PROGRAM STRUCTURE AND SYLLABUS
For
M. PHARM

MPH R 20 PCI Regulations

(Applicable for batches admitted from 2024-2025)

ADITYA PHARMACY COLLEGE

(An Autonomous Institution)
Approved by PCI, Permanently Affiliated to JNTUK,
Recognized by UGC (sections 2f) ISO 9001: 2015 Certified Institution,
Accredited by NAAC with "A" Grade
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Table of Contents

S.No.	Content	Page. No.
	Regulations	05
1.	Short Title and Commencement	05
2.	Minimum qualification for admission	05
3.	Duration of the program	05
4.	Medium of instruction and examinations	05
5.	Working days in each semester	05
6.	Attendance and progress	05
7.	Program/Course credit structure	06
8.	Academic work	06
9.	Course of study	07
10.	Program Committee	19
11.	Examinations/Assessments	19
12.	Promotion and award of grades	31
13.	Carry forward of marks	31
14.	Improvement of internal assessment	31
15.	Reexamination of end semester examinations	32
16.	Allowed to keep terms (ATKT)	32
17.	Grading of performances	32
18.	The Semester grade point average (SGPA)	32
19.	Cumulative Grade Point Average (CGPA)	33
20.	Declaration of class	33
21.	Project work	33
22.	Award of Ranks	34
23.	Award of degree	34
24.	Duration for completion of the program of study	34
25.	Revaluation I Retotaling of answer papers	34
26.	Re-admission after break of study	34
27.	Pharmaceutics (MPH)	35
28	Pharmaceutical Analysis (MPA)	48
29.	Research Methodology & Biostatistics (MRM)	77

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PHARMACY COUNCIL OF INDIA

NOTIFICATION

New Delhi, the 10th December, 2014

The Master of Pharmacy (M.Pharm) Course Regulations, 2014

No. 14-136/ 2014-PCI.—In exercise of the powers conferred by Sections 10 and 18 of the Pharmacy Act, 1948 (8 of 1948), the Pharmacy Council of India, with the approval of the Central Government hereby makes the following regulations; namely–

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 2016-17. 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 4years 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 becancelled.

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 Phamacy 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 lessthan 100 working days. The odd semesters shall be conduted 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 student shall be eligible to write University examinations if he acquires a minimum of 75% of attendance in aggregate of all the subjects/courses, and with minimum 50% in each and every course including practicals.
- Condonation of shortage of attendance in aggregate up to 10% (65% and above and below 75%) in each semester shall be granted by the College Academic Committee.
- Shortage of Attendance below 65% in aggregate shall not be condoned and not eligible to write their end semester examination of that class.
- Students whose shortage of attendance is not condoned in any semester are not eligible to write their end semester examination of that class.
- A prescribed fee shall be payable towards Condonation of shortage of attendance.
- A student shall not be promoted to the next semester unless, he satisfies the attendance requirement of the present semester, as applicable. They may seek re- admission into that semester when offered next. If any candidate fulfills the

attendance requirement in the present semester, he shall not be eligible for re-admission into the same class.

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.

7.1. Credit assignment

7.1.1. Theory and Laboratory courses

Courses are broadly classified as Theory and Practical. Theory courses consist of lecture (L) and Practical (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.

7.2. 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 14. 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.

M.Pharm I & II Semester Practicals:

- The individual student of the respective specialization need to carry out at least 75% of the practical prescribed in the syllabus.
- Based and depending upon the software available with the institute the practical can be designed.
- Some experiments have to be carried out only by Demonstration. Students are advised to know the Principle and Protocol of the experiment.

9. Course of study

The specializations in M.Pharm program is given in Table 1.

Table – 1: List of M.Pharm. Specializations and their Code

S. No.	Specialization	Code
1.	Pharmaceutics	MPH
5.	Pharmaceutical Quality Assurance	MQA

The course of study for M.Pharm specializations shall include Semester wise Theory & Practical as given in Table – 2&3 . The number of hours to be devoted to each theory and practical course in any semester shall not be less than that shown in Table –2 &3 .

Table – 2: Course of study for M. Pharm. (Pharmaceutics)

Course Code	Course	Credit Hours	Credit Points	Hrs./ wk	Marks
Semester I					
MPH101T	Modern Pharmaceutical Analytical Techniques	4	4	4	100
MPH102T	Drug Delivery System	4	4	4	100
MPH103T	Modern Pharmaceutics	4	4	4	100
MPH104T	Regulatory Affair	4	4	4	100
MPH105PA	Pharmaceutics Practical I	6	3	6	75
MPH105PB	Pharmaceutical Practical II	6	3	6	75
-	Seminar/Assignment	7	4	7	100
Total		35	26	35	650
Semester II					
MPH201T	Molecular Pharmaceutics (Nano Technology and Targeted DDS) (NTDS)	4	4	4	100
MPH202T	Advanced Biopharmaceutics & Pharmacokinetics	4	4	4	100
MPH203T	Computer Aided Drug Development	4	4	4	100
MPH204T	Formulation Development of Pharmaceutical and Cosmetic Products	4	4	4	100
MPH205PA	Pharmaceutics Practical III	6	3	6	75
MPH205PB	Pharmaceutics Practical IV	6	3	6	75
-	Seminar/Assignment	7	4	7	100
	Total	35	26	35	650

Table – 3: Course of study for M. Pharm. (Pharmaceutical Analysis)

Course Code	Course	Credit Hours	Credit Points	Hrs./wk	Marks
Semester I					
MPA101T	Modern Pharmaceutical Analytical Techniques	4	4	4	100
MPA102T	Advanced Pharmaceutical Analysis	4	4	4	100
MPA103T	Pharmaceutical Validation	4	4	4	100
MPA104T	Food Analysis	4	4	4	100
MPA105PA	Pharmaceutical Analysis Practical I	6	3	6	75
MPA105PB	Pharmaceutical Analysis Practical II	6	3	6	75
-	Seminar/Assignment	7	4	7	100
Total		35	26	35	650
Semester II					
MPA201T	Advanced Instrumental Analysis	4	4	4	100
MPA202T	ModernBio-Analytical Techniques	4	4	4	100
MPA203T	Quality Control and Quality Assurance	4	4	4	100
MPA204T	Herbal and Cosmetic Analysis	4	4	4	100
MPA205PA	Pharmaceutical Analysis Practical III	6	3	6	75
MPA205PB	Pharmaceutical Analysis Practical IV	6	3	6	75
-	Seminar/Assignment	7	4	7	100
	Total	35	26	35	650

Table–4: Course of study for M.Pharm. III Semester
(Common for All Specializations)

Course Code	Course	Credit Hours	Credit Points
MRM301T	Research Methodology and Biostatistics*	4	4
-	Journal club	1	1
-	Discussion / Presentation (Proposal Presentation)	2	2
-	Research Work	28	14
Total		35	21

* Non University Exam

Table–13: Course of study for M.Pharm. IV Semester
(Common for All Specializations)

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

Table – 14: 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 – 5: Guidelines for Awarding Credit Points for Co-curricular Activities

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

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

*The credit points assigned for extra curricular 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.

One Research/Review publication is necessary for all M.Pharm students before the completion of IV Semester. The Research/Review article need to be published/acceptance in UGC care list journals or any other reputed journals.

1. Program Committee

The M. Pharm. programme shall have a Programme Committee constituted by the Head of the Institution in consultation with all the Heads of thedepartments.

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.

Duties of the Programme Committee:

Periodically reviewing the progress of the classes.

Discussing the problems concerning curriculum, syllabus and the conduct of classes.

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.

1. Communicating its recommendation to the Head of the Institution on academic matters.
2. The Programme Committee shall meet at least twice in a semester preferably at the end of each sessional exam and before the end semesterexam.

11. Examinations/Assessments

The schemes for internal assessment and end semester examinations are given from Table–16.

11.1. 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 (*) for which examinations shall be conducted by the subject experts at college level and the marks/grades shall be submitted to the university.

Tables – 16: Schemes for internal assessments and end semester (Pharmaceutics- MPH)

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continues Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
SEMESTER I								
MPH101T	Modern Pharmaceutical Analytical Techniques	10	15	1Hr	25	75	3Hr	100
MPH102T	Drug Delivery Systems	10	15	1Hr	25	75	3Hr	100
MPH103T	Modern Pharmaceutics	10	15	1Hr	25	75	3Hr	100
MPH104T	Regulatory Affairs	10	15	1Hr	25	75	3Hr	100
MPH105PA	Pharmaceutics Practical I	10	15	3Hr	25	50	3Hr	75
MPH105PB	Pharmaceutics Practical II	10	15	3Hr	25	50	3Hr	75
-	Seminar/Assignment	-	-	-	-	-	-	100
Total								650
SEMESTER II								
MPH201T	Molecular Pharmaceutics (Nano Tech and Targeted DDS) (NTDS)	10	15	1Hr	25	75	3Hr	100
MPH202T	Advanced Biopharmaceutics & Pharmacokinetics	10	15	1Hr	25	75	3Hr	100
MPH203T	Computer Aided Drug Development	10	15	1Hr	25	75	3Hr	100
MPH204T	Formulation Development of Pharmaceutical and Cosmetic Products	10	15	1Hr	25	75	3Hr	100
MPH205PA	Pharmaceutics Practical I	10	15	3Hr	25	50	3Hr	75
MPH205PB	Pharmaceutics Practical I	10	15	3Hr	25	50	3Hr	75
-	Seminar/Assignment	-	-	-	-	-	-	100
Total								650

Tables – 19: Schemes for internal assessments and end semester (Pharmaceutical Analysis-MPA)

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continues Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
SEMESTER I								
MPA101T	Modern Pharmaceutical Analytical Techniques	10	15	1Hr	25	75	3Hr	100
MPA102T	Advanced Pharmaceutical Analysis	10	15	1Hr	25	75	3Hr	100
MPA103T	Pharmaceutical Validation	10	15	1Hr	25	75	3Hr	100
MPA104T	Food Analysis	10	15	1Hr	25	75	3Hr	100
MPA105PA	Pharmaceutical Analysis Practical I	10	15	3Hr	25	50	3Hr	75
MPA105PB	Pharmaceutical Analysis Practical II	10	15	3Hr	25	50	3Hr	75
	Seminar/Assignment	-	-	-	-	-	-	100
Total								650
SEMESTER II								
MPA201T	Advanced Instrumental Analysis	10	15	1Hr	25	75	3Hr	100
MPA202T	Modern Bio-Analytical Techniques	10	15	1Hr	25	75	3Hr	100
MPA203T	Quality Control and Quality Assurance	10	15	1Hr	25	75	3Hr	100
MPA204T	Herbal and Cosmetic Analysis	10	15	1Hr	25	75	3Hr	100
MPA205PA	Pharmaceutical Analysis Practical III	10	15	3Hr	25	50	3Hr	75
MPA205PB	Pharmaceutical Analysis Practical IV	10	15	3Hr	25	50	3Hr	75
	Seminar/Assignment	-	-	-	-	-	-	100
Total								650

