ANDHRA UNIVERSITY

MASTER OF PHARMACY

(2020)

Regulations and Syllabus

Four semester pattern

With effect from 2020-21

M.PHARM (2020) REGULATIONS AND SYLLABUS

INDEX:

1. Admission, instruction and attendance

The degree of Master of Pharmacy of the Andhra University will be conferred on a candidate who has satisfied the following conditions:

1.1. The candidate must have passed the B.Pharm. Degree examination of this University or B.Pharm. Degree examinations of any other University recognized by the Academic Council as equivalent thereto in First or Second class; and must have qualified in any entrance examination, if prescribed.

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

1.3. The candidate should have undergone a regular course of study as prescribed hereunder extending over a period of four semesters, ordinarily consecutive, and satisfied the academic requirements as prescribed hereinafter. The course of instruction and periods of study shall be as given in the scheme of instruction and in the syllabus.

1.4. The subjects of specializations for Master of Pharmacy Course shall be as follows:

1. Pharmaceutical Analysis
2. Pharmaceutical Chemistry
3. Pharmaceutics
4. Pharmaceutical Biotechnology
5. Pharmacology
6. Pharmacognosy
7. Pharmaceutical Regulatory Affairs
8. Pharmaceutical Quality Assurance
9. Industrial Pharmacy
10. Pharmacy Practice

1.5. Instruction and examination in each academic year is spread over two semesters with a minimum of 96 working days in each semester (192 in any given academic year). The odd semesters shall be conducted from the month of July to November and the even semesters shall be conducted from the month of December to April.

1.6. Each period of instruction is of 45 minutes duration. Eight periods of instruction are provided on each day and there are six working days in a week (Monday to Saturday).

1.7. Attendance Requirements: A regular course of study during an academic semester means a minimum of average attendance of 80% of all the courses of the semester computed by totaling the number of periods of lectures and practicals, as the case may be, held in every course. In special cases where sufficient causes were shown, the Vice-

Chancellor may on the recommendation of the Principal concerned condone the deficiency in the average attendance to an extent of 9% for reasons such as ill health, if the application for condonation is submitted at the time of actual illness and is supported by certificate of; authorized Medical officer approved by the Principal. However, in the case of students, who participate in activities like N.S.S., N.C.C., Inter-Collegiate tournaments conducted by Andhra University, Inter-University tournaments conducted by Inter-university Board and any such other activities involving the representation of the College/University with the prior approval of the principal, the candidate may be deemed to have attended the college during the period solely for the purpose of the examination.

1.7. A candidate who cannot satisfy the attendance requirements in clause 1.5 because of late admission under special circumstances reasonable and acceptable to the University on the basis of document, shall fulfill the following conditions; Average attendance: A candidate shall have attended at least a total of 90% of the periods-lectures/practicals as the case may be held from the date of admission and also shall attend at least 50% of the total working days during that academic semester (Late admission means, admissions made after 45 days from date of commencement of the academic semester for the course).

1.8. If any candidate fails to satisfy the regulation under 1.5 or 1.6 she/he shall not be allowed for the University Examinations at the end of the semester, and he/she shall not be allowed for promotion to the next higher class of study. He/she shall be required to repeat the regular course of study of that academic semester along with the next regular batch.

1.9. A regular record of attendance 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.

2. Examinations – Internal assessment and Semester-end

2.1. Assessment for the award of degree shall consists of (a) internal assessment for 30 marks in each of the theory and practical courses separately. (b) Semester-end examination as detailed in the scheme of examination for 70 marks in each of the theory and practical separately.

2.2. Regulations concerning internal assessment: Internal assessment consist of continuous mode (10 marks for theory and 15 marks for practical) and sessional examinations (20 marks for theory and 15 marks for practical)

2.2.1. Scheme for awarding continuous mode marks for theory and practical

Theory-Criteria	**Marks**
Attendance	5
Student-Teacher Interaction	5
Theory sessional examination	20
Total theory internal assessment	**30**
Practical-Criteria	
Attendance	5
Record + Viva-voce	10
Practical sessional examination	15
Total practical internal assessment	**30**

2.2.1.1. Guidelines for the allotment of marks for attendance

Percentage of Attendance	Theory/Practical
95 -100	5
90-94	4
85-89	3
80-84	2
Less than 80	0

2.2.1.2. Guidelines for allotment of marks for Student-Teacher interaction

The teacher shall create some interactive sessions for theory topics and every student shall interact on the given topic relating to its application in pharmacy. The teacher should assess the student capacity for understanding of the concept taught. It shall not be like seminars.

2.2.1.3. Guidelines for allotment of marks Record + Viva-voce

The teacher should conduct viva-voce at the end of each practical and evaluate the record on continuous mode and shall award these marks.

2.2.4. Guidelines for sessional examinations

Two sessional examinations shall be conducted for each theory/practical course. The average marks of the two shall be computed.

The teacher who teaches the subject shall ordinarily to be the internal examiner.

There shall be no provision for the improvement of the sessional marks.

There is no minimum mark prescribed for sessional examination for pass in the end semester examination.

If any student is absent for a single or both sessional examinations, the candidate will be awarded “ZERO” in the respective examination.

The theory average sessional mark shall be finally computed for 20 marks and average practical sessional mark shall be finally computed for 15 marks.

2.3. Regulations concerning M.Pharm I and II semester evaluation pattern:

2.3.1. There shall be one semester end examination in each theory course based on the question paper set by an external paper setter and there shall be single valuation. There shall be one semester end examination in each practical course as per the scheme of examination and valuation shall be done by examiner. The duration of the practical examination is of 6 hours as prescribed.

2.3.2. However the student may apply for revaluation of any subject in theory papers after declaring the results as per University examination guide lines.

2.3.3. Seminar

A seminar at the end of first and second semesters is separately conducted keeping in view of the enrichment of required communication, presentation and explanatory skills. A minimum of four seminars shall be given during the semester before the Program Committee and other students and documented separately for record in a Semester Seminar Register.

2.3.4. Comprehensive viva

At the end of II Semester comprehensive viva will be conducted for all the subjects

covering the theory subjects of I & II semesters by the external examiner and eligible internal examiners (at least two from the college) who taught these subjects. The candidate should obtain minimum of 50% marks for passing the examination.

2.3.4. Journal Club

In case of Journal Club, based on the research proposal, each student shall collect a minimum of 5 research papers (published in a reputed journal with impact factor of Thomson & Reuters of not less than 1.0) and should discuss in a Programme Committee (consisting of Head of the Department, Research Supervisor and other Senior faculty members) and documented separately for record in a Journal Club Register.

