41**	**0**	**19**	**15**	**75**

Suggestion for End Semester Assessment

Suggested Specification Table (For ESA)

Course Outcome	Unit Title	Marks Distribution			Total Marks
		A	C	E	
CO-MRM 101T-1:	Understand General Research Methodology.	08	09	03	20
CO-MRM 101T-2:	Evaluation of Biostatistics: Definition, application, sample size, importance of sample size, factors influencing sample size, dropouts, (students "t" test, ANOVA, Correlation coefficient, regression), null hypothesis.	09	08	03	20
CO-MRM 101T-3:	Analysis of Medical Research: History, values in medical ethics, autonomy, beneficence, non-maleficence, double effect, conflicts between autonomy and beneficence/non-maleficence, euthanasia.	08	09	03	20
CO-MRM 101T-4:	Understand CPCSEA guidelines for laboratory animal facility.	09	08	03	20
CO-MRM 101T-5:	Understand Declaration of Helsinki: History, introduction, basic principles for all medical research, and additional principles for medical research combined with medical care.	08	09	03	20
Total		**42**	**43**	**15**	**100**

Legend: A: Analyze, C: create, E: Evaluate

The end of semester assessment for Research Methodology & Biostatistics will be held with written examination of 75 marks.

Note. Detailed Assessment rubric need to be prepared by the course wise teachers for above tasks.
Teachers can also design different tasks as per requirement, for end semester assessment.

Suggested Instructional/Implementation Strategies:

1. Improved Lecture
2. Tutorial
3. Case Method
4. Group Discussion
5. Role Play
6. Demonstration
7. ICTBasedTeachingLearning(VideoDemonstration/TutorialsCBT,Blog, Face book,Twitter,Whatsapp,Mobile,Onlinesources)
8. Brainstorming

Suggested Learning Resources:

S. No.	Title	Author	Publisher	Edition & Year
1	Research Methodology	C.R KOTHARI	New Age International Publishers	5TH edition 2023
2	Research Methodology and Strategy: Theory and Practice	Patrick X.W. Zou Xiaoxiao Xu	John Wiley & Sons, Ltd.	First published: 2023

Curriculum Development Team:

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2. **Ms. Neha Goel,** Associate Professor, Rajiv Gandhi Institute of Pharmacy, AKS University
3. **Mr. Abu Tahir,** Assistant professor, Rajiv Gandhi Institute of Pharmacy, AKS University

Course Outcome & Program Outcome Mapping

Course Outcome	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PSO1	PSO2	PSO3	PSO4
	Scientific Knowledge	Technological Application	Modern tool usage	Entrepreneur ship	Practical Skill	Applied Science	Computational and Statistical methodologies	Pharmaceutical Ethics	Environment and sustainability	Life-long learning	Formulation strategies	Emerging science	Computational literacy	Pharmaceutical regulations
CO-MRM 301T-1: Research Methodology	3	2	3	1	3	2	1	3	2	3	3	2	3	1
CO-MRM 301T-2: Evaluation of Biostatistics	2	2	3	2	1	3	2	2	1	3	2	3	2	2
CO-MRM 301T-3: Analysis of Medical Research	1	2	1	3	3	2	3	3	2	2	2	3	3	1
CO-MRM 301T-4: CPCSEA guidelines	2	1	3	2	2	3	2	2	2	3	1	2	3	2
CO-MRM 301T-5: Declaration of Helsinki	3	2	2	1	3	2	3	3	1	2	2	2	3	3

