FACULTY OF PHARMACY

KARPAGAM ACADEMY OF HIGHER EDUCATION

Deemed to be University

(Established Under Section 3 of UGC Act 1956)

Eachanari Post, Pollachi Main Road, Coimbatore – 641021.

M.PHARMACY DEGREE COURSE (2024-25)

(PHARMACEUTICS)

Enable | Enlighten | Enrich

KARPAGAM

ACADEMY OF HIGHER EDUCATION

(Deemed to be University)

(Established Under Section 3 of UGC Act, 1956)

REGULATIONS 2024

COURSE OF STUDY AND SCHEME OF EXAMINATION

& SYLLABUS

CHAPTER – I: REGULATIONS

1. Short Title and Commencement

These regulations shall be called as "The Revised Regulations for the Master of Pharmacy (M. Pharm.)Degree Program - Credit Based Semester System (CBSS) of the Pharmacy Council of India, New Delhi". They shall come into effect from the Academic Year 2023-23. The regulations framed are subject to modifications from time to time by the authorities of the university.

2. Minimum qualification for admission

A Pass in the following examinations

a) B. Pharm Degree examination of an Indian university established by law in India from an institution approved by Pharmacy Council of India and has scored not less than 55 % of the maximum marks (aggregate of 4 years of B.Pharm.).

b) Every student, selected for admission to post graduate pharmacy program in any PCI approved institution should have obtained registration with the State Pharmacy Council or should obtain the same within one month from the date of his/her admission, failing which the admission of the candidate shall be cancelled.

Note: It is mandatory to submit a migration certificate obtained from the respective university where the candidate had passed his/her qualifying degree (B.Pharm).

3. Duration of the program

The program of study for M.Pharm shall extend over a period of four semesters (two academic years). The curricula and syllabi for the program shall be prescribed from time to time by Pharmacy Council of India, New Delhi.

4. Medium of instruction and examinations

Medium of instruction and examination shall be in English.

5. Working days in each semester

Each semester shall consist of not less than 100 working days. The odd semesters shall be conducted from the month of June/July to November/December and the even semesters shall be conducted from the month of December/January to May/June in every calendar year.

6. Attendance and progress

A candidate is required to put in at least 80% attendance in individual courses considering theory and practical separately. The candidate shall complete the prescribed course satisfactorily to be eligible to appear for the respective examinations.

7. Program/Course credit structure

As per the philosophy of Credit Based Semester System, certain quantum of academic work viz. theory classes, practical classes, seminars, assignments, 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/per activity.

Credit assignment

Theory and Laboratory courses

Courses are broadly classified as Theory and Practical. Theory courses consist of lecture (L) andPractical (P) courses consist of hours spent in the laboratory. Credits (C) for a course is dependent on the number of hours of instruction per week in that course, and is obtained by using a multiplier of one (1) for lecture and a multiplier of half (1/2) for practical (laboratory) hours. Thus, for example, a theory course having four lectures per week throughout the semester carries a credit of 4. Similarly, a practical having four laboratory hours per week throughout semester carries a credit of 2.

The contact hours of seminars, assignments and research work shall be treated as that of practical courses for the purpose of calculating credits. i.e., the contact hours shall be multiplied by 1/2. Similarly, the contact hours of journal club, research work presentations and discussions with the supervisor shall be considered as theory course and multiplied by 1.

Minimum credit requirements

The minimum credit points required for the award of M.Pharm degree is 95. However based on the credit points earned by the students under the head of co- curricular activities, a student shall earn a maximum of 100 credit points. These credits are divided into Theory courses, Practical, Seminars, Assignments, Research work, Discussions with the supervisor, Journal club and Co- Curricular activities over the duration of four semesters. The credits are distributed semester- wise as shown in Table V. Courses generally progress in sequence, 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.

8. Academic work

A regular record of attendance both in Theory, Practical, Seminar, Assignment, Journal club, Discussion with the supervisor, Research work presentation and Dissertation shall be maintained by the department / teaching staff of respective courses.

9. Course of study

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

Course Code	Course	Credit Hours	Credit Points	Hrs./week	Marks
Semester I					
24MPH101T	Modern Pharmaceutical Analytical Techniques - Theory	4	4	4	100
24MPH102T	Drug Delivery System - Theory	4	4	4	100
24MPH103T	Modern Pharmaceutics - Theory	4	4	4	100
24MPH104T	Regulatory Affairs - Theory	4	4	4	100
24MPH105P	Pharmaceutics - Practical I	6	3	6	75
24MPH106P	Modern Pharmaceutical Analytical Techniques - Practical	6	3	6	75
24MPH107S	Seminar/Assignment	7	4	7	100
Total		35	26	35	650
Semester II					
24MPH201T	Molecular Pharmaceutics - Theory (Nano Technology and Targeted DDS) (NTDS)	4	4	4	100
24MPH202T	Advanced Biopharmaceutics and Pharmacokinetics -Theory	4	4	4	100
24MPH203T	Computer Aided Drug Delivery System - Theory	4	4	4	100
24MPH204T	Cosmetic and Cosmeceuticals - Theory	4	4	4	100
24MPH205P	Pharmaceutics - Practical II	12	6	12	150
24MPH206S	Seminar/Assignment	7	4	7	100
Total		35	26	35	650

Table II: Course of study for M. Pharm III Semester (M.PHARM Pharmaceutics)

Course Code	Course	Credit Hours	Credit Points
24MPH301T	Research Methodology and Biostatistics- Theory*	4	4
24MPH302J	Journal Club	1	1
24MPH303D	Discussion / Presentation (Proposal Presentation)	2	2
24MPH304RW	Research Work	28	14
Total		35	21

*** Non University Exam**

Table III: Course of study for M. Pharm IV Semester

(M.PHARM Pharmaceutics)

Course Code	Course	Credit Hours	Credit Points
24MPH401J	Journal Club	1	1
24MPH402RW	Research Work	31	16
24MPH403D	Discussion / Presentation(Proposal Presentation)	3	3
Total		35	20

Table IV: Semester wise credits distribution

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

*Credit Points for Co-curricular Activities

Table V: Guidelines for Awarding Credit Points for Co-curricular Activities

Name of the Activity	Maximum Credit Points Eligible / Activity
Participation in National Level Seminar/Conference/Workshop/Symposium/Training Programs (related to the specialization of the student)	01
Participation in international Level Seminar/Conference/Workshop/Symposium/Training Programs (related to the specialization of the student)	02
Academic Award/Research Award from State Level/National Agencies	01
Academic Award/Research Award from International Agencies	02
Research / Review Publication in National Journals (Indexed in Scopus / Web of Science)	01

Research / Review Publication in International Journals (Indexed in Scopus / Web of Science)	02

Note: International Conference: Held outside India International Journal: The Editorial Board outside India

* The credit points assigned for extracurricular and or co-curricular activities shall be given by the Principals of the colleges and the same shall be submitted to the University. The criteria to acquire this credit point shall be defined by the colleges from time to time.

10. Program Committee

1. The M. Pharm programme shall have a Programme Committee constituted by the Head of the institution in consultation with all the Heads of the departments.
2. The composition of the Programme Committee shall be as follows:

   A teacher at the cadre of Professor shall be the Chairperson; One Teacher from each M.Pharm specialization and four student representatives (two from each academic year),nominated by the Head of the institution.
3. Duties of the Programme Committee:

i. Periodically reviewing the progress of the classes.
ii. Discussing the problems concerning curriculum, syllabus and the conduct of classes.
iii. Discussing with the course teachers on the nature and scope of assessment for the course and the same shall be announced to the students at the beginning of respective semesters.
iv. Communicating its recommendation to the Head of the institution on academic matters.
v. The Programme Committee shall meet at least twice in a semester preferably at the end of each sessional exam and before the end semester exam.

11. Examinations/Assessments

The schemes for internal assessment and end semester examinations are given in Table – VIII.