2.3.5. A student shall be eligible to carry forward all the courses of I, II semesters. However, he/she shall not be eligible to attend the courses of IV semester until the candidate clears III semester Midterm Project Review.

2.4. Regulations concerning M. Pharm. III and IV Semester evaluation pattern:

2.4.1. Evaluation of the seminar on the objectives and work plan of the proposed project is to be completed within one month from the commencement of the project date with three examiners from the same college consisting of research guide, another teacher in the concerned specialization and third teacher from different specialization. These teachers must fulfill the eligibility criteria laid down in Section 3.

2.4.2. Evaluation of the M.Pharm III Semester Mid-term project review and seminar on selected topic will be done by the research guide and external examiner. The seminar on the selected topic shall not be the one connected with the topic of the thesis work but should be related to concerned specialization.

2.4.3. A candidate shall submit four copies of his/her thesis either printed or typed, embodying the results of research work done by him under direction of an approved research director following the specific guidelines as stipulated under Section 5. All the candidates must submit their thesis within the prescribed date as per the academic calendar.

2.4.4. The thesis submitted by the candidate shall be examined by a Board of Examiners consisting of an External Examiner and the research director and shall have to be approved after holding a viva voce examination to test the knowledge of the candidate in the subject. The thesis will be evaluated independently by the external examiner and research director and in case the difference between examiners is more than 20%, the thesis shall be sent to a second external examiner whose award shall be the final. The viva-voce examination will be jointly conducted both by the external examiner and research director. A candidate can re-submit the thesis in a revised form after further work, if required to do so.

2.4.5. A candidate desires of improving his/her class shall take either or both of the first two semesters as a whole.

2.5. Guidelines for writing the thesis

The thesis should have the following pages in order:

1. Title page highlighting the title, name of the candidate, reg. no., guide name, college name and month and year of submission.
2. The inner title page containing the same details on white background.
3. Certificate from the Head of the institution
4. Certificate from the Research Director
5. Certificate from the ethical committees for approval of study, if any

6. Declaration by the student
7. Acknowledgements
8. Index highlighting chapter titles and sections titles
9. Index for tables, figures and plates, if any
10. Abbreviations and symbols
11. Materials used in the investigation with their procurement details like name of the company, batch number etc.
12. Equipment used in the study with the model number and other details
13. The thesis should contain the following chapters:
    a) Aim and objectives of the investigation
    b) Introduction and literature survey
    c) Description: Methods and Materials, etc.
    d) Experimental work
    e) Results and discussion
    f) Summary and conclusions
    g) References (The references may be included at the end of each chapter or at the end of the thesis according to the convenience)

2.5.1. The thesis should be typed in times new roman in 12 font size with 1.5 line spacing from the beginning of the thesis including titles to the chapters and sections. Bold font may be used wherever necessary. The students are expected to follow scientific grammar for writing *in vivo* etc. which should be in italics.

2.5.2. The citation of references should be done carefully by citing the complete reference i.e. name of all the authors. Usage of et al. is not allowed in the citation of reference. The students are expected to give the primary references rather than secondary or higher levels of references. The presentation of reference must be in Vancouver style.

2.5.3. No code names or numbers are allowed to be written in the thesis for the materials used in the project.

2.5.4. The examiners of thesis evaluation are expected to verify all this and appropriate corrections are to be made before conducting the viva-voce examination.

2.5.5 Project Work/IV Semester Assessment – Division of Marks:

Course 402 -Thesis Evaluation (Max. Marks – 150)

Criteria of Evaluation	**Marks**
Seminar/Presentation of work	20
Objective(s) of the work done	20
Methodology adopted	40
Results and Discussion	40
Conclusions and Outcomes	30
Total	**150**

The division of marks shall be clearly indicated for every candidate in the marks statement being sent to the University.

2.6. End Semester examinations

The End Semester examination for each theory, practical and other courses through

semesters I to IV shall be conducted by the University except for the subject with asterisk symbol (*) in the tables of the each specialization courses (Non University Examinations) for which examinations shall be conducted by the subject experts at college level and the marks/grades shall be submitted to the University. In case of theory examinations, the question paper of the corresponding subject shall be mailed (Official mail id) to the Controller of Examinations and Chairman, BOS with signature of the Head of the Institute in PDF format within twenty four hours after completion of the examination.

3. Eligibility criteria for appointment as examiner for M.Pharm examination

3.1. In order to eligible to be appointed as an internal examiner for the semester end examination in the respective specialization, a teacher shall have M. Pharm. or Ph.D. in the respective specialization with at least three years of M.Pharm teaching experience for the course concerned.

3.2. The eligibility of a teacher for guiding the M.Pharm III and IV semester project is as follows:

3.2.1. The teacher must have M.Pharm/Ph.D. in the respective specialization with an experience of minimum 3 years of Post Graduate teaching in the respective specialization.

3.2.2. The eligibility of such teachers qualified for guiding M.Pharm projects must be ratified by the Board of Studies before commencement of M.Pharm guidance.

3.2.3. The recognized M.Pharm guides are not eligible to guide more than **6** students in one academic year including joint guidance.

4. Regulations for pursuing M.Pharm III and IV Semester project

4.1. Students desirous of pursuing M.Pharm III and IV semester projects outside college are required to get the approval from the college before one month from the commencement of the project work. The research work can be carried out in a GMP compliant industry (as approved by WHO, USFDA etc.) and Central research laboratories like IICT, CDRI, NIH etc. or DSIR and Drug Control Administration recognized laboratories. A certificate to that effect must be incorporated in the M.Pharm thesis indicating the duration of stay. If the duration of stay is less than nine months the remaining period of stay in the college should be certified by the research supervisor and the Principal.

4.2. All the students should present a seminar on the objectives of their work, work plan, etc. within one month from the commencement of the project. The students should attend a mid-term review seminar in the presence of a committee consisting of one external examiner, research director. The suggestions made by the committee are to be taken into consideration for further work and should be presented in the thesis.

5. Declaration of results and classification:

5.1. A candidate shall be declared to have passed the examination held at the end of each semester if obtains i) not less than 40% in the each theory and 50% in each practical, seminar, comprehensive viva, thesis and thesis viva-voce at the end of each semester end examination and ii) an aggregate of 50% of all examinations of that semester including sessoinals. There are no minimum marks prescribed for sessional examination.

