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 (2022-23)

Enable | Enlighten | Enrich

KARPAGAM

ACADEMY OF HIGHER EDUCATION

(Deemed to be University)

(Established Under Section 3 of UGC Act, 1956)

REGULATIONS 2022

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 2022-23. 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. (Pharmaceutical Analysis)

Course Code	Course	Credit Hours	Credit Points	Hrs./week	Marks
Semester I					
22MPAT101T	Modern Pharmaceutical Analytical Techniques Theory	4	4	4	100
22MPA102T	Advanced Pharmaceutical Analysis Theory	4	4	4	100
22MPA103T	Pharmaceutical Validation Theory	4	4	4	100
22MPA104T	Food Analysis Theory	4	4	4	100
22MPAT105P	Pharmaceutical Analysis Practical I	12	6	12	150
22MPA106S	Seminar/Assignment	7	4	7	100
Total		**35**	**26**	**35**	**650**
Semester II					
22MPA201T	Advanced Instrumental Analysis Theory	4	4	4	100
22MPA202T	Modern Bio-Analytical Techniques Theory	4	4	4	100
22MPA203T	Quality Control and Quality Assurance Theory	4	4	4	100
22MPA204T	Herbal and Cosmetic Analysis Theory	4	4	4	100
22MPA205P	Pharmaceutical Analysis Practical II	12	6	12	150
22MPA206S	Seminar/Assignment	7	4	7	100
Total		**35**	**26**	**35**	**650**

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

Course Code	Course	Credit Hours	Credit Points	Hrs./week	Marks
Semester I					
22MPAT101T	Modern Pharmaceutical Analytical Techniques	4	4	4	100
22MPH102T	Drug Delivery System	4	4	4	100
22MPH103T	Modern Pharmaceutics	4	4	4	100
22MPH104T	Regulatory Affair	4	4	4	100
22MPH105P	Pharmaceutics Practical I	12	6	12	150
22MPH106S	Seminar/Assignment	7	4	7	100
Total		**35**	**26**	**35**	**650**

Semester II					
22MPH201T	Molecular Pharmaceutics (Nano Tech and Targeted DDS)	4	4	4	100
22MPH202T	Advanced Biopharmaceutics & Pharmacokinetics	4	4	4	100
22MPH203T	Computer Aided Drug Delivery System	4	4	4	100
22MPH204T	Cosmetic and Cosmeceuticals	4	4	4	100
22MPH205P	Pharmaceutics Practical II	12	6	12	150
22MPH206S	Seminar/Assignment	7	4	7	100
Total		**35**	**26**	**35**	**650**

Table III: Course of study for M. Pharm. (Pharmaceutical Chemistry)

Course Code	Course	Credit Hours	Credit Points	Hrs./week	Marks
Semester I					
22MPAT101T	Modern Pharmaceutical Analytical Techniques	4	4	4	100
22MPC102T	Advanced Organic Chemistry -I	4	4	4	100
22MPC103T	Advanced Medicinal chemistry	4	4	4	100
22MPC104T	Chemistry of Natural Products	4	4	4	100
22MPC105P	Pharmaceutical Chemistry Practical I	12	6	12	150
22MPC106S	Seminar/Assignment	7	4	7	100
Total		**35**	**26**	**35**	**650**
Semester II					
22MPC201T	Advanced Spectral Analysis	4	4	4	100
22MPC202T	Advanced Organic Chemistry -II	4	4	4	100
22MPC203T	Computer Aided Drug Design	4	4	4	100
22MPC204T	Pharmaceutical Process Chemistry	4	4	4	100
22MPC205P	Pharmaceutical Chemistry Practical II	12	6	12	150
22MPC206S	Seminar/Assignment	7	4	7	100
Total		**35**	**26**	**35**	**650**

Table IV: Course of study for M. Pharm III Semester
(M.PHARM Pharmaceutical analysis)

Course Code	Course	Credit Hours	Credit Points
22MPA301T	Research Methodology and Biostatistics Theory*	4	4
22MPA302J	Journal club	1	1
22MPA303D	Discussion/Presentation(Proposal Presentation)	2	2
22MPA304RW	Research Work	28	14
Total		35	21

*** Non University Exam**

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

Course Code	Course	Credit Hours	Credit Points
22MPH301T	Research Methodology and Biostatistics Theory*	4	4
22MPH302J	Journal club	1	1
22MPH303D	Discussion / Presentation (Proposal Presentation)	2	2
22MPH304RW	Research Work	28	14
Total		**35**	**21**

Table VI: Course of study for M. Pharm III Semester (M.PHARM Pharmaceutical chemistry)

Course Code	Course	Credit Hours	Credit Points
22MPC301T	Research Methodology and Biostatistics Theory*	4	4
22MPC302J	Journal club	1	1
22MPC303D	Discussion / Presentation(Proposal Presentation)	2	2
22MPC304RW	Research Work	28	14
Total		**35**	**21**

Table VII: Course of study for M. Pharm IV Semester
(M.PHARM Pharmaceutical Analysis)

Course Code	Course	Credit Hours	Credit Points
22MPA401J	Journal club	1	1
22MPA402RW	Research Work	31	16
22MPA403D	Discussion / Presentation (Proposal Presentation)	3	3
Total		**35**	**20**

Table VIII: Course of study for M. Pharm IV Semester
(M.PHARM Pharmaceutics)

Course Code	Course	Credit Hours	Credit Points
22MPA401J	Journal club	1	1
22MPA402RW	Research Work	31	16
22MPA403D	Discussion / Presentation (Proposal Presentation)	3	3
Total		**35**	**20**

Table XI: Course of study for M. Pharm IV Semester
(M.PHARM Pharmaceutical Chemistry)

Course Code	Course	Credit Hours	Credit Points
22MPA401J	Journal club	1	1
22MPA402RW	Research Work	31	16
22MPA403D	Discussion / Presentation (Proposal Presentation)	3	3
Total		**35**	**20**

Table X: Semester wise credits distribution

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

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

Name of the Activity	Maximum Credit PointsEligible / 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 – XVII.

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 XII: Schemes for Internal Assessments and End Semester Examinations (Pharmaceutical Analysis)

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
SEMESTER I								
22MPAT101T	Modern Pharmaceutical Analytical Techniques Theory	10	15	1 Hr	25	75	3 Hrs	100
22MPA102T	Advanced Pharmaceutical Analysis Theory	10	15	1 Hr	25	75	3 Hrs	100
22MPA103T	Pharmaceutical Validation Theory	10	15	1 Hr	25	75	3 Hrs	100
22MPA104T	Food Analysis Theory	10	15	1 Hr	25	75	3 Hrs	100
22MPA105P	Pharmaceutical Analysis Practical-I	20	30	6 Hrs	50	100	6 Hrs	150
22MPA106S	Seminar /Assignment	-	100	-	100	-	-	100
Total								**650**
SEMESTER II								
22MPA201T	Advanced Instrumental Analysis Theory	10	15	1 Hr	25	75	3 Hrs	100
22MPA202T	Modern Bio-Analytical Techniques Theory	10	15	1 Hr	25	75	3 Hrs	100
22MPA203T	Quality Control And Quality Assurance Theory	10	15	1 Hr	25	75	3 Hrs	100
22MPA204T	Herbal and Cosmetic Analysis Theory	10	15	1 Hr	25	75	3 Hrs	100
22MPA205P	Pharmaceutical Analysis Practical-II	20	30	6 Hrs	50	100	6 Hrs	150
22MPA206S	Seminar /Assignment	-	100	-	100	-	-	100
Total								**650**

Table XIII: 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								
22MPAT101T	Modern Pharmaceutical Analytical Techniques	10	15	1 Hr	25	75	3 Hrs	100
22MPH102T	Drug Delivery System	10	15	1 Hr	25	75	3 Hrs	100
22MPH103T	Modern Pharmaceutics	10	15	1 Hr	25	75	3 Hrs	100
22MPH104T	Regulatory Affair	10	15	1 Hr	25	75	3 Hrs	100
22MPH105P	Pharmaceutics Practical I	20	30	6 Hrs	50	100	6 Hrs	150
22MPH106P	Seminar /Assignment	-	-	-	-	-	-	100
Total								**650**

SEMESTER II								
22MPH201T	Molecular Pharmaceutics (Nano Tech and Targeted DDS)	10	15	1 Hr	25	75	3 Hrs	100
22MP202T	Advanced Biopharmaceutics& Pharmacokinetics	10	15	1 Hr	25	75	3 Hrs	100
22MPH203T	Computer Aided Drug Delivery System	10	15	1 Hr	25	75	3 Hrs	100
22MPH204T	Cosmetic and Cosmeceuticals	10	15	1 Hr	25	75	3 Hrs	100
22MPH205T	Pharmaceutics Practical I	20	30	6 Hrs	50	100	6 Hrs	150
22MPH206S	Seminar /Assignment							
Total								**650**

Table XIV: Schemes for Internal Assessments and End Semester Examinations (Pharmaceutical Chemistry)

Course Code	Course	Internal Assessment				EndSemester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
SEMESTER I								
22MPAT101T	ModernPharmaceutical Analytical Techniques	10	15	1 Hr	25	75	3 Hrs	100
22MPC102T	Advanced Organic Chemistry -I	10	15	1 Hr	25	75	3 Hrs	100
22MPC103T	Advanced Medicinal chemistry	10	15	1 Hr	25	75	3 Hrs	100
22MPC104T	Chemistry of Natural Products	10	15	1 Hr	25	75	3 Hrs	100
22MPC105P	Pharmaceutical Chemistry Practical I	20	30	6 Hrs	50	100	6 Hrs	150
22MPC106S	Seminar /Assignment	-	-	-	-	-	-	100
Total								**650**

SEMESTER II								
22MPC201T	Advanced Spectral Analysis	10	15	1 Hr	25	75	3 Hrs	100
22MPC202T	Advanced Organic Chemistry -II	10	15	1 Hr	25	75	3 Hrs	100
22MPC203T	ComputerAidedDrug Design	10	15	1 Hr	25	75	3 Hrs	100
22MPC204T	Pharmaceutical Process Chemistry	10	15	1 Hr	25	75	3 Hrs	100
22MPC205P	Pharmaceutical Chemistry Practical II	20	30	6 Hrs	50	100	6	150
22MPA206	Seminar /Assignment -	-	-	-	-	-		100
Total								**650**

Table XV: Schemes for internal assessments and end semester examinations(Semester III& IV) (Pharmaceutical Analysis)

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
SEMESTER III								
22MPA301T	Research Methodology and Biostatistics theory *	10	15	1 HR	25	75	3 HR	100
22MPA302J	Journal club	-	-	-	25	-	-	25
22MPA303D	Discussion / Presentation (Proposal Presentation)	-	-	-	50	-	-	50
22MPA304RW	Research Work	-	-	-	-	350	1 HR	350
Total								**525**
SEMESTER IV								
22MPA401J	Journal club	-	-	-	25	-	-	25
22MPA402RW	Research Work	-	-	-	-	400	1 HR	400
22MPA403D	Discussion/Final Presentation	-	-	-	75	-	-	75
Total								**500**

Table XVI: 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								
22MPH301T	Research Methodology and Biostatistics theory *	10	15	1 HR	25	75	3 HR	100
22MPH302J	Journal club	-	-	-	25	-	-	25
22MPH303D	Discussion / Presentation (Proposal Presentation)	-	-	-	50	-	-	50
22MPH304RW	Research Work	-	-	-	-	350	1 HR	350
Total								**525**
SEMESTER IV								
22MPH401J	Journal club	-	-	-	25	-	-	25
22MPH402RW	Research Work	-	-	-	-	400	1 HR	400
22MPH403D	Discussion/Final Presentation	-	-	-	75	-	-	75
Total								**500**

Schemes for internal assessments and end semester examinations(Semester III& IV) (Pharmaceutical Chemistry)

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
SEMESTER III								
22MPC301T	Research Methodology and Biostatistics theory *	10	15	1 HR	25	75	3 HR	100
22MPC302J	Journal club	-	-	-	25	-	-	25
22MPC303D	Discussion / Presentation (Proposal Presentation)	-	-	-	50	-	-	50
22MPC304RW	Research Work	-	-	-	-	350	1 HR	350
Total								**525**
SEMESTER IV								
22MPC401J	Journal club	-	-	-	25	-	-	25
22MPC402RW	Research Work	-	-	-	-	400	1 HR	400
22MPC403D	Discussion/Final Presentation	-	-	-	75	-	-	75
Total								**500**

Internal assessment: Continuous mode

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

Table: XVII: 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)	10
Based on Practical Records, Regular viva voce, etc.	10
Total	**20**

Table XVIII: 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 – X.

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 examcomponent 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 XIX: 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 XX: 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:

$$SGPA = \frac{C_1G_1 + C_2G_2 + C_3G_3 + C_4 * ZERO}{\text{----------}}$$

$C_1 + C_2 + C_3 + C_4$

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 theuniversity by paying a condonation fee.