End semester examinations

The End Semester Examinations for each theory and practical course through semesters I to IV shall be conducted by the respective university except for the subject with asterix symbol (*) in table I and II for which examinations shall be conducted by the subject experts at college level and the marks/grades shall be submitted to the university.

Table VI: Schemes for Internal Assessments and End Semester Examinations (Pharmaceutics)

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
SEMESTER I								
24MPH101T	Modern Pharmaceutical Analytical Techniques - Theory	10	15	1 Hr	25	75	3 Hrs	100
24MPH102T	Drug Delivery System - Theory	10	15	1 Hr	25	75	3 Hrs	100
24MPH103T	Modern Pharmaceutics - Theory	10	15	1 Hr	25	75	3 Hrs	100
24MPH104T	Regulatory Affairs - Theory	10	15	1 Hr	25	75	3 Hrs	100
24MPH105P	Pharmaceutics - Practical I	10	15	3 Hrs	25	50	3 Hrs	75
24MPH106P	Modern Pharmaceutical Analytical Techniques - Practical	10	15	3 Hrs	25	50	3Hrs	75
24MPH107S	Seminar /Assignment	-	100	-	100	-	-	100
Total								650

SEMESTER II								
24MPH201T	Molecular Pharmaceutics - Theory (Nano Technology and Targeted DDS) (NTDS)	10	15	1 Hr	25	75	3 Hrs	100
24MPH202T	Advanced Biopharmaceutics and Pharmacokinetics - Theory	10	15	1 Hr	25	75	3 Hrs	100
24MPH203T	Computer Aided Drug Delivery System - Theory	10	15	1 Hr	25	75	3 Hrs	100
24MPH204T	Cosmetic and Cosmeceuticals - Theory	10	15	1 Hr	25	75	3 Hrs	100
24MPH205T	Pharmaceutics - Practical II	20	30	6 Hrs	50	100	6 Hrs	150
24MPH206S	Seminar /Assignment	-	100	-	100	-	-	100
Total								650

Table VII: Schemes for internal assessments and end semester examinations(Semester III& IV) (Pharmaceutics)

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
SEMESTER III								
24MPH301T	Research Methodology and Biostatistics-Theory *	10	15	1 HR	25	75	3 HR	100
24MPH302J	Journal Club	-	-	-	25	-	-	25
24MPH303D	Discussion / Presentation (Proposal Presentation)	-	-	-	50	-	-	50
24MPH304RW	Research Work	-	-	-	-	350	1 HR	350
Total								525
SEMESTER IV								
24MPH401J	Journal club	-	-	-	25	-	-	25
24MPH402RW	Research Work	-	-	-	75	-	-	75
24MPH403D	Discussion/Final Presentation	-	-	-	-	400	1 HR	400
Total								500

*Non University Exam

Internal assessment: Continuous mode

The marks allocated for Continuous mode of Internal Assessment shall be awarded as per the scheme given below.

Table: VIII: Scheme for awarding internal assessment: Continuous mode

Theory		
Criteria	Maximum Marks	
Attendance (Refer Table– 30)	8	
Student – Teacher interaction	2	
Total	10	
Practical		
Attendance (Refer Table– 30)	5	10
Based on Practical Records, Regular viva voce, etc.	5	10
Total	10	20

Table IX: 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

Sessional Exams

Two Sessional exams shall be conducted for each theory / practical course as per the schedule fixed by the college(s). The scheme of question paper for theory and practical sessional examinations is given below.

The average marks of two Sessional exams shall be computed for internal assessment as per theRequirements given in tables – VI.

12. Promotion and award of grades

A student shall be declared PASS and eligible for getting grade in a course of M.Pharm programmeif he/she secures at least 50% marks in that particular course including internal assessment.

13. Carry forward of marks

In case a student fails to secure the minimum 50% in any Theory or Practical course as

specified in 12, then he/she shall reappear for the end semester examination of that course. However his/her marks of the Internal Assessment shall be carried over and he/she shall be entitled for grade obtainedby him/her on passing.

14. Improvement of internal assessment

A student shall have the opportunity to improve his/her performance only once in the sessional exam component of the internal assessment. The re-conduct of the sessional exam shall be completed before the commencement of next end semester theory examinations.

15. Re-examination of end semester examinations

Reexamination of end semester examination shall be conducted as per the schedule given in table XIII.The exact dates of examinations shall be notified from time to time.

Table X: Tentative schedule of end semester examinations

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

16. Allowed to keep terms (ATKT):

No student shall be admitted to any examination unless he/she fulfills the norms given in 6. ATKTrules are applicable as follows:

A student shall be eligible to carry forward all the courses of I and II semesters till the III semester examinations. However, he/she shall not be eligible to attend the courses of IV semester until all thecourses of I, II and III semesters are successfully completed.

A student shall be eligible to get his/her CGPA upon successful completion of the courses of I to IVsemesters within the stipulated time period as per the norms.

Note: Grade AB should be considered as failed and treated as one head for deciding ATKT. Suchrules are also applicable for those students who fail to register for examination(s) of any course in any semester.

17. Grading of performances

17.1. Letter grades and grade points allocations:

Based on the performances, each student shall be awarded a final letter grade at the end of thesemester for each course. The letter grades and their corresponding grade points are given in Table–10.

Table XI: Letter grades and grade points equivalent to Percentage of marks and performances

Letter Grade	Marks Range	Grade Point	Description
O	91 – 100	10	OUTSTANDING
A+	81 – 90	9	EXCELLENT
A	71-80	8	VERY GOOD
B+	66-70	7	GOOD
B	61-65	6	ABOVE AVERAGE
C	55-60	5	AVERAGE
D	50-54	4	PASS
RA	<50	0	REAPPEARANCE
AB	-	0	ABSENT

A learner who remains absent for any end semester examination shall be assigned a letter grade of AB and a corresponding grade point of zero. He/she should reappear for the said evaluation/examination in due course.

18. The Semester grade point average (SGPA)

The performance of a student in a semester is indicated by a number called 'Semester Grade Point Average' (SGPA). The SGPA is the weighted average of the grade points obtained in all the coursesby the student during the semester. For example, if a student takes five courses (Theory/Practical) in asemester with credits C1, C2, C3 and C4 and the student's grade points in these courses are G1, G2,G3 and G4, respectively, and then students' SGPA is equal to:

$$SGPA = \frac{C_1G_1 + C_2G_2 + C_3G_3 + C_4G_4}{C_1 + C_2 + C_3 + C_4}$$

The SGPA is calculated to two decimal points. It should be noted that, the SGPA for any semester shall take into consideration the F and ABS grade awarded in that semester. For example if a learner has a F or ABS grade in course 4, the SGPA shall then be computed as:

$$SGPA = \frac{C_1G_1 + C_2G_2 + C_3G_3 + C_4 * \text{ZERO}}{C_1 + C_2 + C_3 + C_4}$$

19. Cumulative Grade Point Average (CGPA)

The CGPA is calculated with the SGPA of all the IV semesters to two decimal points and is indicated in final grade report card/final transcript showing the grades of all IV semesters and

their courses. The CGPA shall reflect the failed statusin case of F grade(s), till the course(s) is/are passed. When the course(s) is/are passedby obtaining a pass grade on subsequent examination(s) theCGPA shall only reflect the new grade and not the fail grades earned earlier.The CGPA is calculated as:

$$\textbf{CGPA} = \frac{C_1S_1 + C_2S_2 + C_3S_3 + C_4S_4}{C_1 + C_2 + C_3 + C_4}$$

where $C_1, C_2, C_3, \ldots$ is the total number of credits for semester I,II,III,…. and $S_1, S_2, S_3, \ldots$ is the SGPA of semester I,II,III,…..

20. Declaration of class

The class shall be awarded on the basis of CGPA as follows: First Class with Distinction = 8 and above

First Class = 6.50 to 7.99

Second Class = 5.00 to 6.49

21. Project work

All the students shall undertake a project under the supervision of a teacher in Semester III to 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 thetime 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	100 Marks
Communication skills	50 Marks
Question and answer skills	100 Marks

Total 250 Marks

22. Award of Ranks

Ranks and Medals shall be awarded on the basis of final CGPA. However, candidates who fail in one or more courses during the M.Pharm program shall not be eligible for award of ranks. Moreover, the candidates should have completed the M. Pharm program in minimum prescribed number of years, (two years) for the award of Ranks.