Tables– 26: Schemes for internal assessments and end semester examinations (Semester III& IV)

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total			
			Marks	Duration		Marks	Duration	
SEMESTER III								
MRM301T	Research Methodology and Biostatistics*	10	15	1 Hr	25	75	3 Hrs	100
-	Journal club	.	.	.	25	.	.	25
-	Discussion / Presentation (Proposal Presentation)	.	.	.	50	.	.	50
-	Research work	.	.	.	.	350	1 Hr	350
Total								525
SEMESTER IV								
-	Journal club	.	.	.	25	.	.	25
-	Discussion / Presentation (Proposal Presentation)	.	.	.	75	.	.	75
-	Research work and Colloquium	.	.	.	.	400	1 Hr	400
Total								500

*Non University Examination

- The subject 'Research Methodology and Biostatistics (MRM 301T)' in III Semester has to be conducted by respective institute with paper setting followed by evaluation.
- The award of marks to be uploaded in JNTUK portal.

Note: The answer scripts, question paper and attendance sheet need to be packed and kept under the institution safely.

11.2. Internal assessment: Continuous mode

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

Table – 27: Scheme for awarding internal assessment: Continuous mode

Theory	
Criteria	Maximum Marks
Attendance (Refer Table – 28)	8
Student – Teacher interaction	2
Total	10
Practical	
Attendance (Refer Table – 28)	5
Based on Practical Records, Regular viva voce, etc.	5
Total	10

Table – 28: Guidelines for the allotment of marks for attendance

Percentage of Attendance	Theory	Practical
95 – 100	8	5
90 – 94	6	3.75
85 – 89	4	2.5
80 – 84	2	1.25

- Allocation of marks for attendance will be considered on the basis of individual student's punctuality, regularity, attentiveness, conduct and submission of assignments.

11.2.1. 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 in the table. The average marks of two sessional exams shall be computed for internal assessment as per the requirements given in tables.

12. Promotion and award of grades

A student shall be declared PASS and eligible for getting grade in a course of M.Pharm. program me if 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 obtained by him/her on passing.

14. Improvement of internal assessment

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

15. Reexamination of end semester examinations

Revaluation/recounting/challenging valuation as per the University norms is acceptable within stipulated time period. This process is also applicable for all previous batches joined under PCI regulations.

Table – 29: Tentative schedule of end semester examinations

Semester	For Regular Candidates	For Failed Candidates
I and III	November / December	As per University norms
II and IV	May / June	As per University norms

16. Allowed to keep terms (ATKT):

No student shall be admitted to any examination unless he/she fulfills the norms given in 6. ATKT rules 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 the courses 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 IV semesters 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. Such rules 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 the semester for each course. The letter grades and their corresponding grade points are given in Table – 30.

Table–30: Letter grades and grade points equivalent to Percentage of marks and performances.

Percentage of Marks Obtained	Letter Grade	Grade Point	Performance
90.00 – 100	O	10	Outstanding
80.00 – 89.99	A	9	Excellent
70.00 – 79.99	B	8	Good
60.00 – 69.99	C	7	Fair
50.00 – 59.99	D	6	Average
Less than 50	F	0	Fail
Absent	AB	0	Fail

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 courses by the student during the semester. For example, if a student takes five courses (Theory /Practical) in a semester 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:

$$C_1G_1 + C_2G_2 + C_3G_3 + C_4G_4$$

$$SGPA = \frac{}{C_1 + C_2 + C_3 + C_4}$$

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 For ABS grade in course 4, the SGPA shall then be computed as:

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

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 status incase of F grade(s), till the course(s) is/are passed. When the course(s) is/are passed by obtaining a pass grade on subsequent examination(s) the CGPA shall only reflect the new grade and not the fail grades earned earlier. The CGPA is calculated as:

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

where C_1, C_2, C_3,.... is the total number of credits for semester I,II,III,…. and S_1,S_2, S_3,....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 = CGPA of 7.50 and above
First Class = CGPA of 6.00 to 7.49
Second Class = CGPA of 5.00 to 5.99

21. Project work

All the students shall under take 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 than75 pages).

The internal and external examiner appointed by the University shall evaluate the project at the time of the Practical examinations of other semester(s). The projects shall be evaluated as per the criteria given below.

M.Pharm III Semester (research work)

The M.Pharm III Semester for conduct of research work will be evaluated by the external examiner with rich experience and Doctorate holder. Depending upon the number of students in each specialization examiner should be appointed. $C_1G_1 + C_2G_2 + C_3G_3 + C_4G_4$

$$SGPA = \frac{}{C_1 + C_2 + C_3 + C_4}$$

The SGPA is calculated to two decimal points. It should be noted that, the SGPA for any semester

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

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

23. Declaration of class

The class shall be awarded on the basis of CGPA as follows:

First Class with Distinction = CGPA of 7.50 and above
First Class = CGPA of 6.00 to 7.49
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$$SGPA = \frac{C_1G_1 + C_2G_2 + C_3G_3 + C_4G_4}{C_1 + C_2 + C_3 + C_4}$$

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 For ABS grade in course 4, the SGPA shall then be computed as:

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

25. 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 status incase of F grade(s), till the course(s) is/are passed. When the course(s) is/are passed by obtaining a pass grade on subsequent examination(s) the CGPA shall only reflect the new grade and not the fail grades earned earlier. The CGPA is calculated as:

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

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

26. Declaration of class

The class shall be awarded on the basis of CGPA as follows:

First Class with Distinction = CGPA of 7.50 and above
First Class = CGPA of 6.00 to 7.49
Second Class = CGPA of 5.00 to 5.99

27. Project work

All the students shall under take 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 than75 pages).

The internal and external examiner appointed by the University shall evaluate the project at the time of the Practical examinations of other semester(s). The projects shall be evaluated as per the criteria given below.

28. M.Pharm III Semester (research work)

- The M.Pharm III Semester for conduct of research work will be evaluated by the external examiner with rich experience and Doctorate holder. Depending upon the number of students in each specialization examiner should be appointed.

PHARMACEUTICS

(MPH)

Semester- I

L	T	P	C
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MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES

Subject Code: MPH101T

Course Objectives: Upon completion of the subject student shall be

COB1: Understand the spectroscopic concept upon pharmaceuticals, NMR with new compounds

COB2: Integrate the mass data for molecules, chromatography methods

COB3: Differentiate Electrophoresis and X-Ray crystallography, the Unknown concentration sample by potentiometry and weight variation by Thermal methods.

Course Outcomes:

COURSE OUTCOME	STATEMENT
CO1 [L2]	**Understand:** The basic concepts of Spectroscopic method
CO2 [L3]	**Apply: C**omputation of NMR Spectroscopy
CO3 [L6]	**Generate:** Mass spectroscopy of compounds by using instrumentation and ionisation techniques
CO4 [L1]	**Remember:** Quantification methods of Chromatography
CO5 [L4]	**Classify:** analytical method of electrophoresis and x-ray crystallography
CO6 [L5]	**Evaluate:** Predict the unknow concentrations of samples using ion selective methods (Potentiometry) and thermal methods for Pharmaceuticals

Course contents **60Hours**

UNIT-1 **10 Hours**

BASIC METHODS OF SPECTROSCOPY:

1. a. 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.

b. 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.

c. Spectroflourimetry: Theory of Fluorescence, Factors affecting fluorescence (Characterestics of drugs that can be analysed by flourimetry), Quenchers, Instrumentation and Applications of fluorescence spectrophotometer.

d. Flame emission spectroscopy and atomic absorption spectroscopy: Principle, Instrumentation, Interferences and Applications.

UNIT-II **10Hours**

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 **10Hours**

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, Metastable ions, Isotopic peaks and Applications of Mass spectroscopy.

UNIT-IV **10Hours**

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 **10Hours**

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) Isoelectric focusing

b. 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 **10Hours**

a. Potentiometry

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

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

(DDTA). TGA: Principle, instrumentation, factors affecting results, advantage and disadvantages, pharmaceutical applications.

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- PD Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis- Modern Methods– Part B- JW Munson, Vol 11, Marcel. Dekker Series
8. Spectroscopy of Organic Compounds, 2nd edn., P.S /Kalsi, Wileyestern Ltd., Delhi.
9. Textbook of Pharmaceutical Analysis, KA. Connors, 3rdEdition, John Wiley & Sons, 1982.

L	T	P	C
4	0	0	4

DRUG DELIVERY SYSTEMS

Subject Code: MPH102T

Course objective: Upon completion of the subject student shall be

COB 1: To understand the various approaches for development of novel drug delivery systems.

COB 2: To understand the criteria for selection of drugs and polymers for the development of delivering system.

COB 3: To understand the formulation and evaluation of Novel drug delivery systems.

Course Outcomes:

Course outcome	Statement
CO1[L1]	**Describe** the concepts of Sustained release & Controlled release formulations and gain knowledge about the polymers used in Novel formulations and personalized medicines. (Remember)
CO2[L6]	**Formulate** and attain knowledge on fundamentals, types and activation of different modulated drug delivery systems. (Create)
CO3[L5]	**Formulate and Evaluate** Gastro retentive & Buccal drug delivery systems and Know about the modulation of GI transit time & mechanism of drug permeation. (Create)
CO4[L2]	**Recognize** the Barriers involved in ocular and protein drug delivery and mechanisms to overcome the barriers. (Understand)
CO5[L4]	**Classify** Transdermal Drug Delivery Systems and Formulate and Evaluate different Transdermal and Protein Drug Delivery Systems. (Analyse)
CO6[L2]	**Explain** the mechanism of vaccine uptake and delivery of vaccines through different routes. (Understand)

Course contents **60 Hours**

Unit-I **10 Hours**

Sustained Release (SR) and Controlled Release (CR) formulations: Introduction & basic concepts, advantages/ disadvantages, factors influencing, Physicochemical & biological approaches for SR/CR formulation, Mechanism of Drug Delivery from SR/CR formulation. Polymers: introduction, definition, classification, properties and application Dosage Forms for Personalized Medicine: Introduction, Definition, Pharmacogenetics, Categories of Patients for Personalized Medicines: Customized drug delivery systems, Bioelectronic Medicines, 3D printing of pharmaceuticals, Tele pharmacy.

Unit-II **10 Hours**

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

Unit-III **10 Hours**

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

Unit- IV **6 Hours**

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

Unit-V **10 Hours**

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

Unit-VI **8 Hours**

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

Unit-VII **6 Hours**

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 Wiley Inter science 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.

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4	0	0	4

MODERN PHARMACEUTICS

Subject Code: MPH103T

Course Objectives: Upon completion of the subject student shall be

COB1: To know basic concepts of preformulation parameters, useful in product formulation and development.

COB 2: To learn the cGMP concepts in manufacturing to get a qualitative product.

COB 3: To understand the concept of consolidation, useful for formulating a tablet with desired performance.

Course Outcomes

COURSE OUTCOME	Statement
CO1[L]	**Describe** about the basic concepts of preformulation studies, dispersion systems & parenteral
CO2 [L]	**Optimize;** optimization process.
CO3 [L]	**Explain** about the validation of process, equipment and product.
CO4 [L]	**Describe** the cGMP concepts of layout of building, services and their maintenance & about the production management.
CO5 [L]	**Describe** the concepts of compression and compaction.
CO6 [L]	**Explain** about the parameters of consolidation and their applications.

Course contents **60Hours**

UNIT- I **12 Hours**

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 – physiologicaland 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 Hours**

Validation: Introduction to Pharmaceutical Validation, Scope & merits of Validation, Validation and calibration of Master plan, ICH & WHO guidelines for calibration and validation of equipments, Validation of specific dosage form, Types of validation.

Government regulation, Manufacturing Process Model, URS, DQ, IQ, OQ& P.Q. of facilities.

UNIT-III **12 Hours**

cGMP & Industrial Management: Objectives and policies of current good manufacturing practices, layout of buildings, services, equipment's 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 Hours**

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

UNIT-V **12 Hours**

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

REFERENCES

1. Theory and Practice of Industrial Pharmacy By Lachmann and Libermann
2. Pharmaceutical dosage forms: Tablets Vol.1-3 by Leon Lachmann. Pharmaceutical Dosage forms: Disperse systems, Vol, 1-2; By Leon Lachmann.
3. Pharmaceutical Dosage forms: Parenteral medications Vol. 1-2; By Leon Lachmann.
4. Modern Pharmaceutics; By Gillbert and S.Banker.
5. Remington's PharmaceuticalSciences.
6. Advances in Pharmaceutical Sciences Vol. 1-5; By H.S. Bean &A.H.Beckett.
7. Physical Pharmacy; By Alfredmartin
8. Bentley'sTextbookofPharmaceutics–byRawlins.
9. Good manufacturing practices for Pharmaceuticals: A plan for total quality control, Second edition; By Sidney H.Willig.
10. Quality Assurance Guide; By Organization of Pharmaceutical producers of India.
11. Drug formulation manual; By D.P.S. Kohli and D.H.Shah. Eastern publishers, New Delhi.
12. How to practice GMPs; By P.P.Sharma.Vandhana Publications, Agra.
13. Pharmaceutical Process Validation; By Fra.R.Berry and Robert A.Nash.
14. Pharmaceutical Preformulations; By J.J.Wells.
15. Applied production and operations management; By Evans, Anderson, Sweeney and Williams.
16. Encyclopaedia of Pharmaceutical technology, Vol I–

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4	0	0	4

REGULATORY AFFAIRS

Subject Code : MPH104T
Course Objectives: Upon completion of the course the student shall be able to
COB1: The Concepts of innovator and generic drugs, drug development process

COB2: The Regulatory guidance's and guidelines for filing and approval process Preparation of Dossiers and their submission to regulatory agencies in different countries

COB3: 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 Pharmacovigilance and process of monitoring in clinical trials.

Course Outcomes:

COURSE OUTCOME	STATEMENT
CO1 [L2]	**Explain** the requirements for development
CO2 [L5]	**Evaluate**, analyze and apply 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
CO3 [L1]	**Describe** the post approval regulatory requirements for actives and drug products
CO4 [L3]	**Apply** the regulatory requirements for submission of global documents in CTD/ eCTD formats
CO5 [L1]	**Identify** the clinical trials requirements for approvals for conducting clinical trials
CO6 [L5]	**Assess** the requirements of Pharmacovigilance and process of monitoring in clinical trials.

Course contents **60Hours**

UNIT-I **12 Hours**

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

UNIT-II **12 Hours**

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

UNIT-III **12 Hours**

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

UNIT-IV **12 Hours**

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

UNIT-V **12 Hours**

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

REFERENCES

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

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PHARMACEUTICS PRACTICAL-I

Subject Code: MPH105PA

Course Objectives: Upon completion of the course the student shall be able to

COB1: To recall the principles of analysis and instrumentation for testing of drug products.

COB2: To evaluate preformulation, used in development of various dosage forms.

COB3: To evaluate various compressional parameters to formulate a best tablet dosage form.

COURSE OUTCOMES

Course Outcome	Statement
CO1 [L3]	**Testing** of drugs and simultaneously multiple drugs estimation using UV Spectrophotometer.
CO2 [L2]	**Demonstration** of the construction and working of HPLC and GC.
CO3 [L3]	**Testing** of riboflavin/quinine sulphate using fluorimetry and to estimate potassium/sodium by flame photometry.
CO4 [L5]	**Evaluation** of the preformulation studies.
CO5 [L5]	**Evaluation** of effect of binding forces on disintegration of tablets.
CO6 [L3]	**Testing** of difference in micromeritic properties of granules and powders.

List of experiments

S. No	Title of the experiment	CO
1	Analysis of Pharmacopoeial compounds and their formulations by UV Vis spectrophotometer	CO1
2.	Simultaneous estimation of multi component containing formulations by UV spectrophotometry	CO1
3.	Experiments based on HPLC	CO2
4.	Experiments based on Gas Chromatography	CO2
5.	Estimation of riboflavin/quinine sulphate by fluorimetry	CO3
6.	Estimation of sodium/potassium by flame photometry	CO3

7.	To carry out preformulation studies of tablets	CO4
8.	To study the effect of compressional force on tablets disintegration time	CO5
9.	To study Micromeritic properties of powders and granulation	CO6

References

1. Theory and Practice of Industrial Pharmacy by Lachmann and Libermann
2. Modern Pharmaceutics; By Gillbert and S.Banker.
3. Remington's PharmaceuticalSciences.
4. Physical Pharmacy; By Alfredmartin
5. Bentley'sTextbookofPharmaceutics–byRawlins.
6. Pharmaceutical dosage forms: Tablets Vol.1-3 by Leon Lachmann.
7. Pharmaceutical Process Validation; By Fra.R.Berry and Robert A.Nash.

L	T	P	C
0	0	6	3

Pharmaceutics Practical-II

Subject Code: MPH105PB

Course Objectives: Upon completion of the course the student shall be able to

COB1: To learn the design of dosage forms.

COB2: To learn the optimization of formulae.

COB3: To learn the characterization of various dosage forms.

Course Outcomes

CO1 [L5]	**Evaluate** the effect of various factors on drug dissolution.
CO2 [L4]	Study of powder **characteristics** by constructing heckle plots.
CO3 [L2]	Study of **comparative** dissolution studies between various dosage forms.
CO4 [L5]	**Evaluation** of different dosage forms.
CO5 [L6]	**Design** and evaluation of different oral dosage forms
CO6 [L6]	**Design** and evaluation of different trasdermal dosage forms

List of experiments

S. No	Title of the experiment	CO
1.	Study the effect of particle size on dissolution of a tablet.	CO1
2.	Study the effect of binders on dissolution of a tablet.	CO1
3.	Construction of Heckal plot for the given granules	CO2
4.	Construction of Higuchi and peppas plot.	CO3
5.	Determine similarity factor.	CO3
6.	Determine the *in-vitro* dissolution profile of CR/ SR marketed formulation.	CO4
7.	Formulation and evaluation of sustained release matrix tablets.	CO5
8.	Formulation and evaluation osmotically controlled DDS.	CO5
9.	Preparation and evaluation of Floating DDS- hydro dynamically balanced DDS.	CO5
10.	Formulation and evaluation of Mucoadhesive tablets.	CO5
11.	Formulation and evaluation of trans dermal patches.	CO6

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 Wiley Inter science 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).

Semester- II

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4	0	0	4

MOLECULAR PHARMACEUTICS (NANO TECHNOLOGY & TARGETED DDS) (NTDS)

Subject Code: MPH201T

Course Objectives: Upon completion of the course the student shall be able to

COB1: To understand the various approaches for development of novel drug delivery systems.

COB2: To understand the criteria for selection of drugs and polymers for the development of NTDS

COB3: To understand the formulation and evaluation of novel drug delivery systems.

Course Outcomes

COURSE OUTCOME	STATEMENT
CO1 [L2]	**Explain** the concepts, events and biological processinvolved in drug targeting. tumor targeting and brain specific delivery.
CO2 [L2]	**Understand** the introduction preparation and evaluation. nanoparticles & liposomes: types, preparation and evaluation.
CO3 [L2]	**Understand** about the Microspheres and microcapsules & types, preparation and evaluation, monoclonal Antibodies
CO4 [L4]	**Characterize** the niosomes, aquasomes, phytosomes, electrosomes.
CO5 [L1]	**Describe** the pulmonary drug delivery Systems
CO6 [L2]	**Discuss** the nucleic acid based therapeutic delivery system

Course contents **60 Hours**

Unit-I **12 Hours**

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

Unit-II **12 Hours**

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

Unit-III **12 Hours**

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

Unit-IV **12 Hours**

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

Unit-V **12 Hours**

Nucleic acid based therapeutic delivery system: Gene therapy, introduction (ex-vivo & in-vivo gene therapy). Potential target diseases for gene therapy (inherited disorder and cancer). Gene expression systems (viral and nonviral genetransfer). Liposomal gene delivery systems.Bio distribution 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., NewYork, 1992.
2. S.P.Vyas and R.K.Khar, Controlled Drug Delivery - concepts and advances, Vallabh Prakashan, New Delhi, First edition 2002.
3. N.K.Jain, Controlled and Novel Drug Delivery, CBS Publishers & Distributors, NewDelhi, First edition 1997 (reprint in 2001).

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ADVANCED BIOPHARMACEUTICS & PHARMACOKINETICS

Subject Code : MPH202T

Course Objectives : Upon completion of the course the student shall be able to

COB1: The basic concepts in Biopharmaceutics and pharmacokinetics, use of raw data and derive the pharmacokinetic models and parameters the best describe the process of drug absorption, distribution, metabolism and elimination.

COB2: To critically evaluate Biopharmaceutics studies involving drug product equivalency, design and evaluate dosage regimens of the drugs using pharmacokinetic and biopharmaceutic parameters**.**

COB3: The potential clinical pharmacokinetic problems and applications of basics of pharmacokinetics

Course Outcomes:

Course outcome	Statement
CO1 [L2]	**Demonstrate** drug absorption through GIT- Mechanisms, factors & methods of study
CO2 [L6]	**Integrate** biopharmaceutical considerations of drug design & *in-vivo* drug product performance
CO3 [L3]	**Compute** pharmacokinetic models and evaluation of pharmacokinetic parameters by different models
CO4 [L1]	**Recall** bioavailability and bioequivalence protocols & studies
CO5 [L5]	**Evaluate** the applications of pharmacokinetics, pharmacokinetic & Pharmacodynamic drug interactions
CO6 [L4]	**Analyze** Pharmacokinetics and Pharmacodynamics to biotechnological drugs

Course Contents **60 Hours**

Unit-I **12 Hours**

Drug Absorption from The Gastrointestinal Tract: Gastrointestinal tract, Mechanism of drug absorption, Factors affecting, pH–partition theory, Formulation and physicochemical factors: Dissolution rate, Dissolution process, Noyes–Whitney equation and

drug dissolution, Factors affecting the dissolution rate. Gastrointestinal absorption: role of the dosage form: Solution (elixir, syrup and solution) as a dosage form ,Suspension as a dosage form, Capsule as a dosage form, Tablet as a dosage form, Dissolution methods ,Formulation and processing factors, Correlation of in vivo data with in vitro dissolution data.

Transport model: Permeability-Solubility-Charge State and the pH Partition Hypothesis, Properties of the Gastrointestinal Tract (GIT), pH
Microclimate Intracellular pH Environment, Tight-Junction Complex. Solubility: Experimental methods. Permeability: In-vitro, in-situ and In-vivo methods.

Unit-II **12 Hours**

Biopharmaceutic Considerations in Drug Product Design and In Vitro Drug Product Performance: Introduction, Biopharmaceutic Factors Affecting Drug Bioavailability, Rate-Limiting Steps in Drug Absorption, Physicochemical Nature of the Drug Formulation Factors Affecting Drug Product Performance, In Vitro: Dissolution and Drug Release Testing, Compendial Methods of Dissolution, Alternative Methods of Dissolution Testing, Meeting Dissolution Requirements, Problems of Variable Control in Dissolution Testing Performance of Drug Products: In Vitro–In Vivo Correlation, Dissolution Profile Comparisons, Drug Product Stability, Considerations in the Design of a Drug Product

Unit-III **12 Hours**

Pharmacokinetics: Basic considerations, Pharmacokinetic models, Compartment modeling: One compartment model- IV bolus, IV infusion, Extra-vascular; Multi Compartment model: Two compartment - model in brief, Non-Linear Pharmacokinetics: Cause of non-linearity, Michaelis – Menten equation, Estimation Kmax and Vmax. Drug interactions: Introduction,
The effect of protein-binding interactions, The effect of tissue-binding
interactions, Cytochrome P450-based drug interactions, Drug interactions linked to transporters.

Unit-IV **12 Hours**

Drug Product Performance, In Vivo: Bioavailability and Bioequivalence: Drug Product Performance, Purpose of Bioavailability Studies, Relative and Absolute Availability, , Methods for Assessing Bioavailability, Bioequivalence Studies, Design and Evaluation of Bioequivalence Studies, Study Designs, Crossover Study Designs, Evaluation of the Data, Bioequivalence Example, Study Submission and Drug Review Process, The Biopharmaceutics Classification System, Generic Biologics (Biosimilar Drug Products),Clinical Significance of Bioequivalence Studies, Special Concerns in Bioavailability and Bioequivalence Studies, Generic Substitution**.**

Unit-V **12 Hours**

Application of Pharmacokinetics: Modified-Release Drug Products, Targeted Drug Delivery Systems and Biotechnological Products. Relationship between Pharmacokinetics including Pharmacodynamics: Generation of a pharmacokinetic– pharmacodynamic (PKPD) equation, Pharmacokinetic and pharmacodynamic, 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.J aiswal., Vallab Prakashan, Pitampura, Delhi
3. Applied Biopharmaceutics and Pharmacokinetics by Shargel. Land YuABC, 2nd edition, Connecticut Appleton Century Crofts, 1985
4. Textbook of Biopharmaceutics and Pharmacokinetics, Dr. Shobha Rani R. Hiremath,Prism Book
5. Pharmacokinetics by Milo Gibaldi and D. Perrier, 2nd edition, Marcel Dekker Inc.,New York, 1982
6. Current Concepts in Pharmaceutical Sciences: Biopharmaceutics, Swarbrick. J, Lea and Febiger, Philadelphia, 1970
7. Clinical Pharmacokinetics, Concepts and Applications 3rd edition by Malcolm Rowland and Thom~ N. Tozer, Lea and Febiger, Philadelphia, 1995
8. Dissolution, Bioavailability and Bioequivalence, Abdou. H.M, Mack Publishing Company, Pennsylvania 1989
9. Biopharmaceutics and Clinical Pharmacokinetics, An Introduction, 4th edition, revised and 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 Jambhekar and Philip J Breen,pharmaceutical press, RPS Publishing,2009.
13. Absorption and Drug Development- Solubility, Permeability, and Charge State, Alex Avdeef, John Wiley & Sons, Inc,2003

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COMPUTER AIDED DRUG DELIVERY SYSTEM

Course Code: MPH203T

Course Objective: Upon completion of the course the student shall be able to
COB 1: The course aims to provide offering theoretical insights and practical skills in CADDS.
COB 2: Students will learn computational techniques, software tools, and regulatory aspects, empowering them to innovate in drug delivery research and development.
COB 3: Students will learn applications of computers in clinical data management

Course Outcomes :

CO1(L1)	**Recall** the basics of computers in pharmaceutical research and development, population modelling, and sensitivity analysis
CO2(L2)	**Illustrate** the quality by design principles, computational modelling of drug disposition, application of drug transporters
CO3(L3)	**Determine** the concepts for computer-aided formulation development, ethics of computing in pharmaceutical research
CO4(L5)	**Justify** the pharmacokinetic and pharmacodynamic characteristics of drugs by simulations
CO5(L5)	**Assess** the applications of computers in clinical data management
CO6(L2)	**Discuss** the impact of artificial intelligence, robotics, and computational fluid dynamics

Course contents **60 hours**

UNIT-1

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

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

12 Hours

UNIT II

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.

12 Hours

UNIT III

Computer-aided formulation development: Concept of optimization, Optimization parameters, Factorial design, Optimization technology & Screening design. Computers in Pharmaceutical Formulation: Development of pharmaceutical emulsions, microemulsion drug

carriers Legal Protection of Innovative Uses of Computers in R&D, The Ethics of Computing in Pharmaceutical Research, Computers in Market analysis.

UNIT IV **12 Hours**

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

12 Hours

UNIT V

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

REFERENCES

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

Textbooks:

1. Computer Aided Drug Design by Anees Ahmed, Siddiqui, Harish Kumar, Subhi Khisl.

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FORMULATION DEVELOPMENT OF PHARMACEUTICAL AND COSMETIC PRODUCTS

Subject Code: MPH204T
Course Objectives: Upon completion of the course the student shall be able to
COB1: The scheduled activities in a pharmaceutical firm.

COB2: The pre formulation studies of pilot batches of pharmaceutical industry.

COB3: The significance of dissolution and product stability

Course Outcomes:

COURSE OUTCOME	STATEMENT
CO1 [L1]	**Describe** various drug-excipient compatibility studies. crystal morphology and variations, powder flow, structure modification, drug-excipient compatibility studies, methods of determination.
CO2 [L2]	**Summarize** the concept of role of formulation additives in the Design of experiments like factorial design for product and process development.
CO3 [L4]	**Classify** on solubility techniques, Theories and mechanisms of dissolution, in-vitro dissolution testing models – sink and non-sink, Data handling and correction factor. Bio relevant media, in-vitro and in-vivo correlations, levels of correlations.
CO4 [L2]	**Explain** the salient features protocols, reports and ICH guidelines of drugs stability.
CO5 [L6]	**Formulate** the following cosmetic products like Dentifrices, Baby care products, Manicure preparations, Shampoos, Creams.
CO6 [L5]	**Assessment** and packaging of the following cosmetic products like Dentifrices, Baby care products, Manicure preparations, Shampoos, Creams.

Course content **60Hours**

UNIT I **12Hours**

Preformulation Studies: Molecular optimization of APIs (drug substances), crystal morphology and variations, powder flow, structure modification, drug-excipient compatibility studies, methods of determination.

UNIT II **12 Hours**

Formulation Additives: Study of different formulation additives, factors influencing their incorporation, role of formulation development and processing, new developments in excipient science. Design of experiments – factorial design for product and process development.

UNIT III **12 Hours**

Solubility & Dissolution: Importance, experimental determination, phase- solubility analysis, pH-solubility profile, solubility techniques to improve solubility and utilization of analytical methods – cosolvency, salt formation, complexation, solid dispersion, micellar solubilization and hydrotropy. Theories and mechanisms of dissolution, in-vitro dissolution testing models – sink and non-sink. Factor influencing dissolution and intrinsic dissolution studies. Dissolution test apparatus – designs, dissolution testing for conventional and controlled release products. Data handling and correction factor. Bio-relevent media, in-vitro and in- vivo correlations, levels of correlations.

UNIT IV **12 Hours**

Product Stability: Degradation kinetics, mechanisms, stability testing of drugs and pharmaceuticals, factors influencing-media effects and pH effects, accelerated stability studies, interpretation of kinetic data (API & tablets). Solid state stability and shelf life assignment. Stability protocols, reports and ICH guidelines.

UNIT V **12 Hours**

Cosmetics: Formulation, Evaluation and packaging of the following cosmetic products: Dentrifices like tooth powders, pastes and gels. Manicure preparations like nail polish, lipsticks, eye lashes, Baby care products, Moisturizing cream, vanishing cream, cold cream, shampoo, Soaps and syndetbars.

REFERENCES

1. Lachman L, Lieberman HA, Kanig JL. The Theory and Practice of Industrial Pharmacy, 3 rd ed., Varghese Publishers, Mumbai1991.
2. Sinko PJ. Martin's physical pharmacy and pharmaceutical sciences, 5 ed., B.I. Publications Pvt. Ltd, Noida, 2006.
3. Lieberman HA, Lachman L, Schwartz JB. Pharmaceutical dosage forms: tablets Vol. IIII, 2nd ed., CBS Publishers & distributors, New Delhi, 2005.
4. Conners KA. A Text book of pharmaceutical analysis Wells JI. Pharmaceutical preformulation: The physicochemical properties of drug substances. Ellis Horwood Ltd., England, 1998.
5. Yalkowsky SH. Techniques of solubilization of drugs. Vol-12. Marcel Dekker Inc., New York, 1981 6. Dressman J, Kramer J. Pharmaceutical dissolution testing. Saurah printer pvt. Ltd., New Delhi, 2005.

7. Sethi PD. Quantitative analysis of drugs in pharmaceutical formulations, 3 rded., CBS publications, New Delhi,2008.
8. Carstensen JT, Rhodes CT. Drug stability principles and practices, 3 rded., CBS Publishers & distributors, New Delhi,2005.
9. Yoshioka S, Stella VJ. Stability of drugs and dosage forms, Springer (India) Pvt. Ltd., New Delhi, 2006.
10. Banker GS, Rhodes CT. Modern Pharmaceutics, 4th ed., Marcel Dekker Inc, New York, 2005.
11. W. Grimm - Stability testing of drugproducts.
12. Mazzo DJ. International stability testing. Eastern Press Pvt. Ltd., Bangalore, 1999.
13. Beckett AH, Stenlake JB. Practical pharmaceutical chemistry, Part I &II.,4 thed., CBS Publishers & distributors, New Delhi,2004.
14. Indian Pharmacopoeia. Controller of Publication. Delhi, 1996.
15. British Pharmacopoeia. British Pharmacopoeia Commission Office, London, 2008.
16. United States Pharmacopoeia. United States Pharmacopeial Convention, Inc, USA, 2003.
17. Encyclopaedia of Pharm. Technology, Vol I –III.
18. Wells J. I. Pharmaceutical Preformulation: The physicochemical properties of drug substances, Ellis Horwood Ltd. England, 1988.
19. Harry's Cosmeticology. 8 th edition.
20. Poucher's perfume cosmetics and Soaps, 10th edition.
21. Cosmetics - Formulation, Manufacture and quality control, PP.Sharma,4th edition
22. Handbook of cosmetic science and Technology A.O.Barel, M.Paye and H.I. Maibach. 3 rd edition

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PRACTICAL PHARMACEUTICS-III

Subject Code: MPH205PA

Course Objectives: Upon completion of the course the student shall be able to

COB1: To understand the various factors influencing the design of NTDS.

COB2: To learn the formulation and evaluation of various NTDS.

COB3: To learn the IVIVC studies using software and to calculate various pharmacokinetic parameters.

Course Outcomes:

COURSE OUTCOME	STATEMENT
CO1 [L5]	**Assess** the factors influencing preparation of microparticles.
CO2 [L6]	**Formulate** the microparticles and beads.
CO3 [L6]	**Formulate** the niosomes, liposomes & spherules.
CO4 [L2]	**Understand** the preparation of Solid dispersion technique.
CO5 [L4]	**Analyse** the Protein binding studies.
CO6 [L3]	**Determine** *In-vitro*, *in-vivo* parameters and *IVIVC* parameters.

List of experiments

Expt. No	Title	CO
12.	To study the effect of temperature change, non-solvent addition, incompatible polymeraddition in microcapsules preparation.	**CO1**
13.	Preparation and evaluation of Alginate beads.	**CO2**
14.	Formulation and evaluation of gelatin /albumin microspheres.	**CO3**
15.	Formulation and evaluation of liposomes/niosomes.	**CO3**
16.	Formulation and evaluation of spherules.	**CO3**
17.	Improvement of dissolution characteristics of slightly soluble drug by Solid dispersiontechnique.	**CO4**
18.	Comparison of dissolution of two different marketed products /brands	**CO1**
19.	Protein binding studies of a highly protein bound drug & poorly protein bound drug	**CO5**
20.	Bioavailability studies of Paracetamol inanimals.	**CO6**
21.	Pharmacokinetic and IVIVC data analysis by Winnoline^{R} software	**CO6**
22.	In vitro cell studies for permeability and metabolism	**CO6**

References

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

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PRACTICAL PHARMACEUTICS - IV

Subject Code: MPH205PB

Course Objectives: Upon completion of the course the student shall be able to
COB1: To learn the formulation designing techniques by using different computer software tooling.
COB2: To know how to calculate various pharmacokinetic & pharmacodynamic parameters using the computer software tooling
COB3: To learn how to design and evaluate the cosmetics.

COURSE OUTCOME:

Course Outcome	Statement
CO1 [L6]	**Designing** of formulations using computer software tooling.
CO2 [L3]	**Calculation** of pharmacokinetic and pharmacodynamic parameters using computer software tooling.
CO3[l5]	**Assessment** of QbD in Pharmaceutical Development
CO4 [L6]	**Development** of models for calculation of pharmacokinetic and pharmacodynamic parameters.
CO5 [L3]	**Application** of Optimization techniques in formulation development of tablets
CO6 [L6]	**Formulation** and evaluation of Cosmetics & multivitamin preparations

List of experiments

S. No	Title of the experiment	CO
1.	DoE Using Design Expert® Software	CO1
2.	Formulation data analysis Using Design Expert® Software	CO1
3.	Quality-by-Design in Pharmaceutical Development	CO3
4.	Computer Simulations in Pharmacokinetics and Pharmacodynamics	CO2
5.	Computational Modeling of Drug Disposition	CO2
6.	To develop Clinical Data Collection manual	CO4
7.	To carry out Sensitivity Analysis, and Population Modeling.	CO4
8.	Development and evaluation of Creams	CO6
9.	Development and evaluation of Shampoo and Toothpaste base	CO6
10.	Formulation Development of Multi Vitamnin Syrup	CO6
11.	Use of Optimization techniques in Formulation Development of Table	CO5

References

1. Lachman L, Lieberman HA, Kanig JL. The Theory and Practice of Industrial Pharmacy, 3 rd ed., Varghese Publishers, Mumbai1991.
2. Sinko PJ. Martin's physical pharmacy and pharmaceutical sciences, 5 ed., B.I. Publications Pvt. Ltd, Noida, 2006.
3. Lieberman HA, Lachman L, Schwartz JB. Pharmaceutical do
4. sage forms: tablets Vol. I-III, 2nd ed., CBS Publishers & distributors, New Delhi, 2005.
5. Conners KA. A Text book of pharmaceutical analysis Wells JI. Pharmaceutical preformulation: The physicochemical properties of drug substances. Ellis Horwood Ltd., England, 1998.

PHARMACEUTICAL ANALYSIS (MPA)

SEMESTER - I

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MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES

Subject code: MPA101T

Course Objectives: Upon completion of the subject student shall be

COB1: Understand the spectroscopic concept upon pharmaceuticals, NMR with new compounds,

COB2: Apply NMR with new compounds

COB3: Integrate the mass data for molecules

COB4: Enumerate chromatography methods

COB5: Differentiate Electrophoresis and X-Ray crystallography

COB6: Asses the Unknown concentration sample by potentiometry and weight variation by Thermal methods

Course Outcomes:

Course Outcome	STATEMENT
CO1 [L2]	**Understand:** The basic concepts of Spectroscopic method
CO2 [L3]	**Apply: C**omputation of NMR Spectroscopy
CO3 [L6]	**Generate:** Mass spectroscopy of compounds by using instrumentation and ionisation techniques
CO4 [L1]	**Remember:** Quantification methods of Chromatography
CO5 [L4]	**Classify:** analytical method of electrophoresis and x-ray crystallography
CO6 [L5]	**Evaluate:** Predict the unknow concentrations of samples using ion selective methods (Potentiometry) and thermal methods for Pharmaceuticals

Course content **60Hours**

UNIT -I **10 Hours**

Basic Methods of Spectroscopy:

a. 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.

b. 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.

c. Spectroflourimetry: Theory of Fluorescence, Factors affecting fluorescence (Characteristics

of drugs that can be analyzed by flourimetry), Quenchers, Instrumentation and Applications of fluorescence spectrophotometer.
d. Flame emission spectroscopy and atomic absorption spectroscopy: Principle, Instrumentation, Interferences and Applications.

UNIT-II **10Hours**

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 **10Hours**

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, Metastable ions, Isotopic peaks and Applications of Mass spectroscopy.

UNIT-IV **10Hours**

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 **10Hours**

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) Isoelectric focusing
b. 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 **10Hours**

a. Potentiometry

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

b. Thermal Techniques: Principle, thermal transitions and Instrumentation (Heat flux and power-compensation and designs), Modulated DSC, Hyper DSC, experimental parameters

(sample preparation, experimental conditions, calibration, heating and cooling rates, resolution, source of errors) and their influence, advantage and disadvantages, pharmaceutical applications.

Differential Thermal Analysis (DTA): Principle, instrumentation and advantage and disadvantages, pharmaceutical applications, derivative differential thermal analysis (DDTA). TGA: Principle, instrumentation, factors affecting results, advantage and disadvantages, pharmaceutical applications.

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. PracticalPharmaceutical 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- PD Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis- Modern Methods– Part B- JW Munson, Vol 11, Marcel. Dekker Series
8. Spectroscopy of Organic Compounds, 2nd edn., P.S /Kalsi, Wileyestern Ltd., Delhi.
9. Textbook of Pharmaceutical Analysis, KA. Connors, 3rdEdition, John Wiley & Sons, 1982.

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ADVANCED PHARMACEUTICAL ANALYSIS

subject Code: MPA102T

Course Objectives: Upon completion of the subject student shall be
COB1: Understand the impurity profile and stability study
COB2: Need perception upon the Elemental impurities
COB3: Shall able to understand biological products potency and evaluation tests

Course Outcomes :

CO1[L2]	**Understand** the impurity profile and Stability studies in pharmaceuticals
CO2[L1]	**Enumerate** Elemental impurities and stability testing protocol
CO3[L3]	**Apply** knowledge on Impurity profiling and degradant characterization and Impurity profiling and degradant characterization with special emphasis.
CO4[L4]	**Analyse** the Stability testing of phytopharmaceuticals
CO5[L5]	**Evaluate** Biological tests and assays
CO6[L6]	**Construct** the Immunoassays

Course content **60Hours**

UNIT-I

BRIEF UNDERSTANDING OF IMPURITY AND STABILITY STUDIES **10Hours**

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 of batches, 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, and reporting levels of residual solvents.

UNIT-II **10Hours**

ELEMENTAL IMPURITIES AND STABILITY TESTING PROTOCOL

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

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 stability related 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.

UNIT-III **10 Hours**

IMPURITY PROFILING AND DEGRADANT CHARACTERIZATION

Method development, Stability studies and concepts of validation, accelerated stability testing & shelf-life calculation, WHO and ICH stability testing guidelines, Stability zones, steps in development, practical considerations. Basics of impurity profiling and degradent characterization with special emphasis. Photostability testing guidelines, ICH stability

guidelines for biological products.

UNIT –IV **10Hours**

STABILITY TESTING OF PHYTOPHARMACEUTICALS

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

UNIT –V **10Hours**

Biological tests and assays
a. Adsorbed Tetanus vaccine
b. Adsorbed Diphtheria vaccine
c. Human anti haemophilic vaccine
d. Rabies vaccine
e. Tetanus Anti toxin
f. Tetanus Anti serum
g. Oxytocin h. Heparin sodium IP
i. Antivenom. PCR, PCR studies for gene regulation, instrumentation (Principle and Procedures)

UNIT-VI

RADIO IMMUNE ASSAYS (RIA) **10Hours**

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

References

1. Vogel ‘s textbook of quantitative chemical analysis- Jeffery J Bassett, J. Mendham, R. C. Denney, 5th edition, ELBS, 1991.
2. Analytical Profiles of drug substances – Klaus Florey, Volume 1 – 20, Elsevier, 2005
3. Analytical Profiles of drug substances and Excipients– Harry G Brittan, Volume 21 – 30, Elsevier, 2005
4. ICH Guidelines for impurity profiles and stability studies

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PHARMACEUTICAL VALIDATION

Subject Code: MPA103T

COURSE OBJECTIVES: Upon completion of the subject student shall be

COB1: Explain the aspect of validation

COB2: Carryout validation of manufacturing processes

COB3: Apply the knowledge of validation to instruments and equipments

COB4: Validate the manufacturing

Course Outcomes:

Course Outcome	Statement
CO1[L1]	**Describe** about Qualification and Validation, Factory Acceptance Test (FAT)/ Site Acceptance Test (SAT), Types of Qualifications, Re- Qualification.
CO2[L2]	**Demonstrate** Qualification of Manufacturing Equipments, Analytical Instruments and Laboratory equipments.
CO3[L2]	**Summarize** the concept of Qualification of Analytical Instruments, Qualification of Glassware.
CO4[L4]	**Classify** about Validation of utility systems.
CO5[L2]	**Explain** the importance of Analytical Method Validation - General principles, Validation of analytical method as per ICH guidelines and USP. Computerized system validation.
CO6[L2]	**Discuss** about General Principles, Types and Concepts of Intellectual Property Rights.
CO7[L3]	**Contrast** PCT, IPR, Societal Responsibility, Avoiding Unethical Practices.

Course contents **60 Hours**

UNIT-I **12 Hours**

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.

UNIT-II **12 Hours**

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.

UNIT-III **12 Hours**

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 in place (CIP).

UNIT- IV **12 Hours**

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 GAMP 5.

UNIT-V **12 Hours**

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 application; patent application forms and guidelines. Types of 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.

REFERENCES:

1] Validation Master plan by Terveeks or Deeks, Davis Harwood International publishing.

2] The Theory & Practice of Industrial Pharmacy, 3rd edition, Leon Lachman, Herbert A. Lieberman, Joseph. L. Karig, Varghese Publishing House, Bombay.

3] Pharmaceutical Equipment Validation: The Ultimate Qualification Handbook, Phillip A. Cloud, Interpharm Press.

4] B. T. Loftus & R. A. Nash, "Pharmaceutical Process Validation", Drugs and Pharm Sci. Series, Vol. 129, 3rd Ed., Marcel Dekker Inc.,

5] Analytical Method validation and Instrument Performance Verification by Churg Chan, Heiman Lam, Y.C. Lee, Yue. Zhang, Wiley Inter Science.

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FOOD ANALYSIS

Subject code: MPA104T

Course Objectives: Upon completion of the subject student shall be

COB1: To understand analytical techniques in the determination

Food constituents , Food additives, Finished food.

COB2: To understand analytical techniques in the determination Finished food

COB3: To understand analytical techniques in the determination

Pesticides in food & student shall have the knowledge on food regulations and legislations

Course Outcomes:

Course Outcome	STATEMENT
CO1 [L2]	**Explain** about Carbohydrates**,** Dietary fibre, Crude fibre & Chemistry, Classification of amino acids, absorption and metabolism of proteins.
CO2 [L1]	**Enumerate** about Lipids, refining of fats and oils, hydrogenation of vegetable oils.
CO3 [L3]	**Calculate** Adulteration and its types, Vitamins, Methods of analysis of Vitamins, Microbial assay of vitamins of B-series.
CO4 [L5]	**Evaluate** about Food additives, Pigments and synthetic dyes.
CO5 [L4]	**Characterize** the general Analytical methods for milk, milk constituents and milk products and their adulteration & fermentation products.
CO6 [L6]	**Design** Pesticide analysis & effects of pest and insects on various food, Pesticides in agriculture, Pesticide cycle, & Pesticide residues in grain, fruits, vegetables, milk and milk products, BIS, Agmark, FDA and US-FDA.

Course contents

60 HOURS

UNIT-I **12 Hours**

CARBOHYDRATES: Classification and properties of food carbohydrates, General methods of analysis of food carbohydrates, Changes in food carbohydrates during processing, Digestion, absorption and metabolism of carbohydrates, Dietary fibre, Crude fibre and applications of food carbohydrates.

Proteins: Chemistry and classification of amino acids and proteins, Physico - Chemical properties of protein and their structure, general methods of analysis of proteins and amino acids, Digestion, absorption and metabolism of proteins.

UNIT-II **12 Hours**

LIPIDS: Classification, general methods of analysis, refining of fats and oils; hydrogenation of vegetable oils, Determination of adulteration in fats and oils, Various methods used for measurement of spoilage of fats and fatty foods.

Vitamins: classification of vitamins, methods of analysis of vitamins, Principles of microbial assay of vitamins of B-series.

UNIT-III **12 Hours**

FOOD ADDITIVES: Introduction, analysis of Preservatives, antioxidants, artificial sweeteners, flavors, flavor enhancers, stabilizers, thickening and jelling agents.
Pigments and synthetic dyes: Natural pigments, their occurrence and characteristic properties, permitted dyes, non-permitted synthetic dyes used by industries, Method of detection of natural, permitted and non-permitted dyes.

UNIT- IV **12 Hours**

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.

UNIT-V **12 Hours**

PESTICIDE ANALYSIS: Effects of pest and insects on various food, use of pesticides in agriculture, pesticide cycle, organophosphorus and organochlorine 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, FDA and US-FDA.

REFERENCES:

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 & Bartlett publishers, Boston London, 1994.

3] Official methods of analysis of AOAC International, sixth edition, Volume I & II, 1997.

4] Analysis of Food constituents – Multon, Wiley VCH.

5] Dr. William Horwitz, Official methods of analysis of AOAC International, 18th edition, 2005.

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PRACTICAL PHARMACEUTICAL ANALYSIS – I

Subject Code: MPA105PA

Course Objectives:
COB1: Understand about calibration of instruments
COB2: Practical approach for Assay of official compounds
COB3: Estimation of Vitamins, quinine sulphates
COB4: Quantitative determination of Hydroxyl and amino groups in pharmaceuticals
COB5: Application of colorimetric determination of drugs by different reagents

COURSE OUTCOMES :

CO	STATEMENT
CO1[L2]	**Understand** the calibration procedures with acceptance criteria
CO2[L3]	**Determine** the cleaning validation
CO3[L4]	**Apply** the assay methodology for official compounds by different titrations and instrumental methods
CO4[L3]	**Select** the estimation methods for the Vitamins and Ion concentrations.
CO5[L5]	**Judge** the Quantification methods for hydroxyl and amino groups
CO6[L6]	**Design and construct** colorimetric methods for drugs by using different reagents

List of Experiments

Expt. No	Title	CO
1.	Calibration of volumetric apparatus, pH meter, UV and Visible Spectrophotometer, FTIR Spectrophotometer, HPLC and gas chromatography	**CO1**
2.	Assay of Metronidazole	**CO3**
3.	Assay of magnesium sulphate	**CO3**
4.	Assay of ascorbic acid using single- and Double-point standardisation method	**CO3**
5.	Assay of paracetamol using $A^{1\%}_{1CM}$ **OR** Specific Absorbance	**CO3**
6.	Simultaneous estimation of caffeine and sodium benzoate by absorption ratio method	**CO3**
7.	Assay of sulpha acetamide sodium in eye drops using brotton Marshal Reagent	**CO4**
8.	Assay of paracetamol by chemical derivatization method	**CO3**
9.	Assay of furosemide	**CO3**

10.	Assay of Nimesulide using PDAB reagent	**CO6**
11.	Assay of ciprofloxacin using ferric nitrate reagent	**CO6**
12.	Assay of salbutamol using Folin –Ciocalteu reagent	**CO6**
13.	Assay of paracetamol by oxidation method	**CO5**
14.	Assay of salbutamol using Gibbs reagent	**CO5**
15.	Estimation of sodium and potassium ion concentration in the given sample using flame photometry	**CO4**
16.	Assay of Quinine sulphate using Fluorimeter	**CO3**

Reference

1. A.H.Beckett & J.B .Stenlake's , Practical Pharmaceutical Chem Vol I & II ,Stahlone press of university of London.
2. A.I.Vogel , Text book of Quantitative inorganic analysis
3. Bentley and Driver's Text book of Pharmaceutical Chemistry
4. Indian Pharmacopoeia

L	T	P	C
0	0	6	3

PRACTICAL PHARMACEUTICAL ANALYSIS – II

Subject Code : MPA105PB

Course Objectives:

COB1: To learn objective of this course practically for pharmacopoeia compounds
COB2: To handling of HPLC and GC instruments and learn their objectives and applications
COB3: Determination of biological compounds in pharmaceuticals
COB4: Determination of food additive content
COB5: Evaluate the density and specific gravity of foods

COURSE OUTCOMES :

CO	STATEMENT
CO1[L1]	**Remember:** Analyze pharmacopoeial compounds and their formulations using UV-Vis spectrophotometry to determine their concentration and quality
CO2[L5]	**Understand:** Perform simultaneous estimation of multi-component formulations using UV spectrophotometry, applying appropriate techniques for accurate measurement of each component in complex mixtures.
CO3[L3]	**Apply:** Conduct experiments using HPLC to separate, identify, and quantify components in pharmaceutical and food samples, demonstrating competence in method development and optimization.
CO4[L4]	**Analyze;** Perform experiments using Gas Chromatography to analyze volatile compounds in food, including pesticides, food additives, and flavoring agents, ensuring product safety and compliance with standards.
CO5[L5]	**Evaluate:** Evaluate the quality of food products by determining saponification value, iodine value, peroxide value, and acid value to assess the stability and composition of fats and oils in food.
CO6[L5]	**Create:** Employ analytical techniques to determine the presence of food additives, preservatives, and pesticide residues in food products, ensuring safety and compliance with regulatory standards.

List of Experiments

S.No	Title of the experiment	CO
1.	Assay of ascorbic acid using single point standardisation method	**CO1**
2.	Assay of paracetamol using $A^{1\%}{}_{1CM\ OR}$ Specific Absorbance	**CO1**
3.	Assay of furosemide	**CO1**
4.	Simultaneous estimation of caffeine and sodium benzoate by absorption ratio method	**CO1**
5.	Assay of aceclofenac by HPLC	**CO3**
6.	Assay of oestradiol by GC – FID	**CO4**
7.	Estimation of reducing and non-reducing sugars in fresh fruits	**CO2**
8.	Determination of protein by spectrophotometric method	**CO2**
9.	Determination of saponification value from oil	**CO4**
10.	Determination of iodine value, Acid value, Peroxide value from oil	**CO4**
11.	Estimation of rancidity from edible oil	**CO4**
12.	Estimation of fat content	**CO4**
13.	TLC Method for isolation and confirmation of oil soluble colours	**CO3**

14.	Determination of preservatives in foods	**CO6**
15.	Determination of pesticide residue in foods	**CO6**
16.	Vitamin C (ascorbic acid) content in food by UV –Spectroscopy and Titrimetric methods	**CO1**
17.	Determination of density, relative density and specific gravity of foods	**CO5**

Reference

1. A.H.Beckett & J.B .Stenlake's , Practical Pharmaceutical Chem Vol I & II ,Stahlone press of university of London.
2. A.I.Vogel , Text book of Quantitative inorganic analysis
3. Bentley and Driver's Text book of Pharmaceutical Chemistry
4. Indian Pharmacopoeia
5. Here is the corrected table with the six course outcomes based on your provided data:

Semester: II

L	T	P	C
4	0	0	4

ADVANCED INSTRUMENTAL ANALYSIS

Subject code: MPA201T

Course Objectives: Upon completion of the course the student shall be able to

COB1: Interpretation of the NMR, Mass and IR spectra of various organic compounds

COB2: Theoretical and practical skills of the hyphenated instruments

COB3: Identification of organic compounds

COURSE OUTCOMES :

Course outcome	Statement
CO1 [L2]	**Explain-** basics of chromatography and principle, instrumentation, Pharmaceutical applications for HPLC,and HILIC approaches.
CO2 [L1]	**Explain-**size exclusion, ion exchange, affinity, ion pair chromatography for stationary phases and mobile phases, gas chromatography principle, instrumentation, derivatization, head space, columns.
CO3[L3]	**Explain** -High performance Thin Layer chromatography Principles,instrumentation,pharmaceutical applications
CO4 [L2]	**Explain-** principle, instrumentation, Pharmaceutical applications for Supercritical fluid chromatography, capillary electrophoresis, method development.
CO5 [L2]	**Explain**-principle, instrumentation, Pharmaceutical applications for Mass spectroscopy, Ionization Techniques and Mass Analysers.
CO6 [L5]	**Compare-**principle, instrumentation, Pharmaceutical applications for NMR Spectroscopy. FT-NMR, C13NMR , 2-DNMR, LC–NMR

Course contents **60 Hours**

UNIT-I **12 Hours**

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, nano liquid 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, and practical aspects of preparative HPLC.

UNIT-II **12 Hours**

Biochromatography: Size exclusion chromatography, ion exchange chromatography, ion air 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.

UNIT-III **12 Hours**

Supercritical 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.

UNIT-IV **12 Hours**

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, metastable ions, isotopic peaks and applications of mass spectrometry. LC- MS hyphenation and DART MS analysis. Mass analyzers (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.

UNIT-V **12 Hours**

NMR spectroscopy: Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR with reference to 13CNMR: Spin spin and spin lattice relaxation phenomenon. 13CNMR, 1- D and 2-D NMR, NOESY and COSY techniques, Interpretation and Applications of NMR spectroscopy. LC-NMR hyphenations.

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, 5 th edition, Eastern press, Bangalore, 1998.

3. Instrumental methods of analysis – Willards, 7 th edition, CBS publishers.

4. Organic Spectroscopy - William Kemp, 3 rd 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, 3 rd Edition, CBS Publishers, New Delhi, 1997.

7. Pharmaceutical Analysis- Modern methods – Part B - J W Munson, Volume 11, Marcel Dekker Series.

8. Organic Spectroscopy by Donald L. Paviya, 5th Edition.

L	T	P	C
4	0	0	4

MODERN BIOANALYTICAL TECHNIQUES

Subject Code: MBAT202T

Course Objectives: Upon completion of the subject student shall be
COB1: Extraction & Bioanalytical method validation guidelines, Pharmacokinetics and toxicokinetic drug interactions

COB2: Biopharmaceutical factors affecting drug bioavailability and biopharmaceutical system, Cell culture, MTT Assay, flow cytometry

COB3: Metabolite identification and drug product performance

Course Outcomes :

Course outcome	Statement
CO1[L1]	**Remember:** Enumerate the drug extraction
CO2[L2]	**Explain:** Guidelines of Bioanalytical Validation
CO3[L2]	**Summarize:** Bioavailability and BCS Classification
CO4[L2]	**Interpretate:** Drug interactions and Toxicokinetic evaluation
CO5[L5]	**Evaluate:** The Cell culture techniques & MTT Assays
CO6[L6]	**Construct:** Development of protocols for Drug product performance

Course Contents **60Hours**

UNIT-I **12Hours**

Extraction of Drug and Metabolites

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.

UNIT-II **12Hours**

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.

UNIT-III **12Hours**

Pharmacokinetics and Toxicokinetic

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.

UNIT -IV **12Hours**

Cell culture techniques

Basic equipment's 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.

UNIT -V **12Hours**

Metabolite identification

In-vitro / in-vivo approaches, protocols and sample preparation. Microsomal approaches (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.

REFERENCES

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, Timothy A. Nieman, 5th edition, Easternpress, Bangalore, 1998.
3. Pharmaceutical Analysis-Higuchi, Brochmman and Hassen, 2nd Edition, Wiley – Interscience Publications, 1961.
4. Pharmaceutical Analysis- Modern methods– Part B- JW Munson, Volume 11, Marcel Dekker Series
5. Practical HPLC method Development – Snyder, Kirkland, Glaich, 2nd Edition, John Wiley & Sons, New Jercy. USA.
6. Chromatographic Analysis of Pharmaceuticals – John A Adamovics, 2nd Edition, Marcel Dekker, New york, USA. 1997.
7. Chromatographic methods in clinical chemistry & Toxicology– Roger LBertholf, Ruth EWinecker, John Wiley & 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.

L T P C

4 0 0 4

QUALITY CONTROL AND QUALITY ASSURANCE

Subject code: MPA203T

Course Objectives: Upon completion of the course the student shall be able to

COB1: Understand the components of cgmp aspects in a pharmaceutical industry

COB2: To appreciate the importance of documentation

COB3: To understand the scope of quality certifications applicable to Pharmaceutical industries, the responsibilities of QA & QC departments.

Course outcomes:

Course outcome	Statement
CO1 [L2]	**Review** the concepts of QAQC, GLP.GMP, ICH guidelines
CO2 [L1]	**Discuss** about cGMP guidelines according to schedule M, USFDA (inclusive of CDER and CBER), PIC, WHO and EMEA along with CPCSEA guidelines.
CO3[L3]	**Determine** the Analysis of raw materials, finished products, packaging materials, IPQC and Finished product quality control as per IP, BP, USP
CO4 [L2]	**Summarize** the Developing specification (ICH Q6 and Q3)
CO5 [L2]	**Review** the documentation in pharmaceutical industry
CO6 [L5]	**Evaluate** Manufacturing operations and controls in pharmaceutical industry

Course contents **60 Hours**

UNIT-I **12 Hours**

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.

UNIT-II **12 Hours**

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.

UNIT-III **12Hours**

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, parenteral, ophthalmic and surgical products (How to refer pharmacopoeias), Quality control test for containers, closures and secondary packing materials.

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UNIT-IV **12Hours**

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.

UNIT-V **12Hours**

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, and packaging.

References :

1. Quality Assurance Guide by organization of Pharmaceutical Procedures of India, 3rd revised edition, Volume I & II, Mumbai, 1996.
2. Good Laboratory Practice Regulations, 2nd Edition, Sandy Weinberg Vol. 69, Marcel Dekker Series, 1995.
3. Quality Assurance of Pharmaceuticals- A compedium of Guide lines and Related materials Vol I & II, 2nd edition, WHO Publications, 1999.
4. How to Practice GMP's – P P Sharma, Vandana Publications, Agra, 1991.
5. The International Pharmacopoeia – vol I, II, III, IV & V - General Methods of Analysis and Quality specification for Pharmaceutical Substances, Excepients and Dosage forms, 3rd edition, WHO, Geneva, 2005.
6. Good laboratory Practice Regulations – Allen F. Hirsch, Volume 38, Marcel Dekker Series, 1989.
7. ICH guidelines
8. ISO 9000 and total quality management
9. The drugs and cosmetics act 1940 – Deshpande, Nilesh Gandhi, 4th edition, Susmit Publishers, 2006.
10. QA Manual – D.H. Shah, 1st edition, Business Horizons, 2000.
11. Good Manufacturing Practices for Pharmaceuticals a plan for total quality control – Sidney H. Willig, Vol. 52, 3rd edition, Marcel Dekker Series.
12. Steinborn L. GMP/ISO Quality Audit Manual for Healthcare Manufacturers and Their

Suppliers, Sixth Edition, (Volume 1 - With Checklists and Software Package). Taylor & Francis; 2003.
13. Sarker DK. Quality Systems and Controls for Pharmaceuticals. John Wiley & Sons; 2008.

L	T	P	C
4	0	0	4

HERBAL AND COSMETIC ANALYSIS

Subject Code: MPA204T

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

COB1: Principles of performance evaluation of cosmetic products.

COB2: Determination of Herbal drug-drug interaction

COB3: Analysis of natural products and monographs

COB4: Determination of herbal remedies and regulations

COURSE OUTCOMES :

COURSE OUTCOME	STATEMENT
CO1[L1]	**Describe** about Herbal remedies &Toxicity and Regulations WHO and AYUSH guidelines.
CO2[L2]	**Demonstrate** about Adulteration and Deterioration, causes and measures techniques in identification of drugs microbial contamination.
CO3[L6]	**Generate** Regulatory requirements Global marketing management, patent law and its protocol.
CO4[L6]	**Create** Set up for testing of natural products and drugs & monographs
CO5[L2]	**Explain**. Herbal drug-drug interaction, WHO and AYUSH guidelines for safety monitoring.
CO6[L2]	**Discuss** . general methods of analysis of raw material used in cosmetic manufacture as per BIS. Indian Standard specification laid down for sampling and testing of various cosmetics

Course contents **60 Hours**

UNIT-I **12Hours**

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.

UNIT-II **12Hours**

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.

UNIT-III **12Hours**

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**.**

UNIT-IV **12Hours**

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 .

UNIT-V **12Hours**

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 analysis of 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 products and skin creams by the Bureau Indian Standards

REFERENCES

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 by Dr.S.H.Ansari 6. Cosmetics – Formulation, Manufacturing and Quality Control, P.P. Sharma, 4 th edition, Vandana Publications Pvt. Ltd., Delhi

L	T	P	C
0	0	6	3

PRACTICAL PHARMACEUTICAL ANALYSIS – III

Subject code : MPA205P

Course Objectives: Upon completion of the course the student shall be able to

COB1: Wood ward fissure

COB2: FT-IR

COB3: Mass

COB4: Electrophoresis

COB5: HPLC

COB6: Protocol for BA/BE

COURSE OUTCOMES :

CO	STATEMENT
CO1[L2]	**Comparison** of absorption spectra by UV and Wood ward – Fiesure rule.
CO2[L2]	**Interpretation** of organic compounds by FT-IR, NMR, Mass,
CO3[L3]	**Determination** of purity by DSC in pharmaceuticals
CO4[L1]	**Apply** Bio molecules separation utilizing various sample preparation techniques and Quantitative analysis of components by gel electrophoresis.
CO5[L4]	**Evaluate** -Bio molecules separation utilizing various sample preparation techniques and Quantitative analysis of components by HPLC techniques & Isolation of analgesics from biological fluids (Blood serum and urine)
CO6[L2]	**Apply**-Protocol preparation and performance of analytical/Bio analytical method validation and BA/BE studies according to guidelines.

List of Experiments

S.No	Title of the experiment	CO
1.	Comparison of absorption spectra by UV and Wood ward -Fiesure rule	**CO1**
2.	Interpretation of organic compounds by FTIR	**CO2**
3.	Interpretation of organic compounds by ^{1}H NMR	**CO2**
4.	Interpretation of organic compounds by ^{13}C NMR	**CO2**
5.	Interpretation of organic compounds by DEPT Spectra	**CO2**
6.	Interpretation of organic compounds by COSY Spectra	**CO2**
7.	Interpretation of organic compounds by Mass spectra	**CO2**
8.	Distinguish of Pentan -2-one and pentane -3-one compounds by mass spectra	**CO2**
9.	Identification of organic molecules using FT –IR, by ^{1}H NMR, ^{13}C NMR and Mass spectra	**CO2**

10.	Determination of purity by DSC	**CO3**
11.	Isolation of analgesic compounds from biological fluids	**CO5**
12.	Protocol preparation for AMV	**CO6**
13.	Design of Protocol for Bioequivalence studies asper CDSCO	**CO6**

Reference

1. A.H.Beckett & J.B .Stenlake's , Practical Pharmaceutical Chem Vol I & II ,Stahlone press of university of London.
2. A.I.Vogel , Text book of Quantitative inorganic analysis
3. Bentley and Driver's Text book of Pharmaceutical Chemistry
4. Indian Pharmacopoeia

L	T	P	C
0	0	6	3

PRACTICAL PHARMACEUTICAL ANALYSIS – IV

Subject Code: MPA205PB

Course Objectives: Upon completion of the course the student shall be able to understand

COB1: Finished product QC
COB2: Raw material Testing
COB3: Master Formula Record
COB4: Batch Manufacturing Record
COB5: Determination of different products of significant values

COURSE OUTCOMES :

CO	STATEMENT
CO1[L5]	**Evaluation** of in process and finished product
CO2[L5]	**Assessment** of raw materials and drugs
CO3[L2]	**Understand** preparation of BMR and MFR
CO4[L3]	**Apply** the quantitative analysis of rancidity
CO5[L4]	**Characterization** of related substances
CO6[L1]	**Remember** & Determine purity, foam height, fatty mater, acid value for pharmaceuticals

List of Experiments

S.No	Title of Experiment	CO
1	FPQC Test for Pharmaceutical capsules	**CO1**
2.	Finished product quality control tests for paracetamol tablets	**CO1**
3.	Quality control of glass containers asper I.P.	**CO2**
4.	Assay of IBUPROFEN using UV Visible Spectrophotometer	**CO1**
5.	Characterise related substances of caffeine using thin layer chromatography	**CO5**
6.	Instruction for preparation of batch manufacturing report	**CO3**
7.	Instructions for the preparation of master formula record	**CO3**
8.	Estimation of rancidity in hair oil	**CO1**
9.	Estimation of peroxide value in edible oil	**CO1**

10.	Determination of aryl amine content as the active dye in hair dye	**CO3**
11.	Determination of developer in hair dye	**CO3**
12.	Determination of SLS content in shampoo	**CO3**
13.	Determination of foam height in shampoo	**CO3**
14.	Determination of total fatty substance content in hair cream	**CO3**
15.	Determination of total fatty substance content in marketed bath soap	**CO3**
16.	Determination of Acid value	**CO3**
17.	Determination of saponification value	**CO3**
18.	Determination of calcium thioglycolate in depilatories	**CO3**

Reference

1. A.H.Beckett & J.B .Stenlake's , Practical Pharmaceutical Chem Vol I & II ,Stahlone press of university of London.
2. A.I.Vogel , Text book of Quantitative inorganic analysis
3. Bentley and Driver's Text book of Pharmaceutical Chemistry
4. Indian Pharmacopoeia

SEMESTER – III

L	T	P	C
4	0	0	4

Research Methodology & Biostatistics

Subject Code: MRM301

Course Objectives: Upon completion of the subject student shall be

COB1: Understand the perceive problem and hypothesis, test hypothesis, report results

COB2: Importance of statistical investigation -collection data, organisation, presentation, analysis of data.

COB3: Understand the interpretation of data.

Course Outcomes :

COURSE OUTCOME	STATEMENT
CO1 [L1]	**Identify** the General Research Methodology requirements, review of literature. study design
CO2 [L3]	**Summarise:** Sample size, (students "t" test, ANOVA, Correlation coefficient, regression), nonparametric tests (Wilcoxon rank tests, analysis of variance, correlation, chi square test), null hypothesis, P values, degree of freedom, interpretation of P values.
CO3 [L2]	**Apply:** Medical Research: confidentiality, criticisms of orthodox medical ethics, importance of communication, control resolution, guidelines, ethics committees
CO4 [L4]	**Analyse;** conflicts of interest, referral, vendor relationships, treatment of family members, sexual relationships, fatality.
CO5 [L1]	**Evaluate:** CPCSEA guidelines for laboratory animal facility.
CO6 [L3]	**Integrate:** basic principles for all medical research related problem.

Course Contents **60 Hours**

UNIT-I **10 Hours**

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

UNIT-II **20 Hours**

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 (Wilcoxon rank tests, analysis of variance, correlation, chi square test), null hypothesis, P values, degree of freedom, interpretation of P values.

UNIT-III **15 Hours**

Medical Research: History, values in medical ethics, autonomy, beneficence, nonmaleficence, 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 **9 Hours**

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, anaesthesia, physical facilities, environment, animal husbandry, record keeping, SOPs, personnel and training, transport of lab animals.

UNIT-V **6 Hours**

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

REFERENCES:

1. Ackoff, Russell L., The Design of Social Research, Chicago: University of Chicago Press, 1961.2.
2. Ackoff, Russell L., Scientific Method, New York: John Wiley & Sons, 1962.3.
3. Allen, T. Harrell, New Methods in Social Science Research, New York: Praeger Publishers, 1978.4.
4. Anderson, H.H., and Anderson, G.L., An Introduction to Projective Techniques and Other Devices for Understanding the Dynamics of Human Behaviour, New York: Prentice Hall, 1951.5.
5. Anderson, T.W., An Introduction to Multivariate Analysis, New York: John Wiley & Sons, 1958.6.
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