FACULTY OF PHARMACY

PG PROGRAM (CBCS) – M.PHARM

(2022–2023 Batch and onwards)

Course code	Name of the course	Objective sand out comes		Instruction hours / week			Credit(s)	Maximum Marks		
		PEOs	POs	L	T	P		CIA	ESE	Total
								25	75	100
SEMESTER - I										
22MPA101T	Modern Pharmaceutical Analytical Techniques Theory	1,2	a,c,d,h,j	4	-	-	4	25	75	100
22MPA102T	Advanced Pharmaceutical Analysis Theory	1,2	a,c,d,h,i,j	4	-	-	4	25	75	100
22MPA103T	Pharmaceutical Validation Theory	1,2	a,d,h,j	4	-	-	4	25	75	100
22MPA104T	Food Analysis Theory	1,2,3	a,b,h,i	4	-	-	4	25	75	100
22MPA105P	Pharmaceutical Analysis Practical I	1,2,4	a,b,c,d,h,I,j	-	-	12	6	50	100	150
22MPA106S	Seminar/Assignment	-	-	7	-	-	4	100	-	100
Semester Total				**23**	**-**	**12**	**26**	**250**	**400**	**650**
SEMESTER – II										
22MPA201T	Advanced Instrumental Analysis Theory	1,2,4	a,b,c,d,h,i,j	4	-	-	4	25	75	100
22MPA202T	Modern Bio-Analytical Techniques Theory	1,2	a,b,c,d,h,i,j	4	-	-	4	25	75	100
22MPA203T	Quality Control and Quality Assurance Theory	1,2	a,d,f,h,j	4	-	-	4	25	75	100
22MPA204T	Herbal and Cosmetic analysis Theory	1,2	a,b,c,d,f,h,j	4	-	-	4	25	75	100
22MPA205P	Pharmaceutical Analysis Practical II	1,2,4	a,b,c,d,j	-	-	12	6	50	100	150
22MPA206S	Seminar/Assignment	-	-	7	-	-	4	100	-	100
Semester Total				**23**	**-**	**12**	**26**	**250**	**400**	**650**
SEMESTER - III										
22MPA301T	Research Methodology and Biostatistics Theory *	2,5	b,c,j	4	-	-	4	25	75	100
22MPA302J	Journal club	-	-	1	-	-	1	25	-	25
22MPA303D	Discussion / Presentation (Proposal Presentation)	-	-	2	-	-	2	50	-	50
22MPA304RW	Research Work	1,2,3,4,5	a,b,c,d,e,f,g,h,i,j	28	-	-	14	-	350	350
Semester Total				**35**	**-**	**-**	**21**	**100**	**425**	**525**
SEMESTER – IV										
22MPA401J	Journal club	-	-	1	-	-	1	25	-	25
22MPA402RW	Research work	1,2,3,4,5	a,b,c,d,e,f,g,h,i,j	31	-	-	16	75	-	75
22MPA403D	Discussion / Final Presentation	-	-	3	-	-	3	-	400	400
Semester Total				**35**	**-**	**-**	**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 anddocumentation, 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. Honour 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 inpharmaceutical 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)

FACULTY OF PHARMACY
PG PROGRAM (CBCS) – M.PHARM (PHARMACEUTICS)
(2022–2023 Batch and onwards)

Course code	Nameofthecourse	Objectives and out comes		Instruction hours / week			Credit(s)	Maximum Marks		
		PEOs	POs	L	T	P		CIA	ESE	Total
								25	75	100
SEMESTER - I										
22MPAT101T	ModernPharmaceutical AnalyticalTechniques	1,2	a,c,d,hj	4	-	-	4	25	75	100
22MPH102T	DrugDeliverySystem	1,2	a,c,d,h,j	4	-	-	4	25	75	100
22MPH103T	ModernPharmaceutics	1,2,4	a,c,d,h,j	4	-	-	4	25	75	100
22MPH104T	RegulatoryAffair	1,2,3	a,b,d,e,h,i	4	-	-	4	25	75	100
22MPH105P	Pharmaceutics Practical I	1,2,4	a,b,c,d,h,i,j	-	-	12	6	50	100	150
22MPH106P	Seminar/Assignment	-	-	7	-	-	4	100	-	100
SemesterTotal				**23**	**-**	**12**	**26**	**250**	**400**	**650**
SEMESTER – II										
22MPH201T	Molecular Pharmaceutics(Nano Tech andTargetedDDS)	1,2,4	a,c,d,h,j	4	-	-	4	25	75	100
22MP202T	AdvancedBiopharmaceutics&Pharmacokinetics	1,2	a,b,c,d,h,i,j	4	-	-	4	25	75	100
22MPH203T	ComputerAidedDrug DeliverySystem	1,2,4	a,c,d,h,j	4	-	-	4	25	75	100
22MPH204T	Cosmetic andCosmeceuticals	1,2,5	a,c,d,g,h,j	4	-	-	4	25	75	100
22MPH205T	PharmaceuticsPractical I	1,2,4	a,b,c,d,h,i,j	-	-	12	6	50	100	150
22MPH206S	Seminar/Assignment	-	-	7	-	-	4	100	-	100
Semester Total				**23**	**-**	**12**	**26**	**250**	**400**	**650**
SEMESTER- III										
22MPH301T	Research Methodology and Biostatistics theory*	2,5	b,c,j	4	-	-	4	25	75	100
22MPH302J	Journal club	-	-	1	-	-	1	25	-	25
22MPH303D	Discussion/Presentation (Proposal Presentation)	-	-	2	-	-	2	50	-	50

22MPH304RW	Research Work	1,2,3,4,5	a,b,c,d,e,f,g,h,i,j	28	-	-	14	-	350	350
Semester Total				**35**	**-**	**-**	**21**	**100**	**425**	**525**
SEMESTER- IV										
22MPH401J	Journal club	-	-	1	-	-	1	25	-	25
22MPH402RW	Research Work	1,2,3,4,5	a,b,c,d,e,f,g,h,i,j	31	-	-	16	75	-	75
22MPH403D	Discussion/Final Presentation	-	-	3	-	-	3	-	400	400
Semester Total				**35**	**-**	**-**	**20**	**100**	**400**	**500**

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.

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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)

FACULTY OF PHARMACY
PG PROGRAM (CBSS) – M.PHARM
(2020–2021 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										
22MPAT101T	Modern PharmaceuticalAnalytical Techniques	1,2,4	a,c,d,h,j	4	-	-	4	25	75	100
22MPC102T	Advanced OrganicChemistry - I	1,2	a,c,d,h,i,j	4	-	-	4	25	75	100
22MPC103T	Advanced Medicinal Chemistry	1,2	a,c,d,h,j	4	-	-	4	25	75	100
22MPC104T	Chemistry of NaturalProducts	1,2	a,c,d,h,j	4	-	-	4	25	75	100
22MPC105P	PharmaceuticalChemistry Practical I	1,2,4	a,b,c,d,e,h,i,j	-	-	12	6	50	100	150
22MPC106S	Seminar/Assignment	1,2,5	a,b,e,f,h,j	7	-	-	4	-	-	100
Semester Total				**23**	**-**	**12**	**26**	**150**	**400**	**650**
SEMESTER – II										
22MPC201T	Advanced SpectralAnalysis	1,2,4	a,c,d,h,i,j	4	-	-	4	25	75	100
22MPC202T	Advanced OrganicChemistry -II	1,2	a,c,d,h,i,j	4	-	-	4	25	75	100
22MPC203T	Computer Aided DrugDesign	1,2	a,c,d,h,i,j	4	-	-	4	25	75	100
22MPC204T	Pharmaceutical ProcessChemistry	1,2	a,b,c,d,h,j	4	-	-	4	25	75	100
22MPC205P	PharmaceuticalChemistry Practical II	1,2,4	a,b,c,d,e,h,i,j	-	-	12	6	50	100	150
22MPC206S	Seminar/Assignment	1,2,5	a,b,e,f,h,j	7	-	-	4	-	-	100
Semester Total				**23**	**-**	**12**	**26**	**150**	**400**	**650**
SEMESTER - III										
22MPC301T	Research Methodology and Biostatistics	2,5	b,c,j	4	-	-	4	25	75	100
22MPC302J	Journal club	1,2,3,4,5	a,b,c,d,e,f,h,i,j	1	-	-	1	25	-	25
22MPC303D	Discussion / Presentation (Proposal Presentation)	1,2,4,5	a,b,c,d,e,f,h,I,j	2	-	-	2	50	-	50
22MPC304RW	Research Work	1,2,3,4,5	a,b,c,d,e,f,g,h,i,j	28	-	-	14	-	350	350

Semester Total				**35**	**-**	**-**	**21**	**100**	**425**	**525**
SEMESTER – IV										
22MPC401J	Journal club	1,2,3,4,5	a,b,c,d,e,f,h,i,j	1	-	-	1	25	-	25
22MPC402RW	Research work	1,2,3,4,5	a,b,c,d,e,f,g,h,i,j	31	-	-	16	75	-	75
22MPC403D	Discussion / Final Presentation	1,2,4,5	a,b,c,d,e,f,h,i,j	3	-	-	3	-	400	400
Semester Total				**35**	**-**	**-**	**20**	**100**	**400**	**500**

* Non-University Exam

PROGRAMME OUTCOMES (PO)

k. **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.

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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 PHARMACEUTICAL ANALYSIS (MPA)

22MPAT101T FIRST SEMESTER

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES THEORY 4H 4C

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

COURSE OBJECTIVES:

- This subject deals with various advanced analytical instrumental techniques for identification,characterization and quantification of drugs.
- The students will be dealing with instruments like NMR, Mass spectrometer, IR, HPLC, GC etc.
- Acquire skills in selecting the suitable techniques for analysis of drugs
- Validate the instruments used in pharma industry
- Expand the theoretical knowledge on various instrumental techniques available for analysis of organicsubstances
- Expertise in various spectroscopic studies

COURSE OUTCOMES:

After completion of course student will

1. Persuade the theoretical and practical skills of the instruments
2. Analyze various drugs in single and combination dosage forms
3. Acquire skills in selecting the suitable techniques for analysis of drugs
4. Validate the instruments used in pharma industry
5. Expand the theoretical knowledge on various instrumental techniques available for analysis of organicsubstances
6. Expertise in various spectroscopic studies

THEORY **60Hrs**

1. a. UV-Visible spectroscopy: **10Hrs**

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

b. IR spectroscopy:

Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier - Transform IR Spectrometer, Factors affecting vibration frequencies and Applications of IR spectroscopy, Data Interpretation.

c. Spectro flourimetry:

Theory of Fluorescence, Factors affecting fluorescence (Characteristics of drugs that can be analysed byflourimetry), Quenchers, Instrumentation and Applications of fluorescence spectrophotometer.

d. Flame emission spectroscopy and Atomic absorption spectroscopy:

Principle, Instrumentation, Interferences and Applications.

2. NMR spectroscopy: 10Hrs

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.

3. Mass Spectroscopy: 10Hrs

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.

4. Chromatography: 10Hrs

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.

5. a.Electrophoresis: 10Hrs

Principle, Instrumentation, Working conditions, factors affecting separation and applications of

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

b. X ray Crystallography:

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

6. **Potentiometry:**
10Hrs

Principle, working, Ion selective Electrodes and Application of potentiometry. 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.

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, 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, NewDelhi, 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. DekkerSeries

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

22MPA102T FIRST SEMESTER

ADVANCED PHARMACEUTICAL ANALYSIS 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:

- This subject deals with the various aspects of Impurity, Impurities in new drug products, in residualsolvents, Elemental impurities.
- The student will expertise in Impurity profiling and characterization of degradants,
- This subject deals with Stability testing of phytopharmaceuticals and their protocol preparation.
- It also covers the biological testing of various vaccines and their principle and procedure.
- The subject emphasize on assay and different tests for drug products.
- The subject also provides knowledge regarding immunoassay and techniques involved in immunoassay

COURSE OUTCOMES:

After completion of the course students will,

1. Develop appropriate analytical skills required for the analytical method development
2. Discover principles of various reagents used in functional group analysis that renders necessary support inresearch methodology
3. Demonstrates the applications of analytical principles in the practical related problems
4. Design the analysis of impurities in drugs and residual solvents
5. Expertise in stability testing and biological methods of purity determination
6. Acquire skills in identifying the impurities in combinational drugs

THEORY 60Hrs

1. Impurity and stability studies: 10Hrs

Definition, classification of impurities in drug Substance or Active Pharmaceutical Ingredients and quantification of impurities as per ICH guidelines

Impurities in new drug products:

Rationale for the reporting and control of degradation products, reporting degradation products content ofPatches, listing of degradation products in specifications, qualification of degradation

products **Impurities in residual solvents:**

General principles, classification of residual solvents, Analytical procedures, limits of residual solvents,reporting levels of residual solvents

2. Elemental impurities: 10Hrs

Element classification, control of elemental impurities, Potential Sources of elemental Impurities, Identification of Potential Elemental Impurities, analytical procedures, instrumentation & C,H, N and Sanalysis

Stability testing protocols:

Selection of batches, container orientation, test parameters, sampling frequency, specification, storage conditions, recording of results, concept of stability, commitment etc. Important mechanistic and stabilityrelated information provided by results of study of factors like temperature, pH, buffering species ionic strength and dielectric constant etc. on the reaction rates. With practical considerations.