23. Award of degree

Candidates who fulfill the requirements mentioned above shall be eligible for award of degree during the ensuing convocation.

24. Duration for completion of the program of study

The duration for the completion of the program shall be fixed as double the actual duration of the program and the students have to pass within the said period, otherwise they have to get fresh Registration.

25. Revaluation I Retotaling of answer papers

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

26. Re-admission after break of study

Candidate who seeks re-admission to the program after break of study has to get the approval from the university by paying a condonation fee

FACULTY OF PHARMACY
PG PROGRAM (CBCS) – M.PHARM (PHARMACEUTICS)
(2024–2025 Batch and onwards)

Course code	Name of the course	Objectives and out comes		Instruction hours / week			Credit(s)	Maximum Marks		
		PEOs	POs	L	T	P		CIA	ESE	Total
								25	75	100
SEMESTER - I										
24MPH101T	Modern Pharmaceutical Analytical Techniques - Theory	1,2	a,c,d,hj	4	-	-	4	25	75	100
24MPH102T	Drug Delivery System - Theory	1,2	a,c,d,h,j	4	-	-	4	25	75	100
24MPH103T	Modern Pharmaceutics - Theory	1,2,4	a,c,d,h,j	4	-	-	4	25	75	100
24MPH104T	Regulatory Affairs - Theory	1,2, 3	a,b,d,e,h,i	4	-	-	4	25	75	100
24MPH105P	Pharmaceutics - Practical I	1,2, 4	a,b,c,d ,h,I,j	-	-	6	3	25	50	75
24MPH106P	Modern Pharmaceutical Analytical Techniques - Practical	1,2, 4	a,b,c,d ,h,I,j	-	-	6	3	25	50	75
24MPH107S	Seminar/Assignment	-	-	7	-	-	4	100	-	100
Semester Total				**23**	**-**	**12**	**26**	**250**	**400**	**650**
SEMESTER – II										
24MPH201T	Molecular Pharmaceutics - Theory (Nano Technology and Targeted DDS) (NTDS)	1,2,4	a,c,d ,h,j	4	-	-	4	25	75	100
24MPH202T	Advanced Biopharmaceutics and Pharmacokinetics -Theory	1,2	a,b,c,d ,h,i,j	4	-	-	4	25	75	100
24MPH203T	Computer Aided Drug Delivery System -Theory	1,2,4	a,c,d,h ,j	4	-	-	4	25	75	100
24MPH204T	Cosmetics and Cosmeceuticals - Theory	1,2,5	a,c,d,g, h,j	4	-	-	4	25	75	100
24MPH205P	Pharmaceutics – Practical II	1,2,4	a,b,c,d ,h,i,j	-	-	12	6	50	100	150
24MPH206S	Seminar/Assignment	-	-	7	-	-	4	100	-	100
Semester Total				**23**	**-**	**12**	**26**	**250**	**400**	**650**
SEMESTER- III										
24MPH301T	Research Methodology and Biostatistics - Theory*	2,5	b,c,j	4	-	-	4	25	75	100
24MPH302J	Journal Club	-	-	1	-	-	1	25	-	25

24MPH303D	Discussion/Presentation (Proposal Presentation)	-	-	2	-	-	2	50	-	50
24MPH304RW	Research Work	1,2, 3,4, 5	a,b,c,d ,e,f,g,h,i ,j	-	-	28	14	-	350	350
Semester Total				7	**-**	**28**	**21**	**100**	**425**	**525**
SEMESTER- IV										
24MPH401J	Journal Club	-	-	1	-	-	1	25	-	25
24MPH402RW	Research Work	1,2, 3,4, 5	a,b,c,d ,e,f,g,h,i ,j	-	-	31	16	75	-	75
24MPH403D	Discussion/Final Presentation	-	-	3	-	-	3	-	400	400
Semester Total				**4**	**-**	**31**	**20**	**100**	**400**	**500**

*Non university Exam

PROGRAMME OUTCOMES (PO)

a. **Pharmacy Knowledge:** Demonstrate knowledge of the basic pharmaceutical sciences and the ability to acquire, manage and use current information for problem solving. Describe the synthesis, formulation, analysis, pharmacological, Pharmacognostical, biotechnological and regulatory aspects of drugs and biopharmaceuticals. Identify the rules and regulations involved in the drug discovery and development, manufacture, distribution and sale of medicines.

b. **Planning Abilities:** Demonstrate effective planning abilities including time management, resource management, delegation skills and organizational skills. Develop and implement plans and organize work to meet deadlines using modern tools.

c. **Research:** An ability to independently carry out research /investigation and development work to solve practical problems. Apply critical thinking skills, including investigation, application, analysis, creativity, evaluation of information, data and documents related to research investigation.

d. **Problem analysis:** Develop problem-based learning approach and analytical thinking in his/her academic and professional life. Utilize the principles of scientific enquiry, thinking analytically, clearly and critically, while solving problems and making decisions during daily practice. Find, analyze, evaluate and apply information systematically and shall make defensible decisions.

e. **Leadership qualities:** Demonstrate the ability to plan and implement professional activities. Act efficiently as a leader in the diverse areas of the profession.

f. **Communication Skills:** Communicate effectively with the pharmacy community and with society at large, such as, being able to comprehend and write effective reports, make effective presentations and documentation, and give and receive clear instructions. Imbibe the skills of scientific communication and research writing.

g. **The Pharmacist and society:** Apply the knowledge and skills gained through education to gain recognition in professional circle and society. Participate in healthcare initiatives to create awareness in society about the effective and safe use of medicines.

h. **Professional Ethics:** Exercise ethical practices and moral values in personal and professional endeavors. Honor personal values and apply ethical principles in professional and social contexts. Demonstrate behavior that recognizes cultural and 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.

i. **Environment and sustainability:** Understand the impact of the professional pharmacy solutions in societal and environmental contexts, and demonstrate the knowledge of, and need for sustainable development.

j. **Life-long learning:**Tackle professional challenges through lifelong learning attitude. Work in a team and participate in lifelong learning and continuous improvement in the profession.

PROGRAMME SPECIFIC OUTCOMES (PSOs)

PSO k: Understand a core and basic knowledge in different subjects of Pharmaceutical Sciences. To prepare graduate to success in technical or professional careers in various pharmaceutical industry and/ or institute and /or Health care system through excellent real time exposure to rigorous education.

PSO l: Analyse the relationships among Pharmaceutics, Pharmaceutical and Medicinal Chemistry, Pharmacology and Pharmacognosy subjects. Understand the applications of Pharmaceutical Sciences in drug and formulation development, drug analysis, drug safety and efficacy in medicine.

PSO m: Perform procedures as per laboratory standards in the areas of Pharmaceutical Sciences.

PSO n: To strengthen the professional and ethical attitude, effective communication skills, teamwork skills, multidisciplinary approach, and an ability to relate pharmaceutical sciences issues to broader social context.

PSO o: To streams a lifelong career of personal and practicing professional growth with ethical codes and self-esteem for a highly productive career and to relate the concepts of Pharmaceutical Sciences towards serving the cause of the society.

PROGRAMME EDUCATIONAL OBJECTIVES (PEOs)

PEO 1

To provide a comprehensive and advanced pharmaceutical education leading to M. Pharm. Degree.

PEO 2

To integrate pharmacy knowledge and skills with pharmaceutical research.

PEO 3

To develop pharmacists to contribute effectively in the social health care system.

PEO 4

To provide hands on training through state of art infrastructure to inculcate research aptitude in pharmaceutical sciences.

PEO 5

To inculcate leadership and entrepreneurship capabilities in future pharmacy professionals.