5.2. A candidate who has successfully completed the examination in a course by securing not less than 50% of marks shall not be permitted to retake the examination in that course.

5.3. A candidate who fails to secure 50% of marks on the aggregate but secures 50% or

more in some courses and between 40-49% in the other courses, he/she shall be required to retake the semester and supplementary examination in one or more of the courses in which he/she secures less than 50% of marks as per his/her choice to satisfy the requirement of 50% aggregate.

5.4. Declaration of class

The classes 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

6. Grading system:

6.1. Appropriate letter grades are awarded in each theory and practical subject to only such candidates who have passed in the university examinations. Internal assessment marks and university examination marks put together will be taken into account for the letter grading system in each subject separately.

6.2. A candidate registered for the university examination but fails to appear or fails to score the minimum required 40% marks in the university examination will get a grade 'F', indicating failure or grade of incompletion.

6.3. A subject successfully completed cannot be repeated. Final evaluation of each subject (theory and practical separately) will be carried out on a 10- point grading system corresponding to the marks obtained in that subject. Each subject letter grade is converted into a specific grade value associated with the letter grade as given below (Table).

6.4. Grading of performances

Based on the performance, 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 below.

10-Point grading system

Percentage of marks	Grade	Grade points
90.00 - 100	O	10.0
80.00 - 89.99	A	9.0
70.00 – 79.99	B	8.0
60.00 – 69.99	C	7.0
50.00 – 59.99	D	6.0
40.00 – 49.99	E	5.0
< 40.00	F (Fail)	0.0
The grade W represents failure due to insufficient attendance in the semester or year	W	0.0
Incomplete (subsequently to be changed into pass or E or O or F grade in the same semester)	I	0.0

6.5 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:

$$\textbf{SGPA} = \frac{C1G1+C2G2+C3G3+C4G4}{C1+C2+C3+C4}$$

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 AB grade awarded in that semester. For example if a learner has F or AB grade in course 4, the SGPA shall then be computed as:

$$\textbf{SGPA} = \frac{C1G1+C2G2+C3G3+C4*ZERO}{C1+C2+C3+C4}$$

The credits allotted to each course are given in the respective specialization **Tables 1-10**.

6.6. 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 in case 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:

$$\textbf{CGPA} = \frac{C1S1+C2S2+C3S3+C4S4}{C1+C2+C3+C4}$$

Where C_1,C_2,C_3, C4…is the total number of credits for semester I, II, III and IV and S1, S2, S3 and S4 are the SGPA of semester I, II, III and IV.

7. Guidelines for paper setting and model papers.

7.1. Guidelines for theory paper setting for semester end examinations

7.1.1. The semester end question paper in each theory course is to be set for a total of 70 marks by an external paper setter as per the general model given below.

7.1.2. Question paper consists of 5 questions each carrying 5 marks out of which 4 questions are to be answered by the candidate and 7 questions each carrying 10 marks out of which 5 questions are to be answered by the candidate for a total of 70 marks. Each main question may contain subsections like a, b, c etc.

7.1.3. The questions given should be spread over the entire syllabus in an even manner covering all the units as per the pattern of the question paper given below.

7.1.4. Model question paper for theory course:

Course No.

Specialization Name:

Title of the course:

Time: 3 Hours **Max. Marks: 70**

Part A (Question Numbers 1-5)

Answer any **four** questions out of five questions 4X5=20

One question has to be set from each unit.

Part B

Answer any **five** questions out of **seven** questions (Question Numbers 6-12) 5X10=50

Five questions are to be set from five units and the remaining two should cover at least four out of five units. The main questions may contain sub question like 6(a), 6(b) etc.

7.2. Guidelines for practical paper setting for semester end examination

7.2.1. The question paper in each semester end practical examination is to be set jointly by two examiners and evaluated, one external and one internal as per the general model provided below.

7.2.2. Model question paper for practical course:

Course No.

Title of the course

Time: 6 hrs.

1. Synopsis	10 marks
2. Major experiment	30 marks
3. Minor experiment	20 marks
4. Viva voce	10 marks
Total:	**70 marks**

7.3. Guidelines for theory/practical sessional examination paper setting:

Question paper pattern for theory Sessional examinations

Max. Marks: 30

Time: 2 Hours

Part A

Answer any **two** questions out of three questions 2X5=10

Part B

Answer any **two** questions out of three questions 2X10=20

Each of the sessional examination question paper should cover at least half the units of the syllabus.

Question paper pattern for practical sessional examinations

Max. Marks: 30

Time: 4 hours

1. Synopsis	5 Marks
2. Experiment	20 Marks
3. Viva	5 Marks
Total:	**30 Marks**

Table 3: Pharmaceutics (MPH)

Code	Course	Credits	Hours/ week	Internal Assessment			Semester End Exam	Total
				Continuous mode	Sessional Exam	Total		
I Semester								
MPH 101T	Modern Pharmaceutical Analytical Techniques	4	4	10	20	30	70	100
MPH 102T	Advanced Biopharmaceutics & Pharmacokinetics (Common paper for MPH and MIP)	4	4	10	20	30	70	100
MPH 103T	Modern Pharmaceutics	4	4	10	20	30	70	100
MPH 104T	Regulatory Affairs	4	4	10	20	30	70	100
MPH 105P	Pharmaceutics Practical – I	2	6	15	15	30	70	100
MPH 106P	Pharmaceutics Practical – II	2	6	15	15	30	70	100
MPH 107	Seminar*	2	4	50	---	---	---	50
	Total	**22**	**32**	**---**	**---**	**---**	**---**	**650**
II Semester								
MPH 201T	Molecular Pharmaceutics (Nano Technology and Targeted DDS)	4	4	10	20	30	70	100
MPH 202T	Drug Delivery Systems (DDS)	4	4	10	20	30	70	100
MPH 203T	Computer Aided Drug Development (CADD)	4	4	10	20	30	70	100
MPH 204T	Pharmaceutical and Cosmetic Product Development	4	4	10	20	30	70	100
MPH 205P	Pharmaceutics Practical - III	2	6	15	15	30	70	100
MPH 206	Comprehensive Viva	2	---	---	---	---	---	50
MPH 207	Seminar*	2	2	50	---	---	---	50
	Total	**22**	**26**	**---**	**---**	**---**	**---**	**600**