3. Impurity profiling and degradants characterization:

10 Hrs Method development, Stability studies and concepts of validation accelerated stability testing & shelf lifecalculation, WHO and ICH stability testing guidelines, Stability zones, steps in development, practical considerations. Basics of impurity profiling and degradant characterization with special emphasis. Photo stability testing guidelines, ICH stability guidelines for biological products

4 .Stability testing of Phytopharmaceuticals: 10Hrs

Regulatory requirements, protocols, HPTLC/HPLC finger printing, interactions and complexity.

5. Biological tests and assays of the following: 10Hrs

A. Adsorbed Tetanus vaccine
B. Adsorbed Diphtheria vaccine
C. Human anti haemophilic vaccine
D. Rabies vaccine
E. Tetanus Antitoxin
F. Tetanus ntiserum

G. Oxytocin

H. Heparin sodiumIP

I. Antivenom. PCR, PCR studies for generegulation, instrumentation (Principle and Procedures)

6. Immunoassays(IA) 10Hrs

Basic principles, Production of antibodies, Separation of bound and unbound drug, Radioimmunoassay,Optical IA, Enzyme IA, Fluoro IA, Luminiscence IA, Quantification and applications of IA.

Reference Books (Latest Editions):

1. Vogel's textbook of quantitative chemical analysis - Jeffery J Bassett, J.Mendham, R. C.Denney,5th edition, ELBS,1991.
2. Practical Pharmaceutical Chemistry - Beckett and Stenlake, Vol II, 4thEdition, CBS publishers, NewDelhi, 1997.
3. Textbook of Pharmaceutical Analysis - K A Connors, 3rdEdition, John Wiley & Sons,1982.
4. Pharmaceutical Analysis - Higuchi, Brochmman and Hassen, 2nd Edition,Wiley – InterscincePublication,1961.
5. Quantitative Analysis of Drugs in Pharmaceutical formulation – P D Sethi,3rdEdition, CBSPublishersNew Delhi, 1997.
6. Pharmaceutical Analysis- Modern methods - J W Munson – Part B,Volume11, Marcel DekkerSeries.
7. The Quantitative analysis of Drugs - D C Carratt, 3rdedition, CBSPublishers, NewDelhi,1964.
8. Indian Pharmacopoeia Vol I , II & III 2007, 2010,2014.
9. Methods of sampling and microbiological examination of water, firstrevision,BIS
10. Practical HPLC method development – Snyder, Kirkland, Glajch, 2ndedition, John Wiley &Sons.
11. Analytical Profiles of drug substances – Klaus Florey, Volume 1 – 20,Elsevier,2005
12. Analytical Profiles of drug substances and Excipients – Harry G Brittan,Volume 21 – 30, Elsevier,2005.
13. The analysis of drugs in biological fluids - Joseph Chamberlain, 2ndedition, CRC press,London.
14. ICH Guidelines for impurity profiles and stability studies.

22MPA103T FIRST SEMESTER

PHARMACEUTICAL VALIDATION 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 main purpose of the subject is to understand about validation and how it can be applied to industry
- The subject aims to improve the quality of the products.
- The subject covers the complete information about validation, types, methodology and application.
- The student will receive a deep knowledge on intellectual property rights
- The subject provides an advanced knowledge on patents and its specifications
- Different techniques like TOT, IPP and social responsibilities to be followed will be discussed.

COURSE OUTCOMES:

Upon completion of the subject student will

1. Explain the aspect of validation
2. Carry out validation of manufacturing processes
3. Apply the knowledge of validation to instruments and equipment's
4. Validate the manufacturing facilities
5. Revise the importance of patent and intellectual property rights.
6. Construct method validation as per ICH guidelines

THEORY **60Hrs**

12Hrs

1. Introduction: Definition of Qualification and Validation, Advantage of Validation, Streamlining of Qualification & Validation process and Validation Master Plan. Qualification: User Requirement Specification, Design Qualification, Factory Acceptance Test (FAT)/ Site Acceptance Test (SAT), Installation Qualification, Operational Qualification, Performance Qualification, Re- Qualification (Maintaining status Calibration Preventive Maintenance, Change management), Qualification of Manufacturing Equipments, Qualification of Analytical Instruments and Laboratory equipments.

12Hrs

2. Qualification of analytical instruments: Electronic balance, pH meter, UV-Visible spectrophotometer, FTIR, GC, HPLC, HPTLC Qualification of Glassware: Volumetric flask,

pipette, Measuring cylinder, beakers and burette.

3. Validation of Utility systems: Pharmaceutical Water System & pure steam, HVAC system, Compressed air and nitrogen. Cleaning Validation: Cleaning Validation - Cleaning Method development, Validation and validation of analytical method used in cleaning. Cleaning of Equipment, Cleaning of Facilities. Cleaning n place (CIP).

12Hrs

4. Analytical method validation: General principles, Validation of analytical method as per ICH guidelines and USP. Computerized system validation: Electronic records and digital significance-21 CFR part 11 and GAMP5.

12Hrs

5. General Principles of Intellectual Property: Concepts of Intellectual Property (IP), Intellectual Property Protection (IPP), Intellectual Property Rights (IPR); Economic importance, mechanism for protection of Intellectual Property –patents, Copyright, Trademark; Factors affecting choice of IP protection; Penalties for violation; Role of IP in pharmaceutical industry; Global ramification and financial implications. Filing a patent applications; patent application forms and guidelines. Types patent applications-provisional and non- provisional, PCT and convention patent applications; International patenting requirement procedures and costs; Rights and responsibilities of a patentee; Practical aspects regarding maintaining of a Patent file; Patent infringement meaning and scope. Significance of transfer technology (TOT), IP and ethics-positive and negative aspects of IPP; Societal responsibility, avoiding unethical practices

Reference Books (Latest Editions):

1. B. T. Loftus & R. A. Nash, "Pharmaceutical Process Validation", Drugs and Pharm Sci. Series, Vol. 129,3rdEd., Marcel Dekker Inc.,N.Y.
2. The Theory & Practice of Industrial Pharmacy, 3rdedition, Leon Lachman, Herbert A. Lieberman,Joseph. L. Karig, Varghese Publishing House,Bombay.
3. Validation Master plan by Terveeks or Deeks, Davis Harwood International publishing.
4. Validation of Aseptic Pharmaceutical Processes, 2ndEdition, by Carleton &Agalloco, (Marcel Dekker).
5. Michael Levin, Pharmaceutical Process Scale-Up‖, Drugs and Pharm. Sci.Series, Vol. 157,2ndEd.,Marcel Dekker Inc.,N.Y.

6. Validation Standard Operating Procedures: A Step by Step Guide for Achieving

Compliance inthe Pharmaceutical, Medical Device, and Biotech Industries, Syed Imtiaz

Haider

7. Pharmaceutical Equipment Validation: The Ultimate Qualification Handbook, Phillip A. Cloud, InterpharmPress

8. Validation of Pharmaceutical Processes: Sterile Products, Frederick J.Carlton (Ed.)

and JamesAgalloco (Ed.), Marcel Dekker, 2nd Ed.

9. Analytical Method validation and Instrument Performance Verification by Churg Chan, Heiman Lam,

Y.C. Lee, Yue. Zhang, Wiley Inter Science.

22MPA104T FIRST SEMESTER

FOOD ANALYSIS THEORY 4H 4C

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

External Semester Exam: 3Hours

COURSE OBJECTIVES:

- This course is designed to impart knowledge on analysis of food constituents
- This course is designed to impart knowledge on analysis of finished food products.
- The course includes application of instrumental analysis in the determination of pesticides invariety of food products.
- The subject deals with legislation regulations associated with food products
- The subject covers a wide knowledge on analytical techniques to be followed in the determinationof food regulations
- The subject also emphasize on analysis of fermented products like wine, spirits etc

COURSE OUTCOMES:

At completion of this course student will

1. Understand various analytical techniques in the determination of food constituents
2. Devise various analytical techniques in the determination of food additives
3. Create various analytical techniques in the determination of finished food products
4. Demonstrate various analytical techniques in the determination of pesticides in food
5. Review various analytical techniques in the determination of food regulations
6. Recognize various analytical techniques in the determination of food legislations

THEORY **60Hrs**

12Hrs

1. Carbohydrates – Chemistry & classification and properties of food carbohydrates, General methods ofanalysis of food carbohydrates, Changes in food carbohydrates during processing, Digestion, absorptionand metabolism of carbohydrates, Dietary fibre, crude fibre and application of food carbohydrates. Proteins - Chemistry and classification of amino acids and proteins, Physico- Chemical properties ofprotein and their structure, general methods of analysis of proteins and amino acids, Digestion, absorptionand metabolism of proteins.

12Hrs

2.a. Lipids – Classification, general methods of analysis, refining of fats and oils; hydrogenation of vegetableoils, Determination of adulteration in fats and oils, Various methods used for measurement of spoilage of fatsand fatty foods.

Vitamins – classification of vitamins, methods of analysis of vitamins, Principles of microbial assay and physiological significance of vitamins of B-series.

12Hrs

3. Food additives – Introduction, analysis of Preservatives, antioxidants, artificial sweeteners, flavors, flavorenhancers, stabilizers, thickening and jelling agents.
   Pigments and synthetic dyes- Natural pigments their occurrence and characteristic properties, permitted synthetic Dyes, Non-Permitted synthetic dyes used by industries, Method of detection of natural, permitted and non-permitted dyes

12Hrs

4. General Analytical methods for milk, milk constituents and milk products like ice cream, milk powder,butter, margarine, cheese including adulterants and contaminants of milk.
   Analysis of fermentation products like wine, spirits, beer and vinegar.

12Hrs

5. Pesticide analysis-Effects of pesticides insects on various food, use of pesticides in agriculture, pesticide cycle, organophosphorus and organo chlorine pesticides analysis, determination of pesticide residues in grain, fruits, vegetables, milk and milk products.
   Legislation regulations of food products with special emphasis on BIS, Agmark and US-FDA

Reference Books (Latest Editions):

1. The chemical analysis of foods–David Pearson,Seventh edition,Churchill Livingstone,Edinburgh London,1976
2. Introduction to the Chemical analysis of foods– S.Nielsen,Jones&Bartlettpublishers,BostonLondon,1994.
3. Official methods of analysis of AOAC International, sixth edition, VolumeI&II, 1997.
4. Analysis of Food constituents–Multon, Wiley VCH.
5. Dr.William Horwitz, Official methods of analysis of AOAC International,18 th edition,2005.

22MPAT105P FIRSTSEMESTER

PHARMACEUTICAL ANALYSIS PRACTICAL I 12H 6C

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

External Semester Exam: 3Hours

COURSE OBJECTIVES:

- To estimate the samples using analytical instruments.
- To perform assay of official drug samples using analytical instruments
- To determine the impurity profile of drugs.
- To separate the mixtures of sample using chromatographic techniques.
- To demonstrate HPLC.
- To demonstrate gas chromatography.

COURSE OUTCOMES:

At completion of this course student will

1. Demonstrate the analysis of pharmacopieal compounds and simultaneous estimation by UV-VIS
2. Acquire skills in selecting the suitable techniques for analysis of drugs
3. Expertise in stability testing and biological methods of purity determination
4. Validate impurity profiling of drugs
5. Compare and contrast various methods of analysis and their outcomes
6. Demonstrate calibration of various glassware and instruments used in pharma industry

CONTENTS:

1. Analysis of pharmacopoeial compounds and their formulations by UV Vis spectrophotometer
2. Simultaneous estimation of multicomponent 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. Assay of official compounds by different titrations
8. Assay of official compounds by instrumental techniques.
9. Quantitative determination of hydroxyl group.
10. Quantitative determination of amino group
11. Colorimetric determination of drugs by using different reagents

12. Impurity profiling of drugs
13. Calibration of glassware's
14. Calibration of pH meter
15. Calibration of UV-Visible spectrophotometer
16. Calibration of FTIR spectrophotometer
17. Calibration of GC any instrument
18. Calibration of HPLC instrument
19. Cleaning validation of anyone equipment
20. Determination of total reducing sugar
21. Determination of proteins
22. Determination of saponification value, Iodine value, Peroxide value, Acid value in food products
23. Determination of fat content and rancidity in food products
24. Analysis of natural and synthetic colors in food
25. Determination of preservatives in food
26. Determination of pesticide residue in food products
27. Analysis of vitamin content in food product
28. Determination of density and specific gravity of foods
29. Determination of food additive

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.