MAPPING

PO	a	b	c	d	e	f	g	h	I	j	PSO k	PSO l	PSO m	PSO n	PSO o
PEO 1	X						X	X		X	X	X	X	X	
PEO 2	X	X	X	X		X		X		X	X	X	X	X	X
PEO 3	X	X		X		X	X	X	X	X	X	X		X	X
PEO 4	X	X	X	X						X	X	X	X	X	X
PEO 5	X	X	X	X	X	X		X	X	X				X	X

Note: (a-k denoted the above mentioned PO)

M.PHARM
PHARMACEUTICS (MPH)

24MPH101T **SEMESTER I**

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES -THEORY 4H 4C

Instruction hours/ week: L:**4** T:**0** P**:0** Marks: Internal: **25** External: **75** Total: **100**
External Semester Exam: **3 Hours**

COURSE OBJECTIVES:

- This subject deals with the applications of qualitative and quantitative analysis
- To discuss about principle involved in spectroscopy and Separation techniques.
- To discuss the principle involved in X ray diffraction, Thermal analysis and analysis of immunological techniques.
- To discuss the instrumental analysis of spectroscopy and chromatographic techniques
- To acquired skills in basic concepts of spectral data analysis
- To deal with the applications of pharmaceutical dosage forms

COURSE OUTCOMES:

After completion of course student will

COs	Course Outcomes	Blooms Level
CO1	Explain the principle involved in spectroscopy	Understand
CO2	Explain the principle involved in Chromatographic Techniques	Apply
CO3	Describe the instrumentation of various instrumental Techniques	Creat
CO4	Interpret the basic concepts of Spectral data analysis	Evaluate
CO5	Describe the qualitative /quantitative analysis of various API/ drug dosage from through Spectroscopic Techniques.	Understand
CO6	Describe the qualitative /quantitative analysis of various API/ drug dosage from through Chromatographic techniques	Understand

Mapping with Programme Outcomes

COs	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11	PO12
CO1		S										
CO2		S										
CO3			S						M			
CO4			S									
CO5	S											
CO6		S										

S-**Strong**; M-**Medium**; L-**Low**

THEORY **60 hrs**

Unit I **10 h**

1. **UV-Visible spectroscopy:** Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV-Visible spectroscopy, Difference/ Derivative spectroscopy.
2. **IR spectroscopy:** Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier - Transform IR Spectrometer, Factors affecting vibrational frequencies and Applications of IR spectroscopy, Data Interpretation.
3. **Spectroflourimetry:** Theory of Fluorescence, Factors affecting fluorescence (Characteristics of drugs that can be analysed by fluorimetry), Quenchers, Instrumentation and Applications of fluorescence spectrophotometer.
4. Flame emission spectroscopy and atomic absorption spectroscopy: Principle, Instrumentation, Interferences and Applications.

Unit II **8 h**

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

Unit III **8 h**

Mass Spectroscopy: Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules, Meta stable ions, Isotopic peaks and Applications of Mass spectroscopy.

Unit IV **9 h**

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

a) Thin Layer chromatography
b) High Performance Thin Layer Chromatography
c) Ion exchange chromatography
d) Column chromatography
e) Gas chromatography
f) High Performance Liquid chromatography
g) Ultra High-Performance Liquid chromatography
h) Affinity chromatography
i) Gel Chromatography

Unit V **9 h**

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

a) Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresis d) Zone electrophoresis e) Moving boundary electrophoresis f) Iso electric focusing

2. X ray Crystallography: Production of X rays, Different X ray methods, Bragg 's law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X-ray diffraction

.

Unit VI 12 h

1. **Electro Chemical Analysis:** Principle, instrumentation and Application of potentiometry, conductometry, polarography and Amperometry.
2. **Thermal Techniques:** Principle, thermal transitions and Instrumentation (Heat flux and power-compensation and designs), Modulated DSC, Hyper DSC, experimental parameters (sample preparation, experimental conditions, calibration, heating and cooling rates, resolution, source of errors) and their influence, advantage and disadvantages, pharmaceutical applications.
   Differential Thermal Analysis (DTA): Principle, instrumentation and advantage and disadvantages, pharmaceutical applications, derivative differential thermal analysis (DDTA).
   TGA: Principle, instrumentation, factors affecting results, advantage and disadvantages, pharmaceutical applications.
3. **Immunological Assay** Basic concepts of RIA (Radio immuno assay), ELISA, Bioluminescence assay.

REFERENCES

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.
4. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi, 1997.
5. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis - Modern Methods – Part B - J W Munson, Vol 11, Marcel. Dekker Series
8. Spectroscopy of Organic Compounds, 2nd edn., P.S/Kalsi, Wiley estern Ltd., Delhi.
9. Textbook of Pharmaceutical Analysis, KA. Connors, 3rd Edition, John Wiley & Sons, 1982.

24MPH102T **SEMESTER I**

DRUG DELIVERY SYSTEM- THEORY 4H 4C

Instruction hours/ week: L: **4** T: **0** P: **0** Marks: Internal: **25** External: **75** Total: **100**
External Semester Exam: 3 Hours

COURSE OBJECTIVES:

- The various approaches for development of SR and CR formulations.
- The various approaches for development of Rate Controlled Drug Delivery Systems.
- The various approaches for development of Gastro-Retentive Drug Delivery Systems.
- The various approaches for development of Ocular and Transdermal Drug Delivery Systems.
- The various approaches for development of Protein, Peptide and Vaccine delivery systems.
- The criteria for selection of drugs and polymers for the development of delivering systems.

COURSE OUTCOMES:

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

COs	Course Outcomes	Blooms Level
CO1	The various approaches for development of SR and CR formulations.	Understand
CO2	The various approaches for development of Rate Controlled Drug Delivery Systems.	Understand
CO3	The various approaches for development of Gastro-Retentive Drug Delivery Systems.	Understand
CO4	The various approaches for development of Ocular and Trans dermal Drug Delivery Systems.	Understand
CO5	The various approaches for development of Protein, Peptide and Vaccine delivery systems.	Understand
CO6	The criteria for selection of drugs and polymers for the development of delivering systems.	Understand

Mapping with Programme Outcomes

COs	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11	PO12
CO1	S			M								
CO2	S			S				M				
CO3	S											
CO4	S							M				
CO5	S			L				L				
CO6	S							M				

S- **Strong**; M-**Medium**; L-**Low**

THEORY **60 Hrs**

Unit I **12 h**

1. Sustained Release (SR) and Controlled Release (CR) formulations Introduction & basic concepts, advantages/ disadvantages, factors influencing, Physicochemical & biological approaches for SR/CR formulation, Mechanism of Drug Delivery from SR/CR formulation. Polymers: introduction, definition, classification, properties and application

Dosage Forms for Personalized Medicine: Introduction, Definition, Pharmacogenetics, Categories of Patients for Personalized Medicines: Customized drug delivery systems, Bioelectronic Medicines, 3D printing of pharmaceuticals, Tele pharmacy

Unit II **12 h**

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

Unit III **12 h**

Gastro-Retentive Drug Delivery Systems: Principle, concepts advantages and disadvantages, Modulation of GI transit time approaches to extend GI transit. Buccal Drug Delivery Systems: Principle of muco adhesion, advantages and disadvantages, Mechanism of drug permeation, Methods of formulation and its evaluations.

Unit IV **6 h**

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

Unit V **6 h**

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

Unit VI **6 h**

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

Unit VII **6 h**

Vaccine delivery systems: Vaccines, uptake of antigens, single shot vaccines,
Mucosal and transdermal delivery of vaccines.

REFERENCES

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

5. S.P. Vyas and R.K.Khar, Controlled Drug Delivery - concepts and advances, Vallabh Prakashan, New Delhi, First edition 2002

JOURNALS

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

24MPH103T SEMESTER I

MODERN PHARMACEUTICS - THEORY 4H 4C

Instruction hours/ week: L: 4 T: 0 P: 0 Marks: Internal: 25 External:75 Total:100
External Semester Exam: 3Hours

COURSE OBJECTIVES:

- The elements of Preformulation studies.
- The Active Pharmaceutical Ingredients and Generic drug Product development.
- Industrial Management and GMP Considerations.
- Optimization Techniques & Pilot Plant Scale Up Techniques.
- Stability Testing, sterilization process & packaging of dosage form.
- Principles of Compression, Compaction & Consolidation parameters.