Table 3: Pharmaceutics (MPH) continued

III Semester								
MRM 301T	Research Methodology and Biostatistics*	2	4	10	20	30	70	100
MPH 302	Journal Club*	2	2	50	---	---	---	50
MPH 303	Discussion /Presentation (Dissertation Title & Project Proposal)*	2	---	50	---	---	---	50
MPH 304	Seminar on selected topic	4	4	---	---	---	100	100
MPH 305	Research Work Progress (Mid Term Report)	10	20	---			200	100
	Total:	**20**	**30**	**---**	**---**	**---**	---	**400**
IV Semester								
MPH 401	Journal Club*	2	2	50	**---**	**---**	---	50
MPH 402	Thesis evaluation	12	20	---	**---**	**---**	150	150
MPH 403	Thesis viva	4	---	---	**---**	**---**	50	50
	Total:	**20**	**22**	**---**	**---**	**---**	---	**250**

* Non-University Examination

PHARMACEUTICS

PROGRAM OUTCOMES

Upon program completion, the students

PO1: Have to Apply the knowledge of mathematics, science, pharmaceutical fundamentals, and a Pharmacy specialization to the solution of complex pharmaceutical problems

PO2: Should have the knowledge of importance of physical properties of the different pharmaceutical ingredients and the factors influencing them is very valuable for pharmaceutical dosage form design

PO3: Should acquire knowledge on Unit Operations Pharm. Engineering renders knowledge about the basic unit operations that are taking place in pharmaceutical industry and the different factors associated with it. This information is useful for both pharmaceutics and pharmaceutical engineering

PO4: Have to gain the knowledge on different pharmaceutical dosage forms are imparted on students. This knowledge comes while handling a pharmacy or a manufacturing unit or in the further courses

PO5: Have to know the information on solid dosage forms like tablets and capsules, their formulation and quality control serves as an important perquisite for dosage form design

PO6: The knowledge of biopharmaceutics enables the students to visualize the effect of pharmacokinetic (ADME) parameters on the biological effect of the drug. The correlation of pharmacokinetics and pharmacodynamics is thus introduced and is experimentally explained to them

PO7: Able to understand the extension of pharmaceutical dosage forms, and enables the students to learn about different packaging materials used in pharmaceutical industry and the factors governing their use

PO8: Able to understand biopharmaceutical principles and pharmacokinetic principles through different compartment models, multiple dosage regimens, non-linear pharmacokinetics, and assessment of bioavailability and bioequivalence

PO9: Recognize different value systems including your own, understand the moral dimensions of your decisions, and accept responsibility for them

PO10: Understand the issues of environmental contexts and sustainable development

PO11: Acquire the ability to engage in independent and life-long learning in the broadest context socio-technological change

PROGRAM SPECIFIC OUTCOMES

PSO1: The program is designed to impart knowledge and skills necessary for dose calculations and dose adjustments

PSO2: Basic theoretical discussions of the principles of biopharmaceutics and pharmacokinetics are provided to help the students to clarify the concepts

PSO3: Students will be able to understand basic considerations of pharmacokinetic models

PSO4: The design and evaluation of dosage regimens of the drugs using Pharmacokinetic and Biopharmaceutic parameters will be understood by students and this will be helpful in their professional career

PSO5: Select drugs as suitable candidates for various novel drug delivery systems based on their physicochemical properties

PSO6: Students get knowledge on sustained and controlled formulations and activation of modulated drug delivery systems

PSO7: Explain various pharmaceutical excipients in pharmaceutical product development

PROGRAM EDUCATIONAL OBJECTIVES

Upon program completion, the students

1. Can practically know about the physiological difference between marketed formulations
2. Grasp knowledge on in-vivo studies by practically and also by using soft wares
3. Discuss the regulatory guidance's and guidelines for filing and approval process
4. Categorize the preparation of dossiers and their submission to regulatory agencies in different countries

PHARMACEUTICS

MPH102T Advanced Biopharmaceutics and Pharmacokinetics

Course objectives:

1. The course is designed to impart knowledge and skills necessary for dose calculations and dose adjustments.
2. Applications of biopharmaceutics theories in practical problem solving.
3. Basic theoretical discussions of the principles of biopharmaceutics and pharmacokinetics are provided to help the students to clarify the concepts.
4. To gain knowledge on Pharmacokinetic and Pharmacodynamic drug interactions in the design of the Modified release products.

Learning objective:

Unit 1:

1. Drug absorption from the gastrointestinal tract and other routes of administration, Mechanisms and factors affecting drug absorption from different routes and pH-partition theory
2. Correlation of in vivo and invitro dissolution data.

Unit 2:

1. Biopharmaceutical considerations in drug product design and in vitro drug product performance: Introduction, dissolution test apparatus, data handling and correction factor
2. Problems of variable control in the dissolution testing performance of drug products
3. Drug product stability during dissolution testing

Unit 3:
Pharmacokinetics:
1. One compartment and multi compartment models
2. Non-linear pharmacokinetics
3. Concept of Clearence and its applications

Unit 4:
Drug product performance:
1. Methods, protocol design for assessing Bioavailability
2. Design and evaluation of bioequivalence studies

Unit 5:
1. Modified-release drug products. Targeted drug delivery system and biotechnological products.
2. Significance of Pharmacokinetic and Pharmacodynamic drug interactions in the design of the Modified release products.

Course outcomes:
Upon Completion of the course, it is expected that students will be able to understand:

1. The basic concepts in the Biopharmaceutics and Pharmacokinetics.
2. The critical evaluation of Biopharmaceutic studies involving drug product Equivalency
3. The design and evaluation of Dosage regimens of the drugs using Pharmacokinetic and Biopharmaceutic parameters.
4. The potential and clinical Pharmacokinetic problems and application of basics of pharmacokinetic.

	CO1	CO2	CO3	CO4
LO1	✓			
LO2		✓		
LO3			✓	
LO4		✓		
LO5	✓			✓

MODERN PHARMACEUTICS (MPH 103T)

Course educational objectives:

1. To grasp the concepts of preformulation,
2. To get an idea of various optimization techniques.
3. To know about types of validation, cGMP, industrial management.
4. To study the concepts of compression and compaction and also drug release characteristics and modeling.

Learning objectives:

Unit I:
1. Drug excipient interactions, stability studies, pharmaceutical dispersions preparation and stability,
2. Large volume and small volume parenteral manufacturing and evaluation. Optimization techniques, statistical designs and applications in formulation

Unit II:
1. ICH and WHO guidelines for calibration and validation of equipment's,
2. Different types of validation and government regulations.

Unit III:
1. cGMP, production management and organization
2. Concept of total quality management.

Unit IV:
1. Physics of tablet compression,
2. Compaction and consolidation.