Legend: 1- Low, 2-Medium, 3-High

Course Curriculum Mapping

POs & PSOs No.	COs No. & Title	SOs No.	Class Room Instructions	Laboratory Instructions	Self learning
Pos:1,2,3,4,5,6,7,8,9,10 PSOs:1,2,3,4	**CO-MRM 301T-1:** Understand General Research Methodology.	SO1.1 SO1.2 SO1.3 SO1.4	1.1,1.2,1.3,1.4,1.5, 1.6,1.7,1.8,1.9,1.1 0	--	SI-1.1 SI-1.2 SI-1.3
Pos:1,2,3,4,5,6,7,8,9,10 PSOs:1,2,3,4	**CO-MRM 301T-2:** Evaluation of Biostatistics: Definition, application, sample size, importance of sample size, factors influencing sample size, dropouts, (students "t" test, ANOVA, Correlation coefficient, regression), null hypothesis.	SO-2.1 SO-2.2 SO-2.3 SO-2.4 SO-2.5	2.1,2.2,2.3,2.4,2.5, 2.6,2.7,2.8,2.9	--	SI-2.1 SI-2.2 SI-2.3
Pos:1,2,3,4,5,6,7,8,9,10 PSOs:1,2,3,4	**CO-MRM 301T-3:** Analysis of Medical Research: History, values in medical ethics, autonomy, beneficence, non-maleficence, double effect, conflicts between autonomy and beneficence/non-maleficence, euthanasia.	SO-3.1 SO-3.2 SO-3.3 SO-3.4 SO-3.5	3.1,3.2,3.3,3.4,3.5, 3.6,3.7,3.8,3.9	--	SI-3.1 SI-3.2 SI-3.3
Pos:1,2,3,4,5,6,7,8,9,10 PSOs:1,2,3,4	**CO-MRM 301T-4:** Understand CPCSEA guidelines for laboratory animal facility.	SO-4.1 SO-4.2 SO-4.3 SO-4.4 SO-4.5	4.1,4.2,4.3,4.4,4.5, 4.6,4.7,4.8,4.9.	--	SI-4.1 SI-4.2
Pos:1,2,3,4,5,6,7,8,9,10 PSOs:1,2,3,4	**CO-MRM 301T-5:** Understand Declaration of Helsinki: History, introduction, basic principles for all medical research, and additional principles for medical research combined with medical care.	SO-5.1 SO-5.2 SO-5.3	5.1,5.2,5.3,5.4.	--	SI-5.1 SI-5.2 SI-5.3 SI-5.4

Course Code: MPH302

Course Title: Journal Club

Every journal club presentation can be approached in this general format:

Introduction
Explain the clinical question that prompted you to consult the literature and what drew you to the article.

Who wrote the paper?
Consider the title of the paper, the authors and their affiliated institution(s). Are there any outstanding features, e.g. a first study of its kind, a well-known author or institution? What is the impact factor of the journal? What is the circulation (i.e. regional, national or international) and who is the readership? Try to ignore the abstract initially. Reading the author's stated conclusions before forming your own ideas about the validity of the paper may influence your appraisal.

The hypothesis
What is the research question? Is it well constructed? Does it observe the four basic components (PICO) of a good research question? Population – who was studied? Intervention – what was the intervention tested? Control – what was the alternative that the intervention was compared to? Outcome – what was the nature of the outcome measured?

Appraise the evidence base
Read the key references and related papers. What is already known on the subject? Is this correctly presented? Is the hypothesis correct? Is the question relevant and important in the context of the existing literature? What does the study contribute to the existing literature? The introduction will usually contain a statement validating the content of the article by placing it in the context of the wider literature. For example, 'Intervention 'x' has been shown to show significant reduction in patient group 'y'. However, no studies to date have assessed the effect of 'x' in patients with a history of 'z'.'

Study design
Consider the following: The study type is it appropriate to the research question and the subject under investigation, e.g. randomized controlled trial, case control, meta-analysis, cross-sectional, descriptive? The study population Can the results of the study are translated to the general population? Is the patient group representative of the normal population? If not, is this addressed in the text? Randomization how are the participants allocated into the groups? Bias this refers to a flaw in impartiality that introduces systematic error into the methodology and results of a study. Is the research method exposed to bias? Has randomization been used to reduce experiment bias?

What form of blinding or masking has been used to reduce experimental or observational bias? Inclusion and exclusion criteria are these appropriate and clearly stated? Can you identify any oversights that may affect the validity of the study?

Are the methods thorough?