22MPA106S FIRSTSEMESTER

SEMINAR/ASSIGNMENT **7H 4C**

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

22MPA201T SECOND SEMESTER

ADVANCED INSTRUMENTAL ANALYSIS THEORY 4H 4C

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

External Semester Exam: 3Hours

COURSE OBJECTIVES:

- This subject deals with various hyphenate analytical instrumental techniques for identification, characterization and quantification of drugs.
- Instruments dealt are LC-MS, GC-MS, and hyphenated techniques.
- The course provides an elaborate knowledge on HPLC in the field of nanotechnology and approaches for advancement in enantiomeric separations.
- The course offers advanced bio chromatographical techniques, its approaches and derivatization.
- The subject includes hyphenation techniques in LC-MS and DART MS analysis
- 13C NMR, 1-D and 2-D NMR, NOESY and COSY techniques were also included in the study

COURSE OUTCOMES:

After completion of course student will,

1. Interpret NMR, Mass and IR spectra of various organic compounds
2. Demonstrate theoretical and practical skills of the hyphenated instruments
3. Undergo Identification of organic compounds
4. Acquire Practical aspects and troubleshooting techniques for HPLC techniques
5. Expertise in controlling the parameters that affect drug manufacturing
6. Acquire Practical aspects and troubleshooting techniques for GC techniques

THEORY **60Hrs**

12Hrs

1.HPLC: Principle, instrumentation, pharmaceutical applications, peak shapes, capacity factor, selectivity, plate number, plate height, resolution, band broadening, pumps, injector, detectors, columns, column problems, gradient HPLC, HPLC solvents, trouble shooting, sample preparation, method development, New developments in HPLC-role and principles of ultra, nanoliquid chromatography in pharmaceutical analysis. Immobilized polysaccharide CSP's: Advancement in

enantiomeric separations, revised phase Chiral method development and HILIC approaches. HPLC in Chiral analysis of pharmaceuticals. Preparative HPLC, practical aspects of preparative HPLC.

12Hrs

2. Biochromatography: Size exclusion chromatography, ion exchange chromatography, ion pair chromatography, affinity chromatography general principles, stationary phases and mobile phases. Gas chromatography: Principles, instrumentation, derivatization, head space sampling, columns for GC, detectors, quantification. High performance Thin Layer chromatography: Principles, instrumentation, pharmaceutical applications.

12Hrs

3. Super critical fluid chromatography: **Principles, instrumentation, pharmaceutical applications.**

Capillary electrophoresis: Overview of CE in pharmaceutical analysis, basic configuration, CE characteristics, principles of CE, methods and modes of CE. General considerations and method development in CE, Crown ethers as buffer additives in capillary electrophoresis.CE-MS hyphenation.

12Hrs

4. Mass spectrometry: Principle, theory, instrumentation of mass spectrometry, different types of ionization like electron impact, chemical, field, FAB and MALD, APCI, ESI, APPI mass fragmentation and its rules, meta stable ions, isotopic peaks and applications of mass spectrometry. LC-MS hyphenation and DART MS analysis. Mass analysers (Quadrpole, Time of flight,FT-ICR, ion trap and Orbitrap) instruments. MS/MS systems (Tandem: QqQ, TOF-TOF;Q-IT, Q-TOF,LTQ-FT,LTQ-Orbitrap.

12Hrs

5. **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 with reference to 13CNMR:Spin spin and spin lattice relaxation phenomenon. 13C NMR, 1-D and 2-D NMR, NOESY and COSY techniques, Interpretation and Applications of NMR spectroscopy.LC-NMR hyphenations.

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,TimothyA. Nieman, 5thedition, Eastern press, Bangalore,1998.
3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.
4. Organic Spectroscopy - William Kemp, 3rd edition, ELBS,1991.
5. Quantitative analysis of Pharmaceutical formulations by HPTLC- PD Sethi, CBSPublishers , New Delhi.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi,3rd Edition, CBSPublishers, New Delhi,1997.
7. Pharmaceutical Analysis- Modern methods – Part B - J W Munson, Volume 11, MarcelDekkerSeries.
8. Organic Spectroscopy by Donald L. Paviya, 5th Edition.

22MPA202T SECOND SEMESTER

MODERN BIO-ANALYTICAL TECHNIQUES THEORY 4H 4C

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

External Semester Exam: 3Hours

COURSE OBJECTIVES:

- This subject is designed to provide detailed knowledge about the importance of analysis of drugs inbiological matrices.
- The subjects deals with different pharmacokinetic and pharmacodynamic parameters
- The subject emphasize on bioavailability and bioequivalence studies
- The course provides a detailed advancement on toxicokinetic studies and its importance inpreclinical studies.
- The course outlines on cell culture techniques and its applications including MTT.
- The course provides knowledge on LC-MS in bioactivity screening and proteomics

COURSE OUTCOMES:

Upon completion of the course, the student will

1. Undergo Extraction of drugs from biological samples
2. Demonstrate separation of drugs from biological samples using different techniques
3. Interpret the guidelines for BA/BE studies
4. Persuade a deep knowledge on BCS classification system and its applications in new drug discovery process
5. Understand various pharmacokinetics and Pharmacodynamic parameters affecting drug efficacy
6. Acquire knowledge on LC-MS in bioactivity screening and proteomics.

THEORY **60Hrs**

12Hrs

1. Extraction of drugs and metabolites from biological matrices: General need, principle and procedure involved in the Bioanalytical methods such as Protein precipitation, Liquid -Liquid extraction and Solid phase extraction and other novel sample preparation approach.

   Bioanalytical method validation: USFDA and EMEA guidelines.

12 Hrs

2. Biopharmaceutical Consideration: Introduction, Biopharmaceutical Factors Affecting Drug Bioavailability, In Vitro: Dissolution and Drug Release Testing, Alternative

Methods of Dissolution Testing Transport models, Biopharmaceutics Classification System. Solubility: Experimental methods.Permeability*: In-vitro, in-situ* and *In-vivo* methods.

3. Pharmacokinetics and Toxicokinetics: Basic consideration, Drug interaction (PK-PD interactions)

   The effect of protein-binding interactions, The effect of tissue-binding interactions, Cytochrome P450- based drug interactions, Drug interactions linked to transporters. Microsomal assays Toxicokinetics- Toxicokinetic evaluation in preclinical studies, Importance and applications of toxicokinetic studies.LC-MS in bioactivity screening and proteomics.

12 Hrs

4. Cell culture techniques Basic equipments used in cell culture lab. Cell culture media, various types of cell culture, general procedure for cell cultures; isolation of cells, subculture, cryopreservation, characterization of cells and their applications. Principles and applications of cell viability assays (MTT assays), Principles and applications of flow cytometry.

12 Hrs

5. Metabolite identification: In-vitro / in-vivo approaches, protocols and sample preparation. Microsomalapproaches (Rat liver microsomes (RLM) and Human liver microsomes (HLM) in Met –ID. Regulatory perspectives. In-vitro assay of drug metabolites & drug metabolizing enzymes.

   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, Generic Biologics (Biosimilar Drug Products), Clinical Significance of Bioequivalence Studies.

REFERENCE BOOKS (LATEST EDITIONS):

1. Analysis of drugs in Biological fluids - Joseph Chamberlain, 2nd Edition.CRC Press, Newyork.1995.
2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler,TimothyA. Nieman, 5th edition,Eastern press, Bangalore,1998.
3. Pharmaceutical Analysis - Higuchi, Brochmman and Hassen, 2nd Edition,Wiley – Interscience Publications,1961.
4. Pharmaceutical Analysis- Modern methods – Part B - J W Munson,Volume 11, Marcel DekkerSeries
5. Practical HPLC method Development – Snyder, Kirkland, Glaich, 2nd Edition, John Wiley &

Sons, NewJercy.USA.

6. Chromatographic Analysis of Pharmaceuticals – John A Adamovics, 2nd Edition, Marcel Dekker,Newyork,USA. 1997.

7. Chromatographic methods in clinical chemistry & Toxicology – Roger L Bertholf, Ruth E Winecker, JohnWiley & Sons, New Jercy, USA.2007.

8. Good Laboratory Practice Regulations, 2nd Edition, Sandy Weinberg Vol.69, Marcel Dekker Series,1995.

9. Good laboratory Practice Regulations – Allen F. Hirsch, Volume 38, Marcel Dekker Series, 1989.

10. ICH, USFDA & CDSCO Guidelines.

11. Palmer

22MPA203T SECOND SEMESTER

QUALITY CONTROL AND QUALITY ASSURANCE 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:

- This course deals with the various aspects of quality control and quality assurance aspects of pharmaceutical industries.
- It covers the important aspects like cGMP, QCtests, documentation ,quality certifications ,GLP andregulatory affairs.
- Procedures to ensure confidentiality of inventory and source category information, when required areexplained
- Frequency of QA/QC checks on different parts of the inventory was dealt in the subject
- The subject covers about GLP responsibilities and regulatory affairs
- The subject deals with SOPs or standard operating procedures

COURSE OUTCOMES:

At the completion of this subject it is expected that the student will,

1. Understand the cGMP aspects in a pharmaceutical industry
2. Appreciate the importance of documentation
3. Understand the scope of quality certifications applicable to Pharmaceutical industries
4. Recognize the responsibilities of QA & QC departments
5. Acquire knowledge on GLP and regulatory Affairs
6. Interpret CPCSEA guidelines

THEORY **60hrs**

1. Concept and Evolution of Quality Control and Quality Assurance Good Laboratory Practice, GMP, Overview of ICH Guidelines - QSEM, with special emphasis on Q-series guidelines. Good Laboratory Practices: Scope of GLP, Definitions, Quality assurance unit, protocol for conduct of non clinical testing, control on animal house, report preparation and documentation.

12Hrs

cGMP guidelines according to schedule M, USFDA (inclusive of CDER and CBER) Pharmaceutical

Inspection Convention (PIC), WHO and EMEA covering: Organization and personnel responsibilities, training, hygiene and personal records, drug industry location, design, construction and plant lay out, maintenance, sanitation, environmental control, utilities and maintenance of sterile areas, control of contamination and Good Warehousing Practice .CPCSEA guidelines.

12Hrs

2. Analysis of raw materials, finished products, packaging materials, in process quality control (IPQC), Developing specification (ICH Q6 and Q3) Purchase specifications and maintenance of stores for raw materials. In process quality control and finished products quality control for following formulation in Pharma industry according to Indian, US and British pharmacopoeias: tablets, capsules, ointments, suppositories, creams, parenterals, ophthalmic and surgical products (How to refer pharmacopoeias Quality control test for containers, closures and secondary packing materials.

12 Hrs

3.Documentation in pharmaceutical industry: Three tier documentation, Policy, Procedures and Work instructions, and records (Formats), Basic principles- How to maintain, retention and retrieval etc.

Standard operating procedures (How to write), Master Formula Record, Batch Formula Record, Quality audit plan and reports. Specification and test procedures, Protocols and reports. Distribution records. Electronic data.

12Hrs

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

12Hrs

REFERENCE BOOKS (LATEST EDITIONS):

1. Quality Assurance Guide by organization of Pharmaceutical Procedures of India, 3rdrevised edition, olume I & II, Mumbai,1996.

2. Good Laboratory Practice Regulations, 2ndEdition, Sandy Weinberg Vol. 69, Marcel Dekker Series,1995.

3. QualityAssuranceofPharmaceuticals-AcompediumofGuidelinesandRelatedmaterialsVolI&II,2ndedition, WHO Publications,1999.

4. How to Practice GMP's – P P Sharma, Vandana Publications, Agra,1991.

5. The International Pharmacopoeia – vol I, II, III, IV & V - General Methods of Analysis and Quality specification for Pharmaceutical Substances, Excepients and Dosage forms, 3rdedition, WHO, Geneva,2005.

6. Good laboratory Practice Regulations – Allen F. Hirsch, Volume 38, Marcel Dekker Series, 1989.7. ICH guidelines
7. ISO 9000 and total quality management114

8. The drugs and cosmetics act 1940 – Deshpande, Nilesh Gandhi, 4thedition, SusmitPublishers,2006.

9. QA Manual – D.H. Shah, 1stedition, Business Horizons,2000.

10. Good Manufacturing Practices for Pharmaceuticals a plan for total quality control – Sidney H. Willig,Vol. 52, 3rdedition, Marcel Dekker Series. Steinborn L. GMP/ISO Quality Audit Manual for Healthcare Manufacturers and Their Suppliers, Sixth Edition, (Volume 1 - With Checklists and Software Package). Taylor & Francis; 2003.

11. Sarker DK. Quality Systems and Controls for Pharmaceuticals. John Wiley & Sons;2008.

22MPA204T SECOND SEMESTER

HERBAL AND COSMETIC ANALYSIS 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:

- This course is designed to impart knowledge on analysis of herbal products.
- Regulatory requirements, herbal drug interaction with monographs were explained.
- Performance evaluation of cosmetic products is included for the better understanding of the equipmentsused in cosmetic industries for the purpose.
- Describe guidelines for cGMP, GAP, GMP and GLP for quality assurance of herbal drugs in industry
- Describe guidelines for quality control of herbal drugs and evaluation of safety and efficacy of herbalmedicines.
- The subject deals with herbal drug interactions

COURSE OUTCOMES:

At completion of this course student will

1.Determine the herbal remedies and regulations

2.Demonstrate the analysis of natural products and monographs3.Interpret Herbal drug-drug interaction

4.Exploit the principles of performance evaluation of cosmetic products.

5. Understand the pre requisites to be followed in the preparation of the herbal monographs

6. Express the Indian Standard specification laid down for sampling and testing of various cosmetics

THEORY 60Hrs

1. Herbal remedies- Toxicity and Regulations: Herbals vs Conventional drugs, Efficacy of herbal medicine products, Validation of Herbal Therapies, Pharmacodynamic and Pharmacokinetic issues. Herbal drug standardization: WHO and AYUSH guidelines.