Unit V:
Matrix and reservoir systems, diffusion parameters and drug release using different equations.

Course outcomes:

1. Students will know the concepts of preformulation.
2. ICH and WHO guidelines for calibration and validation of equipment's, different types of validation and government regulations.
3. Gain knowledge on validation, cGMP.
4. Study the concepts of compression and compaction.
5. Will get an idea on matrix and reservoir systems.

	CO1	CO2	CO3	CO4	CO5
LO1	✓				
LO2		✓			
LO3			✓		
LO4				✓	
LO5					✓

REGULATORY AFFIRES (MPH 104T)

Course educational objectives:

1. To have knowledge on documentation in pharmaceutical industry.
2. Bioequivalence and drug product assessment, quality by design, ANDA.
3. Regulatory requirements of EU, MHRA, TGA and ROW countries.
4. Developing clinical trial protocols and HIPPA
5. Post approval regulatory affairs and also on intellectual property rights and regulations.

Learning objectives:

Unit I:

Documentation and various types of records, code of federal regulations, ANDA and NDA approval processes.

Unit II:

Bio-equivalence and drug product assessment, quality by design, ANDA applications and examples

Unit III:

Regulations for combination products and medical devices. Regulatory requirements of EU, MHRA, TGA and ROW countries.

Unit IV:

IND, NDA, ANDA. Investigation of IMPD and IB.

Developing clinical trial protocols and HIPPA

Unit V:

Intellectual property rights importance and types along with applications.

Course outcomes:

1. Student should be able to know the importance of documentation
2. Bio-equivalence and drug product assessment, quality by design, ANDA
3. Regulations for combination products and medical devices
4. IND, NDA, ANDA. Investigation of IMPD and IB.
5. Intellectual property rights importance and types

	CO1	CO2	CO3	CO4	CO5
LO1	✓				
LO2		✓			
LO3			✓		
LO4				✓	
LO5					✓

MPH 105PA PHARMACEUTICS PRACTICAL - I

Course educational objectives:

1. Students will acquire knowledge on UV, HPLC, and gas chromatography.
2. They will know how to estimate a compound by fluorimetry, and photometry
3. They practically know the preformulation of any powder and and other characterization studies of tablets.

Learning objectives:

1. Analysis of pharmacopoeia compounds and their formulations by UV Vis spectrophotometer
2. Simultaneous estimation of multi component containing formulations by UV spectrophotometry.
3. Experiments based on HPLC, Gas Chromatography
4. Estimation of riboflavin/quinine sulphate by fluorimetry, sodium/potassium by flame photometry.
5. To carry out preformulation studies of tablets.
6. To study the effect of compressional force on tablets disintegration time, Micromeritic properties of powders and granulation.

Course outcomes:

Upon completion of the course students will:

1. To grasp the concepts of preformulation
2. They can understand the working principle of various instruments for the analysis
3. They can understand the how to evaluate the dosage forms for their characterization.
4. Study the concepts of compression and compaction and its effect on tablet properties.

	CO1	CO2	CO3	CO4
LO1	✓	✓		
LO2		✓		
LO3		✓		
LO4				
LO5	✓		✓	
LO6			✓	✓

PHARMACEUTICS PRACTICAL - II (MPH 105PB)

Course educational objectives:

After completion of the course students will understand the

1. Factors that effecting the dissolution of tablets.
2. They will know the graphs related drug release kinetics from the dosage forms.
3. They can know the dissolution profile of marketed formulations such as CR/SR
4. They can understand the formulation and evaluation of other types of CR tablets

Learning objectives:

1. To study the effect of particle size, and binders on dissolution of a tablet.
2. To plot Heckle plot, Higuchi and peppas plot and determine similarity factors.
3. To perform In-vitro dissolution profile of CR/ SR marketed formulation
4. Formulation and evaluation of sustained release matrix tablets, osmotically controlled DDS, Muco adhesive tablets.
5. Preparation and evaluation of Floating DDS- hydro dynamically balanced DDS
6. Formulation and evaluation of trans dermal patches

.

Course outcomes:

1.The design and evaluation of Dosage regimens of the drugs using Pharmacokinetic and Biopharmaceutic parameters.
2. Practically they know about factors that affecting the dissolution.
3. They will understand the characterization marketed tablets.
4. know the formulation and evaluation of other CR tablets.

	CO1	CO2	CO3	CO4
LO1	✓	✓		
LO2				
LO3	✓		✓	
LO4				✓
LO5				✓
LO6				✓

MOLECULAR PHARMACEUTICS-MPH201T

Course educational Objectives:

This course is designed to impart:

1.Concepts of Drug targeting, Tumour targeting, Brain specific delivery
2.To gain knowledge on Preparation, Evaluation and applications of Nano particles and Liposomes
3.To know about Monoclonal antibodies, Niosomes, Aquasomes, Phytosomes and Electrosomes.
4.To get on idea of various intra nasal drug delivery systems.
5.To study the concepts Nucleic acid based therapeutic delivery systems

Learning objectives:

After completion of the course students will conspire:

Unit I:

Concepts events and biological processes in following

1)Drug targeting

2)Tumour targeting
3)Brain specific delivery
Unit 2:
Introduction, Preparation, Evaluation and applications
1)Nano particles and Liposomes
Unit 3:
Types, Preparation, Evaluation and applications
1)Monoclonal antibodies
2)Niosomes
3)Aquasomes
4)Phytosomes and Electrosomes
Unit 4:
1)Intranasal route delivery systems
2)Aerosols
3)Metered dose inhalers
4)Dry powders inhalers
5)Propellent & containers
Unit -5
Nucleic acid based therapeutic delivery systems
1)Gene therapy
2)Potential targeted diseases
3)Gene expression systems
4)Liposomal gene delivery systems
5)Antisense

Course Outcomes

1) Student able to understand knowledge on targeted drug delivery systems
2)Understand concepts involved in nanotechnology
3)Get enough knowledge on microcapsules, microspheres
4)Formulation development on pulmonary drug delivery systems
5)Basic concepts involved in gene therapy

	CO1	CO2	CO3	CO4	CO5
LO1	✓				
LO2		✓			
LO3			✓		
LO4				✓	
LO5					✓

DRUG DELIVERY SYSTEMS- MPH202T

Course educational objectives:

1. Students should get basic knowledge on Sustained release and controlled release drug delivery systems.
2. To know the concept of rate controlled drug delivery systema
3. To get on idea on gastro retentive drug delivery systems
4. To gain knowledge on occular and transdermal drug delivery systems
5. To study the concepts of Protein, peptide and vaccine drug delivery systems