Course Outcomes

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

COs	Course Outcomes	Blooms Level
CO1	Summarize the elements of Preformulation studies.	Understand
CO2	Identify the importance of Optimization Techniques, Stability Testing & Sterilization process.	Apply
CO3	correlate the role the Pharmaceutical Validation and Government regulations.	Analyze
CO4	Adapt the idea of Industrial Management and GMP Considerations.	Create
CO5	Demonstrate the Principles of Compression & Compaction.	Understand
CO6	Demonstrate the Principles of Consolidation parameters.	Understand

Mapping with Programme Outcomes

COs	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10
CO1	**S**		**L**							
CO2	**S**									
CO3	**S**	**M**								**M**
CO4	**S**									
CO5	**S**			**L**						
CO6	**S**			**L**						

S-Strong; M-Medium; L-Low

Course Content:

THEORY 60 Hrs

Unit I 12 h

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

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

Unit II 12 h

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

Unit III 12 h

3 cGMP & Industrial Management: Objectives and policies of current good manufacturing practices, layout of buildings, services, equipments and their maintenance Production management: Production organization, , materials management, handling and transportation, inventory management and control, production and planning control, Sales forecasting, budget and cost control, industrial and personal relationship. Concept of Total Quality Management.

Unit IV 12 h

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

Unit V 12 h

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

REFERENCES

1. Theory and Practice of Industrial Pharmacy By Lachmann and Libermann
2. Pharmaceutical dosage forms: Tablets Vol. 1-3 by Leon Lachmann.
3. Pharmaceutical Dosage forms: Disperse systems, Vol, 1-2; By Leon Lachmann.
4. Pharmaceutical Dosage forms: Parenteral medications Vol. 1-2; By Leon Lachmann.
5. Modern Pharmaceutics; By Gilbert and S. Banker.
6. Remington’s Pharmaceutical Sciences.
7. Advances in Pharmaceutical Sciences Vol. 1-5; By H.S. Bean & A.H. Beckett.
8. Physical Pharmacy; By Alfred martin
9. Bentley’s Textbook of Pharmaceutics – by Rawlins.

10. Good manufacturing practices for Pharmaceuticals: A plan for total quality control, Second edition; By Sidney H. Willig.
11. Quality Assurance Guide; By Organization of Pharmaceutical producers of India.
12. Drug formulation manual; By D.P.S. Kohli and D.H.Shah. Eastern publishers, New Delhi.
13. How to practice GMPs; By P.P.Sharma. Vandhana Publications, Agra.
14. Pharmaceutical Process Validation; By Fra. R. Berry and Robert A. Nash.
15. Pharmaceutical Preformulations; By J.J. Wells.
16. Applied production and operations management; By Evans, Anderson, Sweeney and Williams.
17. Encyclopaedia of Pharmaceutical technology, Vol I – III.

24MPH104T SEMESTER I
REGULATORY AFFAIRS - THEORY 4C 4H

Instruction hours/ week: L:4 T:0 P:0 Marks: Internal: 25 External:75 Total:100
External Semester Exam: 3Hours
COURSE OBJECTIVES:

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

Course Outcomes (CO's):

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

COs	Course Outcomes	Blooms Level
CO1	The Concepts of innovator and generic drugs, drug development process	Create
CO2	The Regulatory guidance's and guidelines for filing and approval process	Knowledge
CO3	Preparation of Dossiers and their submission to regulatory agencies in different countries	Understand
CO4	Post approval regulatory requirements for actives and drug products	Apply
CO5	Submission of global documents in CTD/ eCTD formats	Apply
CO6	Clinical trials requirements for approvals for conducting clinical trials and Pharmacovigilance and process of monitoring in clinical trials.	Evaluate

Mapping with Programme Outcomes

CO's	POa	POb	POc	POd	POe	POf	POg	POh	POi
CO1	**M**								
CO2	**M**								
CO3	**M**								
CO4	**M**								
CO5	**M**								
CO6	**M**								

S-Strong; M-Medium; L-Low

THEORY **60 Hrs**

Unit I 20 h

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

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

Unit II 15 h

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

Unit III 10 h

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

Unit IV 15 h

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

REFERENCES:

1. Generic Drug Product Development, Solid Oral Dosage forms, Leon Shargel and IsaderKaufer,Marcel Dekker series, Vol.143
2. The Pharmaceutical Regulatory Process, Second Edition Edited by Ira R.
3. Berry and Robert P.Martin, Drugs and the Pharmaceutical Sciences,Vol.185, Informa Health care Publishers.
4. New Drug Approval Process: Accelerating Global Registrations By Richard A Guarino, MD,5th edition, Drugs and the Pharmaceutical Sciences,Vol.190.
5. Guidebook for drug regulatory submissions / Sandy Weinberg. By John Wiley & Sons.Inc.
6. FDA regulatory affairs: a guide for prescription drugs, medical devices, and biologics/edited By Douglas J. Pisano, David Mantus.
7. Clinical Trials and Human Research: A Practical
8. Guide to Regulatory Compliance By Fay A.Rozovsky and Rodney K. Adams
9. www.ich.org/
10. www.fda.gov/
11. europa.eu/index_en.htm
12. https://www.tga.gov.au/tga-basics

24MPH105P SEMESTER I

PHARMACEUTICS PRACTICAL -I 6H 3C

Instruction hours/ week: L:0 T:0 P:6 Marks: Internal: 25 External:50 Total:75
External Semester Exam: 3Hours

COURSE OBJECTIVES:

- To perform in-vitro dissolution analysis of CR/SR marketed formulations.
- To formulate and assess sustained release matrix tablets.
- To prepare and evaluate fast dissolving tablets.
- To formulate and evaluate osmotically controlled drug delivery systems (DDS).
- To develop and assess hydrodynamically balanced floating DDS.
- To formulate and evaluate mucoadhesive tablets.

Course Outcomes

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

COs	Course Outcomes	Blooms Level
CO1	Ability to conduct in-vitro dissolution studies on marketed formulations.	Create
CO2	Proficiency in designing sustained release matrix tablets.	Create
CO3	Competence in formulating fast dissolving tablets.	Create
CO4	Skill in developing and evaluating osmotically controlled DDS.	Evaluate
CO5	Capacity to create and assess hydrodynamically balanced floating DDS.	Create
CO6	Proficiency in formulating and evaluating mucoadhesive tablets.	Evaluate

Mapping with Programme Outcomes

COs	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10
CO1	**S**		**M**							
CO2	**S**		**M**							
CO3	**S**		**M**							
CO4	**S**		**M**	**L**						
CO5	**S**		**M**	**L**						
CO6	**S**		**M**							

S-Strong; M-Medium; L-Low

PRACTICALS

1. To perform In-vitro dissolution profile of CR/ SR marketed formulation
2. Formulation and evaluation of sustained release matrix tablets
3. Preparation and evaluation Fast dissolving tablets
4. Formulation and evaluation osmotically controlled DDS
5. Preparation and evaluation of Floating DDS- hydro dynamically balanced DDS
6. Formulation and evaluation of Muco adhesive tablets.

7. Formulation and evaluation of trans dermal patches.
8. Formulation and evaluation of microspheres
9. To carry out preformulation studies of tablets.
10. To study the effect of compressional force on tablets disintegration time.
11. To study Micromeritic properties of powders and granulation.
12. To study the effect of particle size on dissolution of a tablet.
13. To study the effect of binders on dissolution of a tablet.
14. To plot Heckal plot, Higuchi and peppas plot and determine similarity factors.

24MPH106P SEMESTER I

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES - PRACTICAL 6H 3C

Instruction hours/ week: L:0 T:0 P:06 Marks: Internal: 25 External:50 Total:75

External Semester Exam: 3Hours

COURSE OBJECTIVES:

- To estimate the samples using analytical instruments.
- To perform assay of official drug samples using analytical instruments
- To demonstrate Flash Chromatography.
- To demonstrate HPLC.
- To demonstrate LCMS.
- To demonstrate gas chromatography.

COURSE OUTCOMES:

At completion of this course student will

COs	Course Outcomes	Blooms Level
CO1	demonstrate the analysis of pharmacopieal compounds and simultaneous estimation by UV-VIS	Apply
CO2	acquire skills in selecting the suitable techniques for analysis of drugs	Analyze
CO3	demonstrate HPLC & LCMS	Apply
CO4	estimation of pharmaceutical substance by using fluorimetry / flame photometry	Understand
CO5	Compare and contrast various methods of analysis and their outcomes	Analyze
CO6	demonstrate Flash Chromatography	Apply

Mapping with Programme Outcomes

COs	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11	PO12
CO1				S								
CO2	S											
CO3				S								
CO4	S									S		
CO5	M									S		
CO6	M										S	

Strong; M-Medium; L-Low

CONTENTS:

1.Analysis of Pharmacopoeial compounds and their formulations by UV Vis spectrophotometer

2. Simultaneous estimation of Multicomponent containing formulations by uv spectrophotometry

2. Experiments based on Column chromatography

3. Experiments based on HPLC

4. Experiments based on Gas Chromatography

5. Estimation of various drugs by Spectrofluorimetry

6. Estimation of sodium/potassium level by flame photometry

7. Experiments Based on Flash Chromatography.(Two Experiments)

8. Experiments Based on LC-MS.

9. Experiments based on IR spectroscopy.

10.Experiments based on HPTLC.(Two Experiments)

11. Interpretation of Any two organic compounds by HNMR

REFERENCE BOOKS (LATEST EDITIONS):

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons,2004.
2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5thedition, Eastern press, Bangalore,1998.
3. Instrumental methods of analysis – Willards, 7thedition, CBS publishers.
4. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4thedition, CBS Publishers, New Delhi,1997.
5. Organic Spectroscopy - William Kemp, 3rdedition, ELBS,1991.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rdEdition, CBS Publishers, New Delhi,1997.
7. Pharmaceutical Analysis - Modern Methods – Part B - J W Munson, Vol 11, Marcel. DekkerSeries
a. Spectroscopy of Organic Compounds, 2ndedn., P.S/Kalsi, Wiley estern Ltd.,Delhi.

24MPH107S SEMESTER I

SEMINAR/ASSIGNMENT **7H 4C**

Instruction hours/ week: L: 7 T: 0 P: 0 Marks: Internal: 100 Total: 100

S. No	COMPONENTS	MARKS
1	ATTENDANCE	08
2	CONTENT RELEVANCE AND DEPTH	20
3	ENGAGEMENT AND INTERACTION	12
4	PRESENTATION SKILLS	60
Total	**PASS MARK (50)**	**100**

24MPH201T SEMESTER II

MOLECULAR PHARMACEUTICS - THEORY
(NANO TECHNOLOGY AND TARGETED DDS) (NTDS) 4H 4C

Instruction hours/ week: L:4 T:0 P:0 Marks: Internal: 25 External:75 Total:100
External Semester Exam: 3Hours

COURSE OBJECTIVES:

- The various approaches for development of novel drug delivery systems.
- The criteria for selection of drugs and polymers for the development of NTDS
- The formulation and evaluation of Targeted Drug Delivery Systems.
- The formulation and evaluation of Micro capsules.
- The formulation and evaluation of Nucleic acid based therapeutic Delivery Systems.
- To study the Biodistribution and Pharmacokinetics knowledge of therapeutic antisense molecules and aptamers.

Course Outcomes

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

COs	Course Outcomes	Blooms Level
CO1	The various approaches for development of novel drug delivery systems.	Understand
CO2	The criteria for selection of drugs and polymers for the development of NTDS	Analyze
CO3	The formulation and evaluation of Targeted Drug Delivery Systems	Analyze
CO4	The formulation and evaluation of Micro capsules.	create
CO5	The formulation and evaluation of Nucleic acid based therapeutic Delivery Systems.	Analyze
CO6	The Biodistribution and Pharmacokinetics knowledge of therapeutic antisense molecules and aptamers.	Understand

Mapping with Programme Outcomes

COs	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10
CO1	**S**		**M**				**L**			
CO2		**M**	**S**	**S**						
CO3		**M**	**S**	**S**						
CO4	**M**	**M**	**S**	**S**						
CO5		**M**	**S**	**S**						
CO6		**M**	**M**	**M**			**M**			**M**

S-Strong; M-Medium; L-Low

THEORY **60 Hrs**

Unit I 12 h

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

Unit II 12 h

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

Unit III 12 h

3. Micro Capsules / Micro Spheres: Types, preparation and evaluation , Monoclonal Antibodies ; preparation and application, preparation and application of Niosome, Aquasomes, Phytosomes, Electrosomes.Pulmonary Drug Delivery Systems : Aerosols, propellants Containers Types, preparation and evaluation, Intra Nasal Route Delivery systems; Types, preparation and evaluation.

Unit IV 12 h

4. Nucleic acid based therapeutic delivery system : Gene therapy, introduction (ex-vivo & in-vivo gene therapy). Potential target diseases for gene therapy (inherited disorder and cancer). Gene expression systems (viral and nonviral gene transfer). Liposomal gene delivery systems.

Unit V 12 h

5. Biodistribution and Pharmacokinetics. knowledge of therapeutic antisense molecules and aptamers as drugs of future.

REFERENCES

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

24MPH202T SEMESTER II

ADVANCED BIOPHARMACEUTICS AND PHARMACOKINETICS - THEORY 4H 4C

Instruction hours/ week: L:4 T:0 P:0 Marks: Internal: 25 External:75 Total:100
External Semester Exam: 3Hours

COURSE OBJECTIVES:

- 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.
- The application of basics of pharmacokinetic.

Course Outcomes

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

COs	Course Outcomes	Blooms Level
CO1	understand the basic concepts in biopharmaceutics and pharmacokinetics.	Understand
CO2	analyze raw data and derive the pharmacokinetic models and parameters the best describe the process of drug absorption, distribution, metabolism and elimination.	Analyze
CO3	critical evaluation of biopharmaceutic studies involving drug product equivalency.	Analyze
CO4	design and evaluation of dosage regimens of the drugs using pharmacokinetic and biopharmaceutic parameters.	create
CO5	know the potential clinical pharmacokinetic problems.	Analyze
CO6	Know the application of basics of pharmacokinetic	Understand

Mapping with Programme Outcomes

COs	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10
CO1	**S**		**M**				**L**			
CO2		**M**	**S**	**S**						
CO3		**M**	**S**	**S**						
CO4	**M**	**M**	**S**	**S**						
CO5		**M**	**S**	**S**						
CO6		**M**	**M**	**M**			**M**			**M**

S-Strong; M-Medium; L-Low

THEORY **60 Hrs**

Unit I 12 h

1. Drug Absorption from the Gastrointestinal Tract: Gastrointestinal tract, Mechanism of drug absorption, Factors affecting drug absorption, pH–partition theory of drug absorption. Formuulation and physicochemical factors: Dissolution rate, Dissolution process, Noyes–Whitney equation and drug dissolution, Factors affecting the dissolution rate. Gastrointestinal absorption: role of the dosage form: Solution (elixir, syrup and solution) as a dosage form ,Suspension as a dosage form, Capsule as a dosage form, Tablet as a dosage form ,Dissolution methods ,Formulation and processing factors, Correlation of in vivo data with in vitro dissolution data.Transport model: Permeability-Solubility-Charge State and the pH Partition Hypothesis, Properties of the Gastrointestinal Tract (GIT), pH Microclimate Intracellular pH Environment, Tight-Junction Complex.

Unit II 12 h

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

Unit III 12 h

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

Unit IV 12 h

4. Drug Product Performance, In Vivo: Bioavailability and Bioequivalence: drug product performance, purpose of bioavailability studies, relative and absolute availability. methods for assessing bioavailability, bioequivalence studies, design and evaluation of bioequivalence studies, study designs, crossover study designs, evaluation of the data, bioequivalence example, study submission and drug review process. biopharmaceutics classification system, methods. Permeability: In-vitro, in-situ and In-vivo methods.generic biologics (biosimilar drug products),clinical significance of bioequivalence studies, special concerns in bioavailability and bioequivalence studies, generic substitution.

Unit V 12 h

5. Application of Pharmacokinetics: Modified-Release Drug Products, Targeted Drug Delivery Systems and Biotechnological Products. Introduction to Pharmacokinetics and pharmacodynamic, drug interactions. Pharmacokinetics and pharmacodynamics of biotechnology drugs. Introduction, Proteins and peptides, Monoclonal antibodies, Oligonucleotides, Vaccines (immunotherapy), Gene therapies.

REFERENCES

1. Biopharmaceutics and Clinical Pharmacokinetics by Milo Gibaldi, 4th edition,Philadelphia, Lea and Febiger, 1991
2. Biopharmaceutics and Pharmacokinetics, A. Treatise, D .M. Brahmankar and Sunil B. Jaiswal., VallabPrakashan, Pitampura, Delhi
3. Applied Biopharmaceutics and Pharmacokinetics by Shargel. Land YuABC, 2ndedition, Connecticut Appleton Century Crofts, 1985
4. Textbook of Biopharmaceutics and Pharmacokinetics, Dr. Shobha Rani R. Hiremath,Prism Book
5. Pharmacokinetics by Milo Gibaldi and D. Perrier, 2nd edition, Marcel Dekker Inc.,New York, 1982
6. Current Concepts in Pharmaceutical Sciences: Biopharmaceutics, Swarbrick. J, Leaand Febiger, Philadelphia, 1970
7. Clinical Pharmacokinetics, Concepts and Applications 3rd edition by MalcolmRowland and Thom~ N. Tozer, Lea and Febiger, Philadelphia, 1995
8. Dissolution, Bioavailability and Bioequivalence, Abdou. H.M, Mack PublishingCompany, Pennsylvania 1989
9. Biopharmaceutics and Clinical Pharmacokinetics, An Introduction, 4th edition,revised and expande by Robert. E. Notari, Marcel Dekker Inc, New York and Basel,1987.
10. Biopharmaceutics and Relevant Pharmacokinetics by John. G Wagner and M.Pemarowski, 1st edition, Drug Intelligence Publications, Hamilton, Illinois, 1971.
11. Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James. G.Boylan, Marcel Dekker Inc, New York, 1996.
12. Basic Pharmacokinetics,1 st edition,Sunil S JambhekarandPhilip J
13. Breen,pharmaceutical press, RPS Publishing,2009.
14. Absorption and Drug Development- Solubility, Permeability, and Charge State, Alex Avdeef, John Wiley & Sons, Inc,2003.

24MPH203T SEMESTER II

COMPUTER AIDED DRUG DELIVERY SYSTEM - THEORY 4H 4C

Instruction hours/ week: L:4 T:0 P:0 Marks: Internal: 25 External:75 Total:100
External Semester Exam: 3Hours

COURSE OBJECTIVES:

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

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

COs	Course Outcomes	Blooms Level
CO1	History of Computers in Pharmaceutical Research and Development	Knowledge
CO2	Computational Modeling of Drug Disposition.	Knowledge
CO3	Role of Computers in Preclinical Development, Market Analysis & Clinical Development.	Apply
CO4	The Optimization Techniques in Pharmaceutical Formulation	Apply
CO5	Artificial Intelligence (AI) and Robotics.	Knowledge
CO6	The application of Computational fluid dynamics (CFD).	Apply

Mapping with Programme Outcomes

CO's	PO a	PO b	PO c	PO d	PO e	PO f	PO g	PO h	PO i
CO1	**M**								
CO2			**M**						
CO3			**M**						
CO4			**M**						
CO5			**M**						
CO6			**M**						

S-Strong; M-Medium; L-Low

THEORY 60 Hrs

Unit I 15 h

a. Computers in Pharmaceutical Research and Development: A General Overview: History of Computers in Pharmaceutical Research and Development. Statistical modeling in Pharmaceutical research and development: Descriptive versus Mechanistic Modeling, Statistical Parameters, Estimation, Confidence Regions, Nonlinearity at the Optimum, Sensitivity Analysis, Optimal Design, Population Modeling

b. Quality-by-Design In Pharmaceutical Development:Introduction, ICH Q8 guideline, Regulatory and industry views on QbD, Scientifically based QbD - examples of application.

Unit II 10 h

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

Unit III

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

Unit IV

a. Computer-aided biopharmaceutical characterization: Gastrointestinal absorption simulation. Introduction, Theoretical background, Model construction, Parameter sensitivity analysis, Virtual trial, Fed vs. fasted state, In vitro dissolution and in vitro- in vivo correlation, Biowaiver considerations

b. Computer Simulations in Pharmacokinetics and Pharmacodynamics: Introduction, Computer Simulation: Whole Organism, Isolated Tissues, Organs, Cell, Proteins and Genes.

c. Computers in Clinical Development: Clinical Data Collection and Management, Regulation of Computer Systems

Unit V 10 h

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

REFERENCES

a. Computer Applications in Pharmaceutical Research and Development, Sean Ekins, 2006, John Wiley & Sons.
b. Computer-Aided Applications in Pharmaceutical Technology, 1st Edition, **J**elena Djuris, Woodhead **P**ublishing
c. Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James. G.Boylan, Marcel Dekker Inc, New York, 1996.

24MPH204T SEMESTER II

COSMETICS AND COSMECEUTICALS - THEORY 4H 4C

Instruction hours/ week: L:4 T:0 P:0 Marks: Internal: 25 External:75 Total:100
External Semester Exam: 3Hours

COURSE OBJECTIVES:

- Regulatory requirements 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.
- Study the Principles in Herbal Cosmetics

COURSE OUTCOMES:

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

COs	Course Outcomes	Blooms Level
CO1	Discover the cosmetics in day-to-day life.	Understand
CO2	Understand the Formulation's Development and characteristics of various cosmetic products.	Understand
CO3	Understand about principles and building blocks of skin and hair care products.	Understand
CO4	Understand the role of herbsin cosmetic science	Understand
CO5	Understandtheprinciplesofcosmeticevaluationincludingvariouspar ameters	Understand
CO6	Illustrate the important role of nutraceuticals in day-to-day life.	Understand

Mapping with Programme Outcomes

COs	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11
CO1	**S**		**M**						**L**		
CO2	**S**		**S**								
CO3	**S**		**M**	**M**							
CO4	**S**		**S**	**M**					**M**		
CO5	**S**		**S**	**M**						**L**	
CO6	**S**		**S**							**L**	

S-Strong; M-Medium; L-Low

THEORY **60 Hrs**

Unit I 12 h

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

Unit II 12 h

2. Cosmetics - Biological aspects : Structure of skin relating toproblems like dry skin, acne, pigmentation, prickly heat, wrinkles and body odor. Structure of hair and hair growth cycle.

Common problems associated with oral cavity. Cleansing and care needs for face, eye lids, lips, hands, feet, nail, scalp, neck, body andunder-arm.

Unit III 12 h

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

Unit IV 12 h

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

Unit V 12 h

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

REFERENCES

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

24MPH205P SEMESTER II

PHARMACEUTICS PRACTICAL-II 12H 6C

Instruction hours/ week: L:0 T:0 P:12 Marks: Internal: 50 External:100 Total:150
External Semester Exam: 3Hours

COURSE OBJECTIVES:

- To study the effect of factors in formulating novel drug delivery systems
- To Formulate various novel drug delivery systems
- To Evaluate various novel drug delivery systems
- To study the Protein binding and Bioavailability
- To operate various softwares to optimize product development and analysis
- To Develop and evaluate various cosmetic preparations

COURSE OUTCOMES:

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

COs	Course Outcomes	BloomsLevel
CO1	To study the effect of factors in formulating novel drug delivery systems	Apply
CO2	To Formulate various novel drug delivery systems	Apply
CO3	To Evaluate various novel drug delivery systems	Apply
CO4	To study the Protein binding and Bioavailability	Apply
CO5	To operate various softwares to optimize product development and analysis	Apply
CO6	To Develop and evaluate various cosmetic preparations	Apply

Mapping with Programme Outcomes

COs	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11	PO12
CO1	S	S										
CO2		S										
CO3			S						M			
CO4			S									
CO5	S											
CO6		S										

S-Strong; M-Medium; L-Low

PRACTICALS

1. To study the effect of temperature change, non-solvent addition, incompatible polymer addition in microcapsules preparation
2. Study on diffusion of drugs through various polymeric membranes
3. Preparation and evaluation of Alginate beads
4. Formulation and evaluation of gelatin /albumin microspheres
5. Formulation and evaluation of liposome's/noisome
6. Formulation and evaluation of spherules
7. Improvement of dissolution characteristics of slightly soluble drug by Soliddispersion technique.
8. Comparison of dissolution of two different marketed products /brands
9. Analysis of dissolution by various data-kinetic modelling
10. Protein binding studies of a highly protein bound drug & poorly proteinbound drug
11. Bioavailability studies of Paracetamol in animals.
12. Pharmacokinetic and IVIVC data analysis by Winnoline^{R} software
13. In vitro cell studies for permeability and metabolism
14. DoE Using Design Expert® Software
15. Formulation data analysis Using Design Expert® Software
16. Quality-by-Design in Pharmaceutical Development
17. Computer Simulations in Pharmacokinetics and Pharmacodynamics
18. Computational Modeling of Drug Disposition
19. To develop Clinical Data Collection manual
20. To carry out Sensitivity Analysis, and Population Modeling.
21. Development and evaluation of Creams
22. Development and evaluation of Shampoo and Toothpaste base
23. To incorporate herbal and chemical actives to develop products
24. To address Dry skin, acne, blemish, Wrinkles, bleeding gums anddandruff.
25. Analysis of dissolution by various data- Kinetic Modeling.
26. Study on diffusion of drugs through various Polymeric Membranes.

24MPH206S SEMESTER II

SEMINAR/ASSIGNMENT 7H 4C

Instruction hours/ week: L: 7 T: 0 P: 0 Marks: Internal: 100 Total: 100

S. No	COMPONENTS	MARKS
1	ATTENDANCE	08
2	CONTENT RELEVANCE AND DEPTH	20
3	ENGAGEMENT AND INTERACTION	12
4	PRESENTATION SKILLS	60
Total	**PASS MARK (50)**	**100**

24MPH301T/24MPA301T/24MPC301T SEMESTER III

RESEARCH METHODOLOGY AND BIOSTATISTICS - THEORY 4H 4C

Instruction hours/ week: L: 4 T:0 P:0 Marks: Internal: 25 External: 75 Total:100
External Semester Exam: 3Hours

COURSE OBJECTIVES:

- To design the impart fundamental knowledge of higher education
- To illustrate the Research Processes and Methodologies that was undergone by the Research scholars
- To Explain the Research Skills like Research strategies, Ethics, Code for Research and IPR
- To Illustrate the techniques of teaching and evaluation
- To demonstrate the Essentials that was needed for the effective communication in English
- To describe the Data collection, Data Presentation Skills and Research Writing skills

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

COs	Course Outcomes	Blooms Level
CO1	Understand the general research methodology	Understand
CO2	Explain the importance and methods of literature review	Understand
CO3	Apply biostatistics to the given data sample	Apply
CO4	Discuss the different medical research methodologies	Apply
CO5	Explain the guidelines for animal handling and experimentation	Apply
CO6	Describe the basic principles of research	Understand

Mapping with Programme Outcomes

COs	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11	PO12
CO1		**M**	**S**									
CO2												
CO3				**S**								
CO4		**M**	**S**	**S**								
CO5									**M**			
CO6				**S**						**S**		

S-Strong; M-Medium; L-Low

CONTENTS:

UNIT-I

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

UNIT – II

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

UNIT – III

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

UNIT – IV

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

UNIT – V

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

REFERENCE BOOKS

1. Hubbuch, Susan M., (2005), Writing Research Papers Across the Curriculum, 5th Edition, Thompson.
2. Vedanayagam.E.G (1989), Teaching technology for college teachers New Delhi - Sterling publishers (Pvt) Ltd.
3. Kumar.K.H.(1997), Educational technology, New Delhi- New age international (Pvt) Ltd.
4. Tony Bates.A.N,(2005) Technology, e-learning and distance education, New York, Rout ledge.
5. Aggarwal. J.C. (1995), Essential of educational technology; Teaching Learning innovations in education- New Delhi- Vikas publishing house (p) Ltd.,.
6. Crow & Crow. (1998), Educational Psychology", Erusia Publishing House New Delhi.
   M. Ashraf Rizvi.(2005),Effective technical communication, TataMcGraw Hill Co.Ltd.

24MPH302J SEMESTER III

JOURNAL CLUB **1H 1C**

Instruction hours/ week: L:1 T:0 P:0 Marks: Internal :25 Total:25

S. No	COMPONENTS	MARKS
1	ATTENDANCE	4
2	SLIDES PREPARATION	6
3	RESEARCH GAP IDENTIFICATION	8
4	NARRATION OF ARTICLE	7
Total	**PASS MARK (13)**	**25**

24MPH303D SEMESTER III

DISCUSSION / PRESENTATION (PROPOSAL PRESENTATION) 2H 2C

Instruction hours/ week: L:2 T:0 P:0 Marks: Internal: 50 Total:50

S. No	COMPONENTS	MARKS
1	ATTENDANCE	08
2	SLIDES PREPARATION	12
3	RESEARCH GAP IDENTIFICATION	5
4	PRESENTATION SKILL	5
5	DEFENCE OF VIVA VOCE	20
Total	**PASS MARK (25)**	**50**

24MPH304RW SEMESTER III

RESEARCH WORK **28H 14C**

Instruction hours/ week: L:0 T:0 P: 28 Marks: External :350 Total:350

S. No	COMPONENTS	MARKS
1	ATTENDANCE	8
2	SLIDES PREPARATION	42
3	RESEARCH GAP IDENTIFICATION	50
4	PRESENTATION SKILL	50
5	DEFENCE OF VIVA VOCE	200
Total	**PASS MARK (175)**	**350**

24MPH401J SEMESTER IV

JOURNAL CLUB **1H 1C**

Instruction hours/ week: L:1 T:0 P:0 Marks: Internal: 25 Total: 25

S. No	COMPONENTS	MARKS
1	ATTENDANCE	4
2	SLIDES PREPARATION	6
3	RESEARCH GAP IDENTIFICATION	8
4	NARRATION OF ARTICLE	7
Total	**PASS MARK (13)**	**25**

24MPH402RW SEMESTER IV

RESEARCH WORK 31H 16C

Instruction hours/ week: L:0 T:0 P:31 Marks: Internal: 75 External :0 Total:75

S.No	COMPONENTS	MARKS
1	ATTENDANCE	08
2	SLIDES PREPARATION	12
3	RESEARCH GAP IDENTIFICATION	10
4	PRESENTATION SKILL	10
5	DEFENCE OF VIVA VOCE	35
Total	**PASS MARK (38)**	**75**

24MPH403D SEMESTER IV

DISCUSSION / FINAL PRESENTATION 3H 3C

Instruction hours/ week: L:3 T:0 P:0 Marks: External: 400 Total: 400

S.No	COMPONENTS	MARKS
1	ATTENDANCE	8
2	SLIDES PREPARATION	42
3	RESEARCH GAP IDENTIFICATION	50
4	PRESENTATION SKILL	50
5	DEFENCE OF VIVA VOCE	250
Total	**PASS MARK (200)**	**400**