A flawed methodology will undermine the validity of the results. Consider the following: Was the method and approach to the study appropriately diligent? Were processes consistent? Was follow up complete and consistent in each group? What outcome measures were used and were they appropriate? Are the statistical tools adopted suitable and correctly interpreted by the investigators? Have the authors made a power statement? What significance level has been used (P value)? Has the power of the study been stated, does it exceed 80%? Was a power analysis carried out? Was this before the study or post-Doc? Is the study sufficiently powered to eliminate errors? Do the data exhibit low variability? What is the effect size?

Results

Are the results clearly stated? Is the result statistically significant, i.e. is the P value less than 0.05 (is the null hypothesis rejected)? Remember to review supplementary graphs and tables and consider whether they are accurate and represent the data presented in the text.

Discussion and interpretation

Discuss the strengths and weaknesses of the study. Do the results support the conclusions? Often the conclusions will exceed the scope of the evidence base in the preceding paper. Consider the statistical significance vs. the clinical significance? Does the article acknowledge the relevant literature and other approaches? Before concluding, the authors will often include a discussion of the limitations of the study. Close attention should be paid to this to ensure a fair appraisal of the author's claims. Have the authors declared any conflicts of interest?

Clinical context

End your appraisal by assessing how the paper might change clinical practice. You might refer back to the clinical question that first drew you to the article.

Output

Having critically appraised and presented the article, consider whether your comments would be of interest to the publishing journal in the form of a letter to the editor. Particular points of merit, in addition to inconsistencies or statistical short fallings, are of interest to the journal, its readership and the author. Writing letters to the editor is a useful way to hone writing skills and, if accepted, are often published quickly and enhance Curriculum vitae. Often, the article may suggest areas for further research.

Reference- https://www.uab.edu/medicine/physci/uab-multidisciplinary-research-stewardship/step-by-step-approach-to-presenting-at-journal-club

A K S University

Faculty of Pharmaceutical Science & Technology
Rajiv Gandhi Institute of Pharmacy
Curriculum of M. Pharmacy (Pharmaceutics-MPH) Program
(Revised as on 01 August 2023)
Semester-III

Course Code: MPH303

Course Title: Discussion Presentation (Proposal Presentation)

Discussion presentation can be approached in this general format:

- Introduction
- Statement of Problem
- Rationale of Study
- Objectives of Study
- Conceptual Framework
- Research questions and Hypothesis
- Methodology
- Ethical Consideration
- Action Plan
- Annexure

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(Revised as on 01 August 2023)
Semester-III

Course Code: MPH304

Course Title: Research Work

All the students shall undertake a project under the supervision of a teacher in Semester III and submit a report. 4 copies of the project report shall be submitted (typed & bound copy not less than 75 pages). The internal and external examiner appointed by the University shall evaluate the project at the time of the Practical examinations of other semester(s). The projects shall be evaluated as per the criteria given below-

Evaluation of Dissertation Book:

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

Evaluation of Presentation:

Presentation of work-	
Presentation of work	: 70 Marks
Quality of Power Point Presentation	: 30 Marks
Communication skills-	
Written	: 25 Marks
Verbal	: 25 Marks
Question and answer skills	
Questions	: 50 Marks
Answers	: 50 Marks
Total	250 Marks

Course Code: MPH401

Course Title: Journal Club

Every journal club presentation can be approached in this general format:

Introduction
Explain the clinical question that prompted you to consult the literature and what drew you to the article.

Who wrote the paper?
Consider the title of the paper, the authors and their affiliated institution(s). Are there any outstanding features, e.g. a first study of its kind, a well-known author or institution? What is the impact factor of the journal? What is the circulation (i.e. regional, national or international) and who is the readership? Try to ignore the abstract initially. Reading the author's stated conclusions before forming your own ideas about the validity of the paper may influence your appraisal.

The hypothesis
What is the research question? Is it well constructed? Does it observe the four basic components (PICO) of a good research question? Population – who was studied? Intervention – what was the intervention tested? Control – what was the alternative that the intervention was compared to? Outcome – what was the nature of the outcome measured?

Appraise the evidence base
Read the key references and related papers. What is already known on the subject? Is this correctly presented? Is the hypothesis correct? Is the question relevant and important in the context of the existing literature? What does the study contribute to the existing literature? The introduction will usually contain a statement validating the content of the article by placing it in the context of the wider literature. For example, 'Intervention 'x' has been shown to show significant reduction in patient group 'y'. However, no studies to date have assessed the effect of 'x' in patients with a history of 'z'.'

Study design
Consider the following: The study type is it appropriate to the research question and the subject under investigation, e.g. randomized controlled trial, case control, meta-analysis, cross-sectional, descriptive? The study population Can the results of the study are translated to the general population? Is the patient group representative of the normal population? If not, is this addressed in the text? Randomization how are the participants allocated into the groups? Bias this refers to a flaw in impartiality that introduces systematic error into the methodology and results of a study. Is the research method exposed to bias? Has randomization been used to reduce experiment bias?

What form of blinding or masking has been used to reduce experimental or observational bias? Inclusion and exclusion criteria are these appropriate and clearly stated? Can you identify any oversights that may affect the validity of the study?

Are the methods thorough?

A flawed methodology will undermine the validity of the results. Consider the following: Was the method and approach to the study appropriately diligent? Were processes consistent? Was follow up complete and consistent in each group? What outcome measures were used and were they appropriate? Are the statistical tools adopted suitable and correctly interpreted by the investigators? Have the authors made a power statement? What significance level has been used (P value)? Has the power of the study been stated, does it exceed 80%? Was a power analysis carried out? Was this before the study or post-Doc? Is the study sufficiently powered to eliminate errors? Do the data exhibit low variability? What is the effect size?

Results

Are the results clearly stated? Is the result statistically significant, i.e. is the P value less than 0.05 (is the null hypothesis rejected)? Remember to review supplementary graphs and tables and consider whether they are accurate and represent the data presented in the text.

Discussion and interpretation

Discuss the strengths and weaknesses of the study. Do the results support the conclusions? Often the conclusions will exceed the scope of the evidence base in the preceding paper. Consider the statistical significance vs. the clinical significance? Does the article acknowledge the relevant literature and other approaches? Before concluding, the authors will often include a discussion of the limitations of the study. Close attention should be paid to this to ensure a fair appraisal of the author's claims. Have the authors declared any conflicts of interest?

Clinical context

End your appraisal by assessing how the paper might change clinical practice. You might refer back to the clinical question that first drew you to the article.

Output

Having critically appraised and presented the article, consider whether your comments would be of interest to the publishing journal in the form of a letter to the editor. Particular points of merit, in addition to inconsistencies or statistical short fallings, are of interest to the journal, its readership and the author. Writing letters to the editor is a useful way to hone writing skills and, if accepted, are often published quickly and enhance Curriculum vitae. Often, the article may suggest areas for further research.

Reference- https://www.uab.edu/medicine/physci/uab-multidisciplinary-research-stewardship/step-by-step-approach-to-presenting-at-journal-club

A K S University

Faculty of Pharmaceutical Science & Technology
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Curriculum of M. Pharmacy (Pharmaceutics-MPH) Program
(Revised as on 01 August 2023)
Semester-IV

Course Code: MPH402

Course Title: Research Work

All the students shall undertake a project under the supervision of a teacher in Semester IV and submit a report. 4 copies of the project report shall be submitted (typed & bound copy not less than 75 pages). The internal and external examiner appointed by the University shall evaluate the project at the time of the Practical examinations of other semester(s). The projects shall be evaluated as per the criteria given below-

Evaluation of Dissertation Book:

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

Evaluation of Presentation:

Presentation of work-	
Presentation of work	: 70 Marks
Quality of Power Point Presentation	: 30 Marks
Communication skills-	
Written	: 25 Marks
Verbal	: 25 Marks
Question and answer skills-	
Questions	: 50 Marks
Answers	: 50 Marks
Total	250 Marks

Course Code: MPH403

Course Title: Discussion/ Final Presentation

Discussion presentation can be approached in this general format:

- Introduction
- Statement of Problem
- Rationale of Study
- Objectives of Study
- Conceptual Framework
- Research questions and Hypothesis
- Methodology
- Ethical Consideration
- Action Plan
- Annexures