Learning objectives:

Unit-1

1. Sustained release and Controlled release formulations
2. Basic concepts and physicochemical, biological approaches for SR and CR

Unit-2: Rate controlled drug delivery systems

1) principles and fundamentals ,types ,activation of modullated drug delivery systems

Unit-3: Gastroretentive drug delivery systems

1. Principles, concepts, advantages, disadvantages
2. Approaches and modulation of GI transit time
3. Buccal drug delivery systems

Unit-4: Ocular drug delivery systems

Barriers of drug permeation and methods to overcome

Transdermal drug delivery systems

Unit-5: Protein, peptide and vaccine drug delivery systems

Barriers, formulation and evaluation of proteins and macromolecules

Course outcomes:

1. Students get knowledge on sustained and controlled formulations.
2. activation of modullated drug delivery systems
3. acquires the concepts in gastro-retentive drug delivery systems.
4. grasps the concepts of ocular drug delivery system.
5. Gets command on protein, peptide and vaccine drug delivery systems

	CO1	CO2	CO3	CO4	CO4
LO1	✓				
LO2		✓			
LO3			✓		
LO4				✓	
LO5					✓

COMPUTER AIDED DRUG DEVELOPMENT

(MPH 203T)

Course educational objectives:

1. To introduce the use and applications of computers in pharmaceutical research and development and computer aided biopharmaceutical characterization.
2. Modelling Techniques involved in ADME, active transport, P-gp, BCRP, and Nucleoside Transporters.
3. Use of computers in R&D, clinical development, market analysis and ethics of computing in research.
4. IVIVC, biowaiver considerations, computer Simulations and computers in clinical development.
5. Artificial Intelligence (AI), computational fluid dynamics

Learning objectives:

Unit I

Role of computers in pharmaceutical research and development, statistical modelling, parameters, estimation, confidence region, sensitivity analysis, optimal design population modelling and QbD.

Unit II

Modeling Techniques involved in ADME, active transport, P-gp, BCRP, Nucleoside Transporters, hPEPT1, ASBT, OCT, OATP, BBB-Choline Transporter.

Unit III

Optimization, computer aided formulation's development with examples, Use of computers in R&D, clinical development, market analysis and ethics of computing in research.

Unit IV

Computer-aided biopharmaceutical characterization such as model construction, parameter sensitivity analysis, virtual trial, IVIVC, biowaiver considerations, computer Simulations and computers in clinical development.

Unit V

From this topic student can learn about:

Artificial Intelligence(AI), computational fluid dynamics and pharmaceutical automations.

Course outcomes:

1. After completion of this course student will gain knowledge on statistical modelling in pharmaceutical research and development,
2. computational modelling in drug disposition,
3. computer aided formulation development and also current challenges and
4. future directions in artificial intelligence.

	CO1	CO2	CO3	CO4	CO5
LO1	✓				
LO2		✓			
LO3			✓		
LO4				✓	
LO5					✓

Pharmaceutical and cosmetic product development (mph 204T)

Course educational objectives:

1. Students should acquire knowledge on preformulation.
2. various techniques to improve solubility of drugs and utilization of analytical methods.
3. Mechanism of degradation, stability testing of drugs and pharmaceuticals
4. Various herbal ingredients used in hair care, skin care and oral care.

Learning objectives:

Unit I

Crystal morphology,powder flow, TLC,DTA,DSC and TGA spectral studies and role of formulation additives.

Unit II

Phase solubility studies, pH solubility profile, various techniques to improve solubility of drugs and utilization of analytical methods.

Unit III

Mechanism of degradation, stability testing of drugs and pharmaceuticals, factors influencing stability, accelerated stability studies and stability protocols.

Unit IV

Various herbal ingredients used in hair care, skin care and oral care. Guidelines for herbal cosmetics and challenges in formulating herbal cosmetics.

Unit V

Formulation, manufacturing and quality control methods of hair care products,skin care products.

Course outcomes:

1. After completion of this course student will gain knowledge on preformulaion studies.
2. Gets knowledge on Phase solubility studies, pH solubility profile.
3. factors influencing stability, accelerated stability studies and stability protocols.
4. Guidelines for herbal cosmetics and challenges in formulating herbal cosmetics.
5. Grasp knowledge on formulation and evaluation of both pharmaceuticals and cosmetics.

	CO1	CO2	CO3	CO4	CO4
LO1	✓				
LO2		✓			
LO3			✓		
LO4				✓	
LO5					✓

Pharmaceutics practical - iii (mph 205pa)

Course educational objectives:

1. They will understand the factors that effecting the microcapsules preparation
2. They know about the novel drug delivery systems
3. They can practically know about the physiological difference between marketed formulations.
4. They grasp knowledge on *in-vivo* studies by practically and also by using soft wares.
5. they gain theoretical knowledge on protein binding and cell studies for permeability

Learning objectives:

1. To study the effect of temperature change, non-solvent addition, incompatible polymer addition in microcapsules preparation
2. Preparation and evaluation of Alginate beads
3. Formulation and evaluation of gelatin /albumin microspheres liposomes/niosomes, and spherules
4. Improvement of dissolution characteristics of slightly soluble drug by Solid dispersion technique.
5. Comparison of dissolution of two different marketed products /brands
6. Protein binding studies of a highly protein bound drug & poorly protein bound drug
7. Bioavailability studies of Paracetamol in animals.
8. Pharmacokinetic and IVIVC data analysis by WinnolineR software 11. In vitro cell studies for permeability and metabolism

Course outcomes:

1. They will understand the factors that effecting the microcapsules preparation
2. They know about the novel drug delivery systems
3. They can practically know about the physiological difference between marketed formulations.
4. They grasp knowledge on *in-vivo* studies by practically and also by using soft wares.
5. They gain theoretical knowledge on protein binding and cell studies for permeability.

	CO1	CO2	CO3	CO4	CO5
LO1	✓				
LO2		✓			
LO3		✓	✓		
LO4	✓				
LO5			✓		✓
LO6					
LO7				✓	
LO8				✓	✓

PHARMACEUTICS

PRACTICAL - IV

(MPH205PB)

Course educational objectives: After completion of the course students will gain knowledgeon

1.They can soft wares that used in formulation development and drug discovery.

2.They can understand optimization techniques

3.Formulation development in creams, shampoos and tooth paste.

4. Drug disposition using computational models.

Learning objectives:

1. DoE, Formulation data analysis Using Design Expert®Software
2. Quality-by-Design in Pharmaceutical Development, Computer Simulations inPharmacokinetics and Pharmacodynamics
3. Computational Modeling of Drug Disposition
4. To develop Clinical Data Collection manual, and to carry out Sensitivity Analysis, andPopulation Modeling.
5. Development and evaluation of Creams, Shampoo and Toothpaste base
6. Formulation Development of Multi Vitamnin Syrup, Use of Optimization techniques inFormulation Development of Tablets.

Course outcomes:

After completion of the course students will gain knowledge on

1.They can soft wares that used in formulation development and drug discovery.2.They can understand optimization techniques

3.Formulation development in creams, shampoos and tooth paste.

4. Drug disposition using computational models. And to develop clinical data manual.

	CO1	CO2	CO3	CO4
LO1	✓			
LO2		✓		
LO3	✓			✓
LO4				✓
LO5			✓	
LO6		✓	✓	

PHARMACEUTICS (MPH)

First Semester

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES (MPH 101T)

(Note: Common paper for MPA, MPC, MPH, MPB, MPL, MPG, MQA, & MIP, specializations)

Unit 1:

a. UV-visible spectroscopy: Introduction, theory, laws and instrumentation associated with UV-visible spectroscopy, choice of solvents and solvent effect and applications of UV-visible 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. **12 Hours**

Unit 2:

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. **10 Hours**

Unit 3:

Mass Spectroscopy: Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules, Meta stable ions, Isotopic peaks and Applications of Mass spectroscopy. 1**0 Hours**

Unit 4:

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. **14 Hours**

Unit 5:

a. Electrophoresis: Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following: a) Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresis d) Zone electrophoresis e) Moving boundary electrophoresis f) Iso electric focusing.

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.

c. Thermal Techniques: Principle, instrumentation, advantage and disadvantages, Pharmaceutical applications of DSC, DTA & TGA.

d. Microscopic techniques: Principles and applications of Scanning Electron Microscopy

and Transmission Electron Microscopy analysis. **14 Hours**

REFERENCES

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

ADVANCED BIOPHARMACEUTICS & PHARMACOKINETICS (MPH 102T)

(Common paper for MPH and MIP specializations)

Unit 1:

Drug absorption from the gastrointestinal tract and other routes of administration: Mechanisms and factors affecting drug absorption from different routes, influence of pH–partition theory on drug absorption. Factors affecting dissolution rate and its process, Noyes-Whitney equation. dissolution testing methods for solids - tablets, capsules and for suspensions. Correlation of in vivo and in vitro dissolution data. **12 Hours**

Unit 2:

Biopharmaceutical considerations in drug product design and in vitro drug product performance. Introduction - biopharmaceutical factors affecting bioavailability, rate limiting steps in drug absorption, physicochemical nature of drug, formulation factors affecting drug product performance. In vitro dissolution and drug release testing, dissolution test apparatus and methods as per IP and USP for different types of drug delivery systems, design of dissolution testing for conventional and controlled release products. Data handling and correction factor, bio relevant media, similarity and dissimilarity factors f_1 & f_2, alternative methods of dissolution testing, problems of variable control in dissolution testing performance of drug products. Drug product stability during dissolution testing, in vitro evaluation of drug release from different dosage forms. **12 Hours**

Unit 3:

Pharmacokinetics: Basic considerations, pharmacokinetic models, compartment modeling: one compartment model - IV bolus, IV infusion, extra-vascular. Multi compartment models in brief, calculation of parameters in two compartment models. Non-linear pharmacokinetics: causes of non-linearity, Michaelis – Menten equation, estimation of k_m and V_{max}. Concept of clearance and its applications. Problems related to the above. **12 Hours**

Unit 4:

Drug Product Performance: Bioavailability and bioequivalence, drug product performance, purpose of bioavailability studies, relative and absolute availability. Methods, protocol design for assessing bioavailability, bioequivalence studies, design and evaluation of bioequivalence studies, study designs, cross over study designs, evaluation of the data, bioequivalence example, study submission and drug review process. In vitro - in vivo correlations in protocol

design, levels of correlation, biopharmaceutical classification system, methods. Permeability: Generic biologics (biosimilar drug products), clinical significance of bioequivalence studies. **12 Hours**

Unit 5:

Application of pharmacokinetics: Modified-release drug products, targeted drug delivery systems and biotechnological products. Significance of pharmacokinetic and pharmacodynamic drug interactions in the design of the modified release products. **12 Hours**

REFERENCES

1. Pharmacokinetics - Milo Gibaldi. 2nd ed.
2. Applied Biopharmaceutics and Pharmacokinetics - Leon Shargel. 5th ed.
3. Biopharmaceutics and Clinical Pharmacokinetics - Robert E Notari. 4th ed.
4. Modern Pharmaceutics - Gilbert S. Banker, Christopher T Rhodes. 4th ed.
5. Clinical Pharmacokinetics & Pharmacodynamics - Malcolm Rowland & Tozer. 4th ed. Lippincott Publications.
6. Drug Disposition and Pharmacokinetics - Stephen H Curry. 3rd ed.
7. Current Concepts in the Pharmaceutical Sciences : Biopharmaceutics - James Swarbrick
8. Current Concepts in the Pharmaceutical Sciences:Dosage Form Design and Bioavailability - James Swarbrick.

MODERN PHARMACEUTICS (MPH 103T)

Unit 1:

Preformulation Concepts – Drug excipient interactions-different methods, kinetics of stability, stability testing. Theories of dispersion and pharmaceutical dispersion (emulsions and suspensions, SMEDDS) preparation and stability. Large and small volume parenterals – physiological and formulation consideration, manufacturing and evaluation.

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. **12 Hours**

Unit 2:

Validation: Introduction to pharmaceutical validation, scope & merits of validation. Validation and calibration of master plan, ICH & WHO guidelines for calibration and validation of equipment, validation of specific dosage form, types of validation. Government regulations, manufacturing process model, user requirement specifications (URS), design qualification (DQ), installation qualification (IQ), operational qualification (OQ) & performance qualification (PQ) of facilities. **12 Hours**

Unit 3:

cGMP & industrial management: Objectives and policies of current good manufacturing practices (cGMP), layout of buildings, services, equipment 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 (TQM). **12 Hours**

Unit 4:

Compression and compaction: Physics of tablet compression, compression, consolidation, effect of friction, distribution of forces, compaction profiles. Heckel plots, Strain gauges, evaluation of forces, energy consumption, factors influencing consolidation parameters.

12 Hours

Unit 5:

Drug release characteristics and modeling: Diffusion parameters, evaluation of matrix and reservoir systems and swelling matrix tablets, burst effect, modeling of drug release using different equations (Higuchi model, Peppas model, Hixson Crowell, zero order & first order). Linearity, concept of significance, standard deviation, Chi square test, students T-test, ANOVA test. **12 Hours**

REFERENCES

1. Encyclopedia of Pharmaceutical Technology - James Swarbrick. 3rd ed. Informa Healthcare Publishers.
2. Pharmaceutical Dosage Forms : Tablets - Herbert A Lieberman & Leon Lachman, Volume 1 - 3. Marcel Dekker, Inc.
3. The Theory and Practice of Industrial Pharmacy - Roop K Khar, S.P. Vyas, Farhan J Ahmad, Gaurav K Jain. 4th ed. CBS Publishers, New Delhi.
4. Martin's Physical Pharmacy and Pharmaceutical Sciences - Patrick J Sinko. 6th ed. BI Publications Pvt. Ltd.
5. Pharmaceutical Dosage Forms : Disperse Systems - Herbert A Lieberman, Martin M Rieger & Gilbert S Banker. Vol 1 – 3. Informa Healthcare.
6. Pharmaceutical Dosage Forms : Parenteral Medication – Sandeep Nema & John Ludwig, Vol 1 – 3. 3rd ed. Informa Healthcare.
7. Aulton's Pharmaceutics – The Design and Manufacture of Medicines - M.E. Aulton & M.G. Kevin Taylor. 5th ed. Elsevier.
8. Remington – The Science and Practice of Pharmacy – Loyd V Allen. 22nd ed.

REGULATORY AFFAIRS (MPH 104T)

Unit 1:

Documentation in pharmaceutical industry: Master formula record, DMF drug master file (DMF), distribution records. Generic drugs product development, introduction, Hatch-Waxman Act and amendments, Code of Federal Regulations (CFR), drug product performance in vitro, ANDA regulatory approval process, NDA approval process. **12 Hours**

Unit 2:

Bioequivalence and drug product assessment: Scale up post approval changes, post marketing surveillance, outsourcing BA and BE to CRO. Regulatory requirement for product approval, active pharmaceutical ingredient (API), biologics, novel therapies by obtaining NDA, ANDA generic drugs. Pharmaceutical product development (Q8), quality risk management (Q9) and pharmaceutical quality systems (Q10). Quality by design (Q_bD), principles in pharmaceutical development, regulatory and industry views on Q_bD, elements of Q_bD, ANDA applications and examples. **12 Hours**

Unit 3:

Critical manufacturing controls (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. **12 Hours**

Unit 4:

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

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. **12 Hours**

Unit 5:

General principles of intellectual property rights (IPR): IP protection, economic importance, mechanism of protection. Patents, criteria, types of patent application-steps, trademarks and copy rights. **12 Hours**

REFERENCES

1. The Theory and Practice of Industrial Pharmacy - Leon Lachman, H.A. Lieberman & Joseph L Kanig. 3rd ed. Varghese Publishing, 1991.
2. Lachman/Lieberman's The Theory and Practice of Industrial Pharmacy - Roop K Khar, S.P. Vyas, Farhan J Ahmad & Gaurav K Jain. 4th ed. CBS Publishers, New Delhi.
3. Quality Assurance of Pharmaceuticals – WHO. Vol. 1 & 2. Pharma Book Syndicate.
4. Pharmaceutical Product development - N.K. Jain. CBS Publishers, New Delhi.
5. Law relating to Drugs & Cosmetics - Vijay Malik. Eastern Book Company.

PHARMACEUTICS PRACTICAL - I (MPH 105P)

1. Analysis of Pharmacopoeial compounds and their formulations by UV - Visible spectrophotometer.
2. Colorimetric analysis of aspirin.
3. Kinetic studies of aspirin degradation.
4. Molecular weight determination of polymers by viscosity method.
5. Preparation of granules, drying by conventional dryer and fluidized bed dryer and comparing the granules by their flow property.
6. HPLC analysis of any one drug.
7. GMP audit requirements as per CDSCO.
8. Preparation of check-lists for registration of IND as per ICH CTD format.
9. Preparation of check-lists for registration of NDA as per ICH CTD format.
10. Preparation of check-lists for registration of ANDA as per ICH CTD format.
11. To carry out pre formulation studies of tablets.
12. To study the effect of Compression force on tablets disintegration time.

PHARMACEUTICS PRACTICAL - II (MPH 106P)

1. Improvement of dissolution of drugs by solid dispersions, cyclo dextrin complexation etc.
2. Effect of ointment base on drug diffusion using agar plate method and diffusion membrane.
3. To study the effect of particle size on dissolution of a tablet.
4. To study the effect of binders on dissolution of a tablet.
5. To plot Heckel plot, Higuchi and Peppas plot and determine similarity factors.
6. Improvement of dissolution characteristics of slightly soluble drug by solid dispersion technique.
7. Protein binding studies of a highly protein bound drug and poorly protein bound drug.

8. Absorption kinetics of paracetamol in goat intestine (ex vivo study)
9. Pharmacokinetic and IVIVC data analysis by WinNonlin® Software (Demo).
10. In vitro cell studies for permeability and metabolism (Demo).
11. Effect of surfactant on drug dissolution using BCS II drugs.

Second Semester

MOLECULAR PHARMACEUTICS (NANO TECHNOLOGY & TARGETED DDS) (MPH 201T)

Unit 1:

Targeted drug delivery systems: Concepts, events and biological process involved in drug targeting. Tumor targeting and brain specific delivery. **12 Hours**

Unit 2:

Targeting Methods: Introduction, preparation, evaluation and application of nano particles & liposomes. **12 Hours**

Unit 3:

Micro capsules/micro spheres: Types, preparation, evaluation and applications of monoclonal antibodies, niosomes, aquasomes, phytosomes, electrosomes. **12 Hours**

Unit 4:

Pulmonary drug delivery systems: Aerosols, metered dose inhalers, dry powder inhalers, propellants, containers, types, preparation and evaluation. Intra nasal route delivery systems; types, preparation and evaluation. **12 Hours**

Unit 5:

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 non viral gene transfer). Liposomal gene delivery systems. Bio distribution and pharmacokinetics. Knowledge of therapeutic antisense molecules and aptamers as drