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
Aditya Nagar, ADB Road, Surampalem – 533 437, Kakinada District., A.P.
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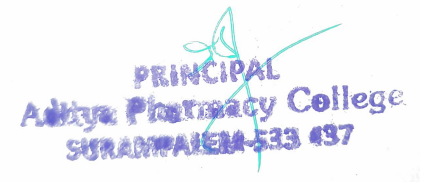

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भारत का राजपत्र
The Gazette of India

असाधारण
EXTRAORDINARY
भाग III—खण्ड 4
PART III—Section 4
प्राधिकार से प्रकाशित
PUBLISHED BY AUTHORITY

सं. 3621] नई दिल्ली, बृहस्पतिवार, दिसम्बर 11, 2014/अग्रहायण 20, 1936
No. 3621] NEW DELHI, THURSDAY, DECEMBER 11, 2014/AGRAHAYANA 20, 1936

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 .

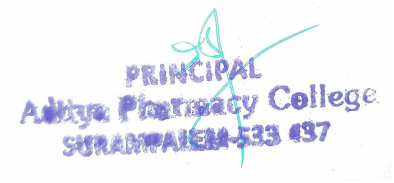

Table – 2: Course of study for M. Pharm. (Pharmaceutics)

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

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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:

$$C_1G_1 + C_2G_2 + C$$

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

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:

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

19. Cumulative Grade Point Average (CGPA)

The CGPA is calculated with the SGPA of all the IV semesters to two decimal points and is indicated in final grade report card/final transcript showing the grades of all IV semesters and their courses. The CGPA shall reflect the failed 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,…. .

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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:

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

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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,…. .

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

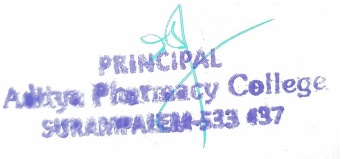
27. Project work

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

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MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES

Subject Code: MPH 101T

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

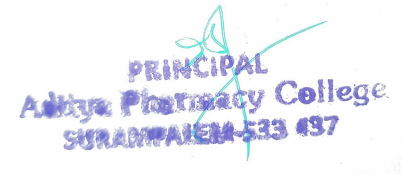
Principle, working, Ion selective Electrodes and Application of potentiometry.

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.



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DRUG DELIVERY SYSTEMS

Subject Code: MPH 102T

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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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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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: MPH 105PA

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.

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Pharmaceutics Practical-II

Subject Code: MPH 105PB

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

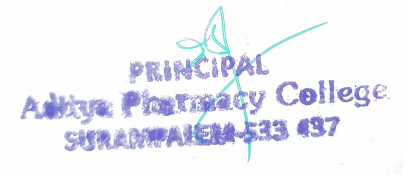
List of experiments

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

Subject Code: MPH 201T

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**

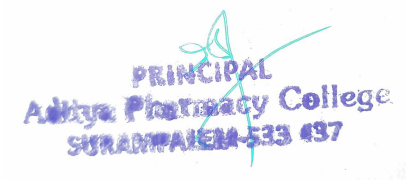
Pulmonary Drug Delivery Systems: Aerosols, propellents, Containers Types preparation and evaluation, Intra Nasal Route Delivery systems; Types, prepara

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 : MPH 202T

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 Pharmacol 4th edition,Philadelphia, Lea and Febiger, 1991
2. Biopharmaceutics and Pharmacokinetics, A. Tre unil

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
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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.
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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

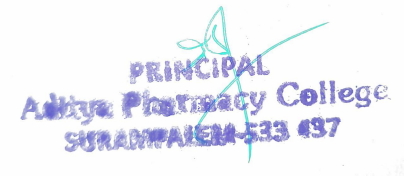
Artificial Intelligence (AI), Robotics and Computational fluid dynamics: General overview, Pharmaceutical Automation, Pharmaceutical applications, Advantages and Disadvantages. Current Challenges and Future Directions.

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.
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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

L	T	P	C
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PHARMACEUTICS-III

Subject Code: MPH 205PA

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**

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L	T	P	C
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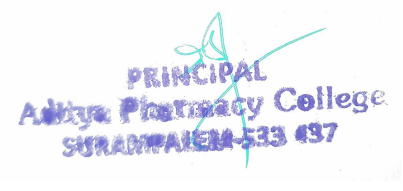
PHARMACEUTICS PRACTICAL- IV

Subject Code: MPH 205PB

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.

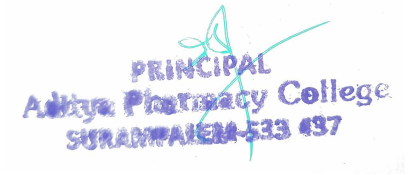
COURSE OUTCOME:

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



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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.