12Hrs

2 .Adulteration and Deterioration: Introduction, types of adulteration/substitution of herbal drugs, Causes and Measure of adulteration, Sampling Procedures, Determination of Foreign Matter, DNA Finger printing Techniques in identification of drugs of natural origin, heavy metals, pesticide residues, phototoxin and microbial contamination in herbal formulations. Regulatory requirements for setting herbal drug industry: Global marketing management, Indian and international patent law as applicable herbal drugs and natural products and its protocol.

12Hrs

3. Testing of natural products and drugs: Effect of herbal medicine on clinical laboratory testing, Adulterant Screening using modern analytical instruments, Regulation and dispensing of herbal drugs, Stability testing of natural products, protocol.

Monographs of Herbal drugs: Study of monographs of herbal drugs and comparative study in IP, USP, Ayurvedic Pharmacopoeia, American herbal Pharmacopoeia, British herbal Pharmacopoeia, Siddha and Unani Pharmacopoeia, WHO guidelines in quality assessment of herbal drugs.

12Hrs

4. Herbal drug-drug interaction: WHO and AYUSH guidelines for safety monitoring of natural medicine, Spontaneous reporting schemes for bio drug adverse reactions, bio drug-drug and bio drug-food interactions with suitable examples. Challenges in monitoring the safety of herbal medicines.

12Hrs

5. Evaluation of cosmetic products: Determination of acid value, ester value, saponification value, iodine value, peroxide value, rancidity, moisture, ash, volatile matter, heavy metals, fineness of powder, density, viscosity of cosmetic raw materials and finished products. Study of quality of raw materials and general methods of analysisof raw material used in cosmetic manufacture as per BIS.

Indian Standard specification laid down for sampling and testing of various cosmetics in finished forms such as baby care products, skin care products, dental products, personal hygiene preparations, lips sticks. Hair productsand skin creams by the Bureau Indian Standards.

REFERENCE BOOKS (LATEST EDITIONS):

1. Pharmacognosy by Trease and Evans

2. Pharmacognosy by Kokate, Purohit and Gokhale

3. Quality Control Methods for Medicinal Plant, WHO, Geneva

4. Pharmacognosy & Pharmacobiotechnology by Ashutosh Kar

5. Essential of Pharmacognosy byDr.S.H.Ansari

6. Cosmetics – Formulation, Manufacturing and Quality Control, P.P.Sharma, 4th edition, VandanaPublications Pvt. Ltd.,Delhi

7. Indian Standard specification, for raw materials, BIS, NewDelhi.

8. Indian Standard specification for 28 finished cosmetics BIS, NewDelhi

9. Harry's Cosmeticology 8th edition

10. Suppliers catalogue on specialized cosmetic excipients

11. Wilkinson, Moore, seventh edition, George Godwin. Poucher's Perfumes, Cosmetics and Soaps

12. Hilda Butler, 10th Edition, Kluwer Academic Publishers. Handbook of Cosmetic Science and Technology,3rd Edition.

22MPA205P SECOND SEMESTER

PHARMACEUTICAL ANALYSIS PRACTICAL II 12H 6C

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

External Semester Exam: 3Hours

COURSE OBJECTIVES:

- To estimate the samples using analytical instruments.
- To perform the interpretation of organic compound by FTIR, NMR, MS etc
- To determine the impurity profile of drugs.
- To separate the mixtures of sample using chromatographic techniques.
- To demonstrate the protocol preparation and performance of bioanalytical method validation
- To demonstrate cosmetic analysis.

COURSE OUTCOMES:

At completion of this course student will

1. Demonstrate the interpretation of various organic compounds by FT-IR
2. Demonstrate the interpretation of various organic compounds by NMR
3. Demonstrate the interpretation of various organic compounds by mass spectroscopy
4. Interpret Protocol preparation and performance of analytical/ Bioanalytical method validation
5. Formulate cosmetics and carry out its evaluation
6. Appreciate the importance of documentation by preparing master formula record, batch manufacturingrecords etc.

CONTENTS:

1. Comparison of absorption spectra by UV and Wood ward – Fiesurerule
2. Interpretation of organic compounds by FT-IR
3. Interpretation of organic compounds by NMR
4. Interpretation of organic compounds by MS
5. Determination of purity by DSC in pharmaceuticals

6. Identification of organic compounds using FT-IR, NMR, CNMR and Mass spectra

7. Bio molecules separation utilizing various sample preparation techniques and Quantitative analysis ofcomponents by gel electrophoresis.

8. Bio molecules separation utilizing various sample preparation techniques and Quantitative analysis ofcomponents by HPLC techniques.

9. Isolation of analgesics from biological fluids (Blood serum and urine).

10. Protocol preparation and performance of analytical/ Bioanalytical method validation.

11. Protocol preparation for the conduct of BA/BE studies according to guidelines.

12. In process and finished product quality control tests for tablets, capsules, parenterals and creams

13. Quality control tests for Primary and secondary packing materials

14. Assay of raw materials as per official monographs

15. Testing of related and foreign substances in drugs and raw materials

16. Preparation of Master Formula Record.

17. Preparation of Batch Manufacturing Record.

18. Quantitative analysis of rancidity in lipsticks and hair oil

19. Determination of aryl amine content and Developer in hair dye

20. Determination of foam height and SLS content of Shampoo.

21. Determination of total fatty matter in creams (Soap, skin and hair creams)

22. Determination of acid value and saponification value.

23. Determination of calcium thioglycolate in depilatories

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, 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, NewDelhi,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. DekkerSeries

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

22MPA206S SECOND SEMESTER

SEMINAR/ASSIGNMENT **7H 4C**

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

22MPA301T THRD SEMESTER

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:

On successful completion of the course the student will

1. Explain the objectives, role, social focus, curricular focus, administrative focus, drivers of changeglobalization in Higher Education
2. Restructure the new patterns of decision making
3. Describe the Expectations by employers, rate of knowledge growth, campus demographics and concern forcommunity
4. Illustrate the Research strategies, Ethics, Code of conduct for Research, Health and Safety and also the IPR
5. Describe the Data collection , Modeling , Simulation , Analysis, Prototyping, Presentation Skills , DataPresentation Skills and Research Writing skills
6. Demonstrate the techniques of teaching and evaluation

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.
7. M. Ashraf Rizvi.(2005),Effective technical communication, TataMcGraw Hill Co.Ltd.

22MPA302J THIRD SEMESTER

JOURNAL CLUB **1H 1C**

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

22MPA303D THIRD SEMESTER

DISCUSSION / PRESENTATON 2H 2C

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

22MPA304RW THIRD SEMESTER

RESEARCH WORK **28H 14C**

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

22MPA401J FOURTH SEMESTER

JOURNAL CLUB **1H 1C**

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

22MPA402R FOURTH SEMESTER

RESEARCH WORK **31H 16C**

Instruction hours/ week: L:0 T:0 P:31 Marks: External :400 Total:400

22MPA403D FOURTH SEMESTER

DISCUSSION / PRESENTATON 3H 3C

Instruction hours/ week: L:0 T:0 P:3

M.PHARM
PHARMACEUTICS (MPH)

22MPH101T SEMESTER I

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES 4H 4C

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

External Semester Exam: 3Hours

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:

- Explain the principle involved in spectroscopy
- Explain the principle involved in Chromatographic Techniques
- Describe the instrumentation of various instrumental Techniques
- Interpret the basic concepts of Spectral data analysis
- Describe the qualitative /quantitative analysis of various API/ drug dosage from through Spectroscopic Techniques.
- Describe the qualitative /quantitative analysis of various API/ drug dosage from through Chromatographic techniques

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 flourimetry), 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 poentiometry, conductometry, polarography and Amprometry.
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.

22MPH102T SEMESTER I

DRUG DELIVERY SYSTEM **4H 4C**

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

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

- 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.

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, Telepharmacy.:

Unit II **12 h**

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

Unit III **12 h**

3 Gastro-Retentive Drug Delivery Systems: Principle, concepts advantages and disadvantages, Modulation

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

Unit IV **6 h**

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

Unit V **6 h**

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

Unit VI **6 h**

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

JOURNALS

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

22MPH103T SEMESTER I

MODERN PHARMACEUTICS 4H 4C

Instruction hours/ week: L:0 T:0 P:3 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:

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

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

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.

22MPH104T SEMESTER I

REGULATORY AFFAIRS **4C 4H**

Instruction hours/ week: L:0 T:0 P:3 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:

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

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

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

22MPH105P SEMESTER I

PHARMACEUTICS PRACTICALS – I **12H 6C**

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

External Semester Exam: 3Hours

COURSE OBJECTIVES:

- To Estimate the quantitative analysis of various pharmaceutical Dosage forms by using UV/Vis spectroscopy.
- To Estimate the quantitative or qualitative analysis of Various pharmaceutical Dosage forms by using HPLC method
- To Formulate various novel drug delivery systems
- To Evaluate various novel drug delivery systems
- To study the preformulation characteristics in product development
- To study the effect of consolidation parameters on tablet manufacturing

COURSE OUTCOMES:

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

- The Estimation of various API/ drug dosage form through Spectroscopic Techniques.
- The Estimation of various API/ drug dosage form through Chromatographic techniques
- The experimental knowledge of blotting techniques.
- Formulation and evaluation methods of various novel drug delivery systems.
- The Preformulation characteristics in product development
- The effect of consolidation parameters on tablet manufacturing

PRACTICALS

1. Analysis of Pharmacopoeial compounds and their formulations by UV Vis spectrophotometer,
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. To perform In-vitro dissolution profile of CR/ SR marketed formulation
8. Formulation and evaluation of sustained release matrix tablets
9. Preparation and evaluation Fast dissolving tablets
10. Formulation and evaluation osmotically controlled DDS
11. Preparation and evaluation of Floating DDS- hydro dynamically balanced DDS
12. Formulation and evaluation of Muco adhesive tablets.

13. Formulation and evaluation of trans dermal patches.
14. Formulation and evaluation of microspheres
15. To carry out preformulation studies of tablets.
16. To study the effect of compressional force on tablets disintegration time.
17. To study Micromeritic properties of powders and granulation.
18. To study the effect of particle size on dissolution of a tablet.
19. To study the effect of binders on dissolution of a tablet.
20. To plot Heckal plot, Higuchi and peppas plot and determine similarity factors.

22MPH201T SEMESTER II

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

Instruction hours/ week: L:0 T:0 P:3 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:

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

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

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).

22MPH202T SEMESTER II

ADVANCED BIOPHARMACEUTICS & PHARMACOKINETICS THEORY 4H 4C

Instruction hours/ week: L:0 T:0 P:3 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:

Upon completion of the course, student shall be able to 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.
- The application of basics of pharmacokinetic.

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.

22MPH203T SEMESTER II

COMPUTER AIDED DRUG DEVELOPMENT 4H 4C

Instruction hours/ week: L:0 T:0 P:3 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).

COURSE OUTCOMES:

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

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

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.

22MPH204T SEMESTER II

COSMETICS AND COSMECEUTICALS 4H 4C

Instruction hours/ week: L:0 T:0 P:3 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:

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

- 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

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.
   Commonproblems associated with oral cavity. Cleansing and care needsfor 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, skin care and oral care. Review of guidelines for herbal cosmetics by private bodies like cosmos with respect to preservatives, emollients, foaming agents, emulsifiers and rheology modifiers. Challenges in formulating herbal cosmetics.

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.

22MPH205T SEMESTER II

PHARMACEUTICS PRACTICALS II 12H 6C

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

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

- 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

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.

22MPH206S SECOND SEMESTER

SEMINAR/ASSIGNMENT **7H 4C**

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

22MPH302J THIRD SEMESTER

JOURNAL CLUB **1H 1C**

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

22MPH303D THIRD SEMESTER

DISCUSSION / PRESENTATON 2H 2C

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

22MPH304RW THIRD SEMESTER

RESEARCH WORK **28H 14C**

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

22MPH401J FOURTH SEMESTER

JOURNAL CLUB **1H 1C**

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

22MPH402R FOURTH SEMESTER

RESEARCH WORK **31H 16C**

Instruction hours/ week: L:0 T:0 P:31 Marks: External :400 Total:400

22MPH403D FOURTH SEMESTER

DISCUSSION / PRESENTATON **3H 3C**

Instruction hours/ week: L:0 T:0 P:3

M.PHARM
PHARMACEUTICAL CHEMISTRY (MPC)

22MPC101T SEMESTER I

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES 4H 4C

Instruction hours/ week: L:0 T:0 P:3 Marks: Internal :75 Total:75

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:

- Explain the principle involved in spectroscopy
- Explain the principle involved in Chromatographic Techniques
- Describe the instrumentation of various instrumental Techniques
- Interpret the basic concepts of Spectral data analysis
- Describe the qualitative /quantitative analysis of various API/ drug dosage from through Spectroscopic Techniques.
- Describe the qualitative /quantitative analysis of various API/ drug dosage from through Chromatographic techniques

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 flourimetry), 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:

j) Thin Layer chromatography
k) High Performance Thin Layer Chromatography
l) Ion exchange chromatography
m) Column chromatography
n) Gas chromatography
o) High Performance Liquid chromatography
p) Ultra High Performance Liquid chromatography
q) Affinity chromatography
r) 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 poentiometry, conductometry, polarography and Amprometry.
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.

22MPC102T SEMESTER I

ADVANCED ORGANIC CHEMISTRY - I 4H 4C

Instruction hours/ week: L:0 T:0 P:3 Marks: Internal :75 Total:75

SCOPE

The subject is designed to provide in-depth knowledge about advances in organic chemistry, different techniques of organic synthesis and their applications to process chemistry as well as drug discovery.

COURSE OBJECTIVES:

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

- The mechanism & applications of various named reactions
- The concept of disconnection to develop synthetic routes for small target molecule.
- The various catalysts used in organic reactions
- The various protecting groups in organic chemistry
- The chemistry of heterocyclic compounds
- The principles and applications of retrosynthesis

COURSE OUTCOMES:

On successful completion of the course the student will

1. Understand the basic concepts of organic chemistry and reaction mechanism.
2. Explain the mechanism and applications of named reactions.
3. Discuss important synthetic reagents and protecting groups.
4. Discuss the importance and applications of protecting groups.
5. Elaborate the mechanism and applications of reactions involved in synthesis of drugs containing five, six membered and fused heterocyclics.
6. Explain synthon and retrosynthetic approaches.

THEORY 60 hrs

Unit I 12 h

1. Basic Aspects of Organic Chemistry:
    a) Organic intermediates: Carbocations, carbanions, free radicals, carbenes and nitrenes. Their method of formation, stability and synthetic applications.
    b) Types of reaction mechanisms and methods of determining them,
    c) Detailed knowledge regarding the reactions, mechanisms and their relative reactivity and

orientations.

2. Addition reactions

a) Nucleophilic uni- and bimolecular reactions (SN1 and SN2)
b) Elimination reactions (E1 & E2; Hoffman & Saytzeff's rule)
c) Rearrangement reaction

Unit II **12 h**

Study of mechanism and synthetic applications of following named Reactions:Ugi reaction, Brook rearrangement, Ullmann coupling reactions, Dieckmann Reaction, Doebner-Mille Reaction, Sandmeyer Reaction, Mitsunobu reaction, Mannich reaction, Vilsmeyer-Haack Reaction, Sharpless asymmetric epoxidation, Baeyer-Villiger oxidation, Shapiro & Suzuki reaction, Ozonolysis and Michael addition reaction

Unit III **12 h**

Synthetic Reagents & Applications:

Aluminium isopropoxide, N-bromosuccinamide, diazomethane, dicyclohexylcarbodiimide, Wilkinson reagent, Witting reagent. Osmium tetroxide, titanium chloride, diazopropane, diethyl azodicarboxylate, Triphenylphosphine, (Benzotriazol-1-yloxy) tris (dimethylamino) phosphonium hexafluoro-phosphate (BOP).

Protecting groups

a) Role of protection in organic synthesis
b) Protection for the hydroxyl group, including 1,2-and 1,3-diols: ethers, esters, carbonates, cyclic acetals & ketals
c) Protection for the Carbonyl Group: Acetals and Ketals
d) Protection for the Carboxyl Group: amides and hydrazides, esters
e) Protection for the Amino Group and Amino acids: carbamates and amides

Unit IV **12 h**

Heterocyclic Chemistry:

Organic Name reactions with their respective mechanism and application involved in synthesis of drugs containing five, six membered and fused heterocyclics such as Debus-Radziszewski imidazole synthesis, Knorr Pyrazole Synthesis, Pinner Pyrimidine Synthesis, Combes Quinoline Synthesis, Bernthsen Acridine Synthesis, Smiles rearrangement and Traube purine synthesis.

Synthesis of few representative drugs containing these heterocyclic nuclei such as Ketoconazole, Metronidazole, Miconazole, celecoxib, antipyrine, Metamizole sodium, Terconazole, Alprazolam, Triamterene, Sulfamerazine, Trimethoprim, Hydroxychloroquine, Quinine, Chloroquine, Quinacrine, Amsacrine, Prochlorperazine, Promazine, Chlorpromazine, Theophylline, Mercaptopurine and

Thioguanine.

Unit V **12 h**

Synthon approach and retrosynthesis applications

a) Basic principles, terminologies and advantages of retrosynthesis; guidelines for dissection of molecules. Functional group interconversion and addition (FGI and FGA)
b) C-X disconnections; C-C disconnections – alcohols and carbonyl compounds; 1,2-, 1,3-,1,4-, 1,5-, 1,6-difunctionalized compounds
c) Strategies for synthesis of three, four, five and six-membered ring.

REFERENCES

1. "Advanced Organic chemistry, Reaction, Mechanisms and Structure", J March, John Wiley and Sons, New York.
2. "Mechanism and Structure in Organic Chemistry", ES Gould, Hold Rinchart and Winston, New York.
3. "Organic Chemistry" Clayden, Greeves, Warren and Woihers., Oxford University Press 2001.
4. "Organic Chemistry" Vol I and II. I.L. Finar. ELBS, Pearson Education Lts, Dorling Kindersley (India) Pvt. Ltd.,
5. A guide to mechanisms in Organic Chemistry, Peter Skyes (Orient Longman, New Delhi).
6. Reactive Intermediates in Organic Chemistry, Tandom and Gowel, Oxford & IBH Publishers.
7. Combinational Chemistry – Synthesis and applications – Stephen R Wilson & Anthony W Czarnik, Wiley – Blackwell.
8. Carey, Organic Chemistry, 5th Edition (Viva Books Pvt. Ltd.)
9. Organic Synthesis - The Disconnection Approach, S. Warren, Wily India
10. Principles of Organic Synthesis, ROC Norman and JM Coxan, Nelson Thorns.
11. Organic Synthesis - Special Techniques. VK Ahluwalia and R Agarwal, Narosa Publishers.
12. Organic Reaction Mechanisms IVth Edn, VK Ahluwalia and RK Parashar, Narosa Publishers.

22MPC103T SEMESTER

ADVANCED MEDICINAL CHEMISTRY 4H 4C

Instruction hours/ week: L:0 T:0 P:3 Marks: Internal :75 Total:75

SCOPE

The subject is designed to impart knowledge about recent advances in the field of medicinal chemistry at the molecular level including different techniques for the rational drug design.

COURSE OBJECTIVES:

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

- Different stages of drug discovery
- The drugs classification, uses, SAR and synthesis.
- Role of medicinal chemistry in drug research
- Different techniques for drug discovery
- Various strategies to design and develop new drug like molecules for biological targets
- Peptidomimetics

COURSE OUTCOMES:

On successful completion of the course the student will

1. Understand the stages of drug discovery and receptors, types and drug receptor interaction.
2. Describe prodrug and analog design in drug discovery.
3. Explain the Classification, Synthesis, therapeutic value and Structural activity relationship of selected CNS, CVS, ANS, autocoid and antimicrobial drugs.
4. Discuss the stereochemical aspects of drug design including case studies.
5. Discuss the enzyme kinetics and rational design of enzyme inhibitors
6. Explain the design and therapeutic value of peptidomimetics and chemistry of prostaglandins.

THEORY **60 hrs**

Unit I **12 h**

Drug discovery: Stages of drug discovery, lead discovery; identification, validation and diversity of drug targets.

Biological drug targets: Receptors, types, binding and activation, theories of drug receptor interaction, drug receptor interactions, agonists vs antagonists, artificial enzymes.

Unit II **12 h**

Prodrug Design and Analog design:

1. **Prodrug design:** Basic concept, Carrier linked prodrugs/ Bio precursors, Prodrugs of functional group, Prodrugs to improve patient acceptability, Drug solubility, Drug absorption and distribution, site specific drug delivery and sustained drug action. Rationale of prodrug design and practical consideration of prodrug design.
2. **Combating drug resistance:** Causes for drug resistance, strategies to combat drug resistance in antibiotics and anticancer therapy, Genetic principles of drug resistance.
3. **Analog Design:** Introduction, Classical & Non classical, Bioisosteric replacement strategies, rigid analogs, alteration of chain branching, changes in ring size, ring position isomers, design of stereo isomers and geometric isomers, fragments of a lead molecule, variation in inter atomic distance.

Unit III **12 h**

1. **Medicinal chemistry aspects of the following class of drugs**

   Systematic study, SAR, Mechanism of action and synthesis of new generation molecules of following class of drugs:Anti-hypertensive drugs, Psychoactive drugs, Anticonvulsant drugs, H1 & H2 receptor antagonist, COX1 & COX2 inhibitors, Adrenergic & Cholinergic agents, Antineoplastic and Antiviral agents.
2. **Stereochemistry and Drug action:** Realization that stereo selectivity is a pre-requisite for evolution. Role of chirality in selective and specific therapeutic agents. Case studies, Enantio selectivity in drug adsorption, metabolism, distribution and elimination.

Unit IV **12 h**

Rational Design of Enzyme Inhibitors

Enzyme kinetics & Principles of Enzyme inhibitors, Enzyme inhibitors in medicine, Enzyme inhibitors in basic research, rational design of non-covalently and covalently binding enzyme inhibitors.

Unit V **12 h**

Peptidomimetics

Therapeutic values of Peptidomimetics, design of peptidomimetics by manipulation of the amino acids, modification of the peptide backbone, incorporating conformational constraints locally or globally. Chemistry of prostaglandins, leukotrienes and thromboxones.

REFERENCES

1. Medicinal Chemistry by Burger, Vol I –VI.
2. Wilson and Gisvold's Text book of Organic Medicinal and Pharmaceutical Chemistry, 12th Edition, Lippincott Williams & Wilkins, Wolters Kluwer (India) Pvt. Ltd, New Delhi.
3. Comprehensive Medicinal Chemistry – Corwin and Hansch.
4. Computational and structural approaches to drug design edited by Robert M Stroud and Janet. F Moore.
5. Introduction to Quantitative Drug Design by Y.C. Martin.
6. Principles of Medicinal Chemistry by William Foye, 7th Edition, Lippincott Williams & Wilkins, Woltess Kluwer (India) Pvt. Ltd, New Delhi.
7. Drug Design Volumes by Ariens, Academic Press, Elsevier Publishers, Noida, Uttar Pradesh.
8. Principles of Drug Design by Smith.
9. The Organic Chemistry of the Drug Design and Drug action by Richard B. Silverman, II Edition, Elsevier Publishers, New Delhi.
10. An Introduction to Medicinal Chemistry, Graham L. Patrick, III Edition, Oxford University Press, USA.
11. Biopharmaceutics and pharmacokinetics, DM. Brahmankar, Sunil B. Jaiswal II Edition, 2014, Vallabh Prakashan, New Delhi.
12. Peptidomimetics in Organic and Medicinal Chemistry by Antonio Guarna and Andrea Trabocchi, First edition, Wiley publishers.

22MPC104T SEMESTER I

CHEMISTRY OF NATURAL PRODUCTS **4H 4C**

Instruction hours/ week: L:0 T:0 P:3 Marks: Internal :75 Total:75

SCOPE

The subject is designed to provide detail knowledge about chemistry of medicinal compounds from natural origin and general methods of structural elucidation of such compounds. It also emphasizes on isolation, purification and characterization of medicinal compounds from natural origin.

COURSE OBJECTIVES:

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

- Different types of natural compounds and their chemistry
- The medicinal importance of natural compounds
- The importance of natural compounds as lead molecules for new drug discovery
- The concept of rDNA technology tool for new drug discovery
- General methods of structural elucidation of compounds of natural origin
- Isolation, purification and characterization of simple chemical constituents from natural source

COURSE OUTCOMES:

On successful completion of the course the student will

1. Explain the chemistry and uses of various drugs from natural sources.
2. Discuss the classification, isolation, purification, modification and activity of alkaloids, flavonoids, steroids.
3. Discuss the classification, isolation, purification, modification and activity of terpenoids and vitamins.
4. Describe the recombinant DNA technology and its application in drug discovery.
5. Elaborate the active constituent of certain crude drugs in indigenous system.
6. Elucidate the structure of some important natural phytoconstituents.

THEORY **60 hrs**

Unit I **12 h**

Study of Natural products as leads for new pharmaceuticals for the following class of drugs

a) Drugs Affecting the Central Nervous System: Morphine Alkaloids
b) Anticancer Drugs: Paclitaxel and Docetaxel, Etoposide, and Teniposide
c) Cardiovascular Drugs: Lovastatin, Teprotide and Dicoumarol
d) Neuromuscular Blocking Drugs: Curare alkaloids
e) Anti-malarial drugs and Analogues
f) Chemistry of macrolide antibiotics (Erythromycin, Azithromycin, Roxithromycin, and Clarithromycin) and β - Lactam antibiotics (Cephalosporins and Carbapenem)

Unit II **12 h**

1. **Alkaloids**

   General introduction, classification, isolation, purification, molecular modification and biological activity of alkaloids, general methods of structural determination of alkaloids, structural elucidation and stereochemistry of ephedrine, morphine, ergot, emetine and reserpine.

2. **Flavonoids**

   Introduction, isolation and purification of flavonoids, General methods of structural determination of flavonoids; Structural elucidation of quercetin.

3. **Steroids**

   General introduction, chemistry of sterols, sapogenin and cardiac glycosides. Stereochemistry and nomenclature of steroids, chemistry of contraceptive agents, male & female sex hormones (Testosterone, Estradiol, Progesterone), adrenocorticoids (Cortisone), contraceptive agents and steroids (Vit – D).

Unit III **12 h**

1. **Terpenoids**

   Classification, isolation, isoprene rule and general methods of structural elucidation of Terpenoids; Structural elucidation of drugs belonging to mono (citral, menthol, camphor), di (retinol, Phytol, taxol) and tri terpenoids (Squalene, Ginsenoside), carotinoids (β carotene).

2. **Vitamins**

   Chemistry and Physiological significance of Vitamin A, B1, B2, B12, C, E, Folic acid and Niacin.

Unit IV **12 h**

1. **Recombinant DNA technology and drug discovery**

   RDNA technology, hybridoma technology, new pharmaceuticals derived from biotechnology; Oligonucleotide therapy. Gene therapy: Introduction, Clinical application and recent advances in gene therapy, principles of RNA & DNA estimation
2. Active constituent of certain crude drugs used in Indigenous system; Diabetic therapy – Gymnema sylvestre, Salacia reticulate, Pterocarpus marsupiam, Swertia chirata, Trigonella foenum graccum; Liver dysfunction – Phyllanthus niruri; Antitumor – Curcuma longa Linn.

Unit V **12 h**

Structural Characterization of natural compounds

Structural characterization of natural compounds using IR, 1HNMR, 13CNMR and MS Spectroscopy of specific drugs e.g., Penicillin, Morphine, Camphor, Vit-D, Quercetin and Digitalis glycosides.

REFERENCES

1. Modern Methods of Plant Analysis, Peech and M.V. Tracey, Springer – Verlag, Berlin, Heidelberg.
2. Phytochemistry Vol. I and II by Miller, Jan Nostrant Rein Hld.
3. Recent advances in Phytochemistry Vol. I to IV – Scikel Runeckles, Springer Science & Business Media.
4. Chemistry of natural products Vol I onwards IWPAC.
5. Natural Product Chemistry Nakanishi Gggolo, University Science Books, California.
6. Natural Product Chemistry "A laboratory guide" – Rapheal Khan.
7. The Alkaloid Chemistry and Physiology by RHF Manske, Academic Press.
8. Introduction to molecular Phytochemistry – CHJ Wells, Chapmannstall.
9. Organic Chemistry of Natural Products Vol I and II by Gurdeep and Chatwall, Himalaya Publishing House.
10. Organic Chemistry of Natural Products Vol I and II by O.P. Agarwal, Krishan Prakashan.
11. Organic Chemistry Vol I and II by I.L. Finar, Pearson education.
12. Elements of Biotechnology by P.K. Gupta, Rastogi Publishers.
13. Pharmaceutical Biotechnology by S.P. Vyas and V.K. Dixit, CBS Publishers.
14. Biotechnology by Purohit and Mathur, Agro-Bios, 13th edition.
15. Phytochemical methods of Harborne, Springer, Netherlands.
16. Burger's Medicinal Chemistry.

22MPC105P SEMESTER I

PHARMACEUTICAL CHEMISTRY PRACTICAL - I 12H 6C

Instruction hours/ week: L:0 T:0 P:3 Marks: Internal :75 Total:75

COURSE OBJECTIVES:

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

- The analysis of drugs and their formulations
- The working of column, HPLC and gas chromatography
- The estimation technique using fluorimetry and flame photometry.
- The synthesis of compounds using named reactions
- The structural characterization of synthetic compounds
- The various degradation studies.

COURSE OUTCOMES:

On successful completion of the course the student will

1. Analyze the drugs and their formulations
2. Perform experiments using column, HPLC and gas chromatography
3. Estimate pharmaceuticals using fluorimetry and flame photometry.
4. Synthesize compounds using few important named reactions.
5. Characterize the synthesized compounds using various analytical techniques
6. Perform degradation studies

COURSE CONTENT

1. Analysis of Pharmacopeial compounds and their formulations by UV spectrophotometer, RNA & DNA estimation
2. Simultaneous estimation of multi component containing formulations by UV spectrophotometry
3. Experiments based on Column chromatography
4. Experiments based on HPLC
5. Experiments based on Gas Chromatography
6. Estimation of riboflavin/quinine sulphate by fluorimetry
7. Estimation of sodium/potassium by flame photometry

To perform the following reactions of synthetic importance

1. Purification of organic solvents, column chromatography
2. Claisen-schmidt reaction.
3. Benzyllic acid rearrangement.
4. Beckmann rearrangement.
5. Hoffmann rearrangement
6. Mannich reaction
7. Synthesis of medicinally important compounds involving more than one step along with purification and Characterization using TLC, melting point and IR spectroscopy (4 experiments)
8. Estimation of elements and functional groups in organic natural compounds
9. Isolation, characterization like melting point, mixed melting point, molecular weight determination, functional group analysis, co-chromatographic technique for identification of isolated compounds and interpretation of UV and IR data.

Some typical degradation reactions to be carried on selected plant constituents

22MPC106S SECOND SEMESTER

SEMINAR/ASSIGNMENT **7H 4C**

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

22MPC201T SEMESTER II

ADVANCED SPECTRAL ANALYSIS 4H 4C

Instruction hours/ week: L:0 T:0 P:3 Marks: Internal :75 Total:75

SCOPE

This subject deals with various hyphenated analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are LC-MS, GC-MS, ATR-IR, DSC etc.

COURSE OBJECTIVES:

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

- The interpretation of the NMR, Mass and IR spectra of various organic compounds
- The theoretical and practical skills required for handling the hyphenated instruments
- The identification methods of organic compounds
- The principle and operations of different spectroscopy, chromatography and thermal techniques
- The applications of different spectroscopy, chromatography and thermal techniques
- The bioassay and immunoassay

COURSE OUTCOMES:

On successful completion of the course the student will

1. Explain the various techniques involves in UV, IR, NMR and mass spectroscopy.
2. Understand the interpretation of the various spectra of organic compounds.
3. Discuss the principle, instrumentation and applications of various chromatography techniques
4. Describe the instrumentation and applications of hyphenated instruments
5. Explain the principle, instrumentation and applications of DSC, TGA, DTA and raman spectroscopy
6. Illustrate the biological standardization using bioassay and immunoassay.

THEORY **60 hrs**

Unit I **12 h**

UV and IR spectroscopy:

Woodward – Fieser rule for 1,3-butadienes, cyclic dienes and α,β-carbonyl compounds and interpretation compounds of enones. ATR-IR, IR Interpretation of organic compounds.

Unit II **12 h**

NMR spectroscopy:

1-D and 2-D NMR, NOESY and COSY, HECTOR, INADEQUATE techniques, Interpretation of organic compounds.

Unit III **12 h**

Mass Spectroscopy

Mass fragmentation and its rules, Fragmentation of important functional groups like alcohols, amines, carbonyl groups and alkanes, Meta stable ions, Mc Lafferty rearrangement, Ring rule, Isotopic peaks, Interpretation of organic compounds.

Unit IV **12 h**

Chromatography:

Principle, Instrumentation and Applications of the following:
a) GC-MS b) GC-AAS c) LC-MS d) LC-FTIR e) LC-NMR f) CE- MS g) High Performance Thin Layer chromatography h) Super critical fluid chromatography i) Ion Chromatography j) I-EC (Ion-Exclusion Chromatography) k) Flash chromatography

Unit V **12 h**

1. Thermal methods of analysis

Introduction, principle, instrumentation and application of DSC, DTA and TGA.

2. Raman Spectroscopy

Introduction, Principle, Instrumentation and Applications.

3. Radio immuno assay

Biological standardization, bioassay, ELISA, Radioimmuno assay of digitalis and insulin.

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. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.
5. Quantitative analysis of pharmaceutical formulations by HPTLC - P D Sethi, CBS Publishers, New Delhi.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis- Modern methods – Part B - J W Munson, Volume 11, Marcel Dekker Series

22MPC202T ADVANCED ORGANIC CHEMISTRY - II 4H 4C

Instruction hours/ week: L:0 T:0 P:3 Marks: Internal :75 Total:75

SCOPE

The subject is designed to provide in-depth knowledge about advances in organic chemistry, different techniques of organic synthesis and their applications to process chemistry as well as drug discovery.

COURSE OBJECTIVES:

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

- The principles and applications of green chemistry
- The concept of peptide chemistry.
- The photochemical reactions
- The mechanism and type of pericyclic reactions
- The various catalysts used in organic reactions
- The concept of stereochemistry and asymmetric synthesis.

COURSE OUTCOMES:

On successful completion of the course the student will

1. Discuss principle and various techniques of green chemistry
2. Describe the chemistry and synthesis of peptides
3. Understand photochemical reactions and its types
4. Explain the mechanism and types of pericyclic reactions
5. Enumerate different types of catalyst and its applications
6. Explain stereochemistry and asymmetric synthesis and its influence on drug action.

THEORY 60 hrs

Unit I 12 h

Green Chemistry:

a. Introduction, principles of green chemistry
b. Microwave assisted reactions: Merit and demerits of its use, increased reaction rates, mechanism, superheating effects of microwave, effects of solvents in microwave assisted synthesis, microwave technology in process optimization, its applications in various organic reactions and heterocycles synthesis
c. Ultrasound assisted reactions: Types of sonochemical reactions, homogenous, heterogeneous liquid-liquid and liquid-solid reactions, synthetic applications
d. Continuous flow reactors: Working principle, advantages and synthetic applications.

Unit II **12 h**

Chemistry of peptides

a. Coupling reactions in peptide synthesis
b. Principles of solid phase peptide synthesis, t-BOC and FMOC protocols, various solid supports and linkers: Activation procedures, peptide bond formation, deprotection and cleavage from resin, low and high HF cleavage protocols, formation of free peptides and peptide amides, purification and case studies, site-specific chemical modifications of peptides
c. Segment and sequential strategies for solution phase peptide synthesis with any two case studies
d. Side reactions in peptide synthesis: Deletion peptides, side reactions initiated by proton abstraction, protonation, over- activation and side reactions of individual amino acids.

Unit III **12 h**

1. **Photochemical Reactions**
   Basic principles of photochemical reactions. Photo-oxidation, photo-addition and photo-fragmentation.
2. **Pericyclic reactions**
   Mechanism, Types of pericyclic reactions such as cyclo addition, electrocyclic reaction and sigmatrophic rearrangement reactions with examples

Unit IV **12 h**

Catalysis:

a. Types of catalysis, heterogeneous and homogenous catalysis, advantages and disadvantages
b. Heterogeneous catalysis – preparation, characterization, kinetics, supported catalysts, catalyst deactivation and regeneration, some examples of heterogeneous catalysis used in synthesis of drugs.
c. Homogenous catalysis, hydrogenation, hydroformylation, hydrocyanation, Wilkinson catalysts, chiral ligands and chiral induction, Ziegler-Natta catalysts, some examples of homogenous catalysis used in synthesis of drugs
d. Transition-metal and Organo-catalysis in organic synthesis:
e. Metal-catalyzed reactions
f. Biocatalysis: Use of enzymes in organic synthesis, immobilized enzymes/cells in organic reaction.

Phase transfer catalysis - theory and applications

Unit V **12 h**

Stereochemistry & Asymmetric Synthesis

a. Basic concepts in stereochemistry – optical activity, specific rotation, racemates and resolution of racemates, the Cahn, Ingold, Prelog (CIP) sequence rule, meso compounds, pseudo asymmetric centers, axes of symmetry, Fischers D and L notation, cis-trans isomerism, E and Z notation.
b. Methods of asymmetric synthesis using chiral pool, chiral auxiliaries and catalytic asymmetric synthesis, enantiopure separation and Stereo selective synthesis with examples.

REFERENCES

1. "Advanced Organic chemistry, Reaction, mechanisms and structure", J March, John Wiley and sons, New York.
2. "Mechanism and structure in organic chemistry", ES Gould, Hold Rinchart and Winston, NewYork.
3. "Organic Chemistry" Clayden, Greeves, Warren and Woihers., Oxford University Press 2001.
4. "Organic Chemistry" Vol I and II. I.L. Finar. ELBS, Sixth ed., 1995.
5. Carey, Organic chemistry, 5th edition (Viva Books Pvt. Ltd.)
6. Organic synthesis-the disconnection approach, S. Warren, Wily India
7. Principles of organic synthesis, ROC Norman and JM Coxan, Nelson thorns
8. Organic synthesis- Special techniques VK Ahluwalia and R Aggarwal, Narosa Publishers.
9. Organic reaction mechanisms IV edn, VK Ahluwalia and RK Parashar, Narosa Publishers.

22MPC203T SEMESTER II

COMPUTER AIDED DRUG DESIGN 4H 4C

Instruction hours/ week: L:0 T:0 P:3 Marks: Internal :75 Total:75

SCOPE

The subject is designed to impart knowledge on the current state of the art techniques involved in computer assisted drug design.

COURSE OBJECTIVES:

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

- Role of CADD in drug discovery
- Different CADD techniques and their applications
- Various strategies to design and develop new drug like molecules.
- Working with molecular modeling softwares to design new drug molecules
- The prediction of ADMET properties
- The *in silico* virtual screening protocols

COURSE OUTCOMES:

On successful completion of the course the student will

1. Understand the various parameters in QSAR calculations
2. Discuss the applications of QSAR and 3D QSAR approach including the statistical methods involved.
3. Describe the different methodologies involved in molecular modeling and docking.
4. Predict the ADMET properties of a drug candidate.
5. Discuss the methods of drug design
6. Explain pharmacophore mapping and virtual screening approaches.

THEORY 60 hrs

Unit I 12 h

1. Introduction to Computer Aided Drug Design (CADD)
2. History, different techniques and applications.]
3. Quantitative Structure Activity Relationships: Basics
4. History and development of QSAR: Physicochemical parameters and methods to calculate physicochemical parameters: Hammett equation and electronic parameters (sigma), lipophilicity effects and parameters (log P, pi-substituent constant), steric effects (Taft steric and MR parameters) Experimental and theoretical approaches for the determination of these physicochemical parameters.

Unit II 12 h

1. Quantitative Structure Activity Relationships: Applications Hansch analysis, Free Wilson analysis and relationship between them, Advantages and disadvantages; Deriving 2D-QSAR equations.
2. 3D-QSAR approaches and contour map analysis.
3. Statistical methods used in QSAR analysis and importance of statistical parameters.

Unit III **12 h**

Molecular Modeling and Docking

a. Molecular and Quantum Mechanics in drug design.
b. Energy Minimization Methods: comparison between global minimum conformation and bioactive conformation
c. Molecular docking and drug receptor interactions: Rigid docking, flexible docking and extra-precision docking. Agents acting on enzymes such as DHFR, HMG-CoA reductase and HIV protease, choline esterase (AchE & BchE)

Unit IV **12 h**

Molecular Properties and Drug Design

a. Prediction and analysis of ADMET properties of new molecules and its importance in drug design.
b. De novo drug design: Receptor/enzyme-interaction and its analysis, Receptor/enzyme cavity size prediction, predicting the functional components of cavities, Fragment based drug design.
c. Homology modeling and generation of 3D-structure of protein.
d.

Unit V **12h**

Pharmacophore Mapping and Virtual Screening

a. Concept of pharmacophore, pharmacophore mapping, identification of Pharmacophore features and Pharmacophore modeling; Conformational search used in pharmacophore mapping.
b. In Silico Drug Design and Virtual Screening Techniques
c. Similarity based methods and Pharmacophore based screening, structure based In-silico virtual Screening protocols.

REFERENCES

1. Computational and structural approaches to drug discovery, Robert M Stroud and Janet. F Moore, RCS Publishers.
2. Introduction to Quantitative Drug Design by Y.C. Martin, CRC Press, Taylor & Francis group.
3. Drug Design by Ariens Volume 1 to 10, Academic Press, 1975, Elsevier Publishers.
4. Principles of Drug Design by Smith and Williams, CRC Press, Taylor & Francis.
5. The Organic Chemistry of the Drug Design and Drug action by Richard B. Silverman, Elsevier Publishers.

6. Medicinal Chemistry by Burger, Wiley Publishing Co.
7. An Introduction to Medicinal Chemistry –Graham L. Patrick, Oxford University Press.
8. Wilson and Gisvold's Text book of Organic Medicinal and Pharmaceutical Chemistry, Lippincott Williams & Wilkins.
9. Comprehensive Medicinal Chemistry – Corwin and Hansch, Pergamon Publishers.
10. Computational and structural approaches to drug design edited by Robert M Stroud and Janet. F Moore

22MPC204T

PHARMACEUTICAL PROCESS CHEMISTRY 4H 4C

Instruction hours/ week: L:0 T:0 P:3 Marks: Internal :75 Total:75

SCOPE

Process chemistry is often described as scale up reactions, taking them from small quantities created in the research lab to the larger quantities that are needed for further testing and then to even larger quantities required for commercial production. The goal of a process chemist is to develop synthetic routes that are safe, cost-effective, environmentally friendly, and efficient. The subject is designed to impart knowledge on the development and optimization of a synthetic route/s and the pilot plant procedure for the manufacture of Active Pharmaceutical Ingredients (APIs) and new chemical entities (NCEs) for the drug development phase.

COURSE OBJECTIVES:

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

- The strategies of scale up process of APIs and intermediates
- The various unit operations in process chemistry
- The various reactions in process chemistry
- The fermentation and process of production of antibiotics
- The methods to characterize the reaction progress kinetics
- The industrial safety procedures to be followed.

COURSE OUTCOMES:

On successful completion of the course the student will

1. Explain the strategies of scale up process of APIs and intermediates
2. Discuss the various unit operations in process chemistry
3. Describe nitration, halogenation, oxidation and reduction reactions
4. Elaborate the fermentation process with example of production of antibiotics
5. Characterization of reaction progress and kinetics
6. Understand industrial safety methods and procedures

THEORY **60 hrs**

Unit I **12 h**

Process chemistry

a. Introduction, Synthetic strategy
b. Stages of scale up process: Bench, pilot and large-scale process. In-process control and validation of large-scale process.
c. Case studies of some scale up process of APIs.
d. Impurities in API, types and their sources including genotoxic impurities

Unit II **12 h**

Unit operations

a. Extraction: Liquid equilibria, extraction with reflux, extraction with agitation, counter current extraction.
b. Filtration: Theory of filtration, pressure and vacuum filtration, centrifugal filtration,
c. Distillation: azeotropic and steam distillation
d. Evaporation: Types of evaporators, factors affecting evaporation.
e. Crystallization: Crystallization from aqueous, non- aqueous solutions factors affecting crystallization, nucleation. Principle and general methods of Preparation of polymorphs, hydrates, solvates and amorphous APIs.

Unit III **12 h**

Unit Processes - I

a. **Nitration:** Nitrating agents, Aromatic nitration, kinetics and mechanism of aromatic nitration, process equipment for technical nitration, mixed acid for nitration,
b. **Halogenation:** Kinetics of halogenations, types of halogenations, catalytic
c. halogenations. Case study on industrial halogenation process.
d. **Oxidation:** Introduction, types of oxidative reactions, Liquid phase oxidation with oxidizing agents. Nonmetallic Oxidizing agents such as H_2O_2, sodium hypochlorite, Oxygen gas, ozonolysis.

Unit IV **12 h**

Unit Processes - II

a. **Reduction:** Catalytic hydrogenation, Heterogeneous and homogeneous catalyst; Hydrogen transfer reactions, Metal hydrides. Case study on industrial reduction process.
b. **Fermentation:** Aerobic and anaerobic fermentation.
   Production of
   i) Antibiotics; Penicillin and Streptomycin,
   ii) Vitamins: B2 and B12
   iii) Statins: Lovastatin, Simvastatin

c. Reaction progress kinetic analysis

i) Streamlining reaction steps, route selection,

ii) Characteristics of expedient routes, characteristics of cost-effective routes, reagent selection, families of reagents useful for scale-up.

Unit V **12 h**

Industrial Safety

a. MSDS (Material Safety Data Sheet), hazard labels of chemicals and Personal Protection Equipment (PPE)
b. Fire hazards, types of fire & fire extinguishers
c. Occupational Health & Safety Assessment Series 1800 (OHSAS-1800) and ISO-14001 (Environmental Management System), Effluents and its management

REFERENCES

1. Process Chemistry in the Pharmaceutical Industry: Challenges in an Ever- Changing Climate-An Overview; K. Gadamasetti, CRC Press.
2. Pharmaceutical Manufacturing Encyclopedia, 3rd edition, Volume 2.
3. Medicinal Chemistry by Burger, 6th edition, Volume 1-8.
4. W.L. McCabe, J.C Smith, Peter Harriott. Unit operations of chemical engineering, 7th edition, McGraw Hill
5. Polymorphism in Pharmaceutical Solids. Dekker Series Volume 95 Ed: H G Brittain (1999)
6. Regina M. Murphy: Introduction to Chemical Processes: Principles, Analysis, Synthesis
7. Peter J. Harrington: Pharmaceutical Process Chemistry for Synthesis: Rethinking the Routes to Scale-Up
8. P.H. Groggins: Unit processes in organic synthesis (MGH)
9. F.A. Henglein: Chemical Technology (Pergamon)
10. M. Gopal: Dryden's Outlines of Chemical Technology, WEP East-West Press
11. Clausen, Mattson: Principle of Industrial Chemistry, Wiley Publishing Co.,
12. Lowenheim & M.K. Moran: Industrial Chemicals
13. S.D. Shukla & G.N. Pandey: A text book of Chemical Technology Vol. II, Vikas Publishing House
14. J.K. Stille: Industrial Organic Chemistry (PH)
15. Shreve: Chemical Process, Mc Grawhill.
16. B.K. Sharma: Industrial Chemistry, Goel Publishing House
17. ICH Guidelines
18. United States Food and Drug Administration official website www.fda.gov

22MPC205P SEMESTER II

PHARMACEUTICAL CHEMISTRY PRACTICALS – II 12H 6C

Instruction hours/ week: L:0 T:0 P:3 Marks: Internal :75 Total:75

COURSE OBJECTIVES:

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

- The synthesis of organic compounds using various approaches
- The synthetic procedure for API and intermediate preparation
- The interpretation of spectra and identify the organic compounds
- The methods to determine the purity of pharmaceuticals
- The various computational approaches in drug design
- The importance of 2D/3D QSAR in drug design.

COURSE OUTCOMES:

On successful completion of the course the student will

1. Synthesis organic compounds using different approaches
2. Compare the synthesis if APIs/intermediates by different synthetic routes
3. Compare, interpret different spectra and identify the organic compounds
4. Determine the purity of pharmaceuticals
5. Apply different computational approaches to determine physicochemical properties and perform ADMET, pharmacophore modeling, molecular modeling and docking.
6. Determine 2D/3D QSAR for the therapeutic class of drugs

COURSE CONTENT

1. Synthesis of organic compounds by adapting different approaches involving (3 experiments)
    a. Oxidation
    b. Reduction/hydrogenation
    c. Nitration
2. Comparative study of synthesis of APIs/intermediates by different synthetic routes (2 experiments)
3. Assignments on regulatory requirements in API (2 experiments)
4. Comparison of absorption spectra by UV and Wood ward – Fieser rule
5. Interpretation of organic compounds by FT-IR
6. Interpretation of organic compounds by NMR
7. Interpretation of organic compounds by MS
8. Determination of purity by DSC in pharmaceuticals
9. Identification of organic compounds using FT-IR, NMR, CNMR and Mass spectra
10. To carry out the preparation of following organic compounds
11. Preparation of 4-chlorobenzhydrylpiperazine. (An intermediate for cetirizine HCl).
12. Preparation of 4-iodotolene from p-toluidine.

13. NaBH4 reduction of vanillin to vanillyl alcohol
14. Preparation of umbelliferone by Pechhman reaction
15. Preparation of triphenyl imidazole
16. To perform the Microwave irradiated reactions of synthetic importance (Any two)
17. Determination of log P, MR, hydrogen bond donors and acceptors of selected drugs using softwares
18. Calculation of ADMET properties of drug molecules and its analysis using softwares
19. Pharmacophore modeling
20. 2D-QSAR based experiments
21. 3D-QSAR based experiments
22. Docking study-based experiment
23. Virtual screening-based experiment

22MPC206S SECOND SEMESTER

SEMINAR/ASSIGNMENT **7H 4C**

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

22MRM301T SEMESTER III

RESEARCH METHODOLOGY & BIOSTATISTICS

Instruction hours/ week: L:0 T:0 P:3 Marks: Internal :75 Total:75

COURSE OBJECTIVES:

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

- The general research methodology
- The importance and methods of literature review
- The application of biostatics methods to various data
- The different medical research methodologies
- The guidelines for animal handling and experimentation
- The basic principles of research

COURSE OUTCOMES:

On successful completion of the course the student will

1. Understand the general research methodology
2. Explain the importance and methods of literature review
3. Apply biostatistics to the given data sample
4. Discuss the different medical research methodologies
5. Explain the guidelines for animal handling and experimentation
6. Describe the basic principles of research

Course Content

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.

22MPC302J THIRD SEMESTER

JOURNAL CLUB **1H 1C**

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

22MPC303D THIRD SEMESTER

DISCUSSION / PRESENTATON 2H 2C

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

22MPC304RW THIRD SEMESTER

RESEARCH WORK **28H 14C**

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

22MPC401J FOURTH SEMESTER

JOURNAL CLUB **1H 1C**

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

22MPC402R FOURTH SEMESTER

RESEARCH WORK **31H 16C**

Instruction hours/ week: L:0 T:0 P:31 Marks: External :400 Total:400

22MPC403D FOURTH SEMESTER

DISCUSSION / PRESENTATON 3H 3C

Instruction hours/ week: L:0 T:0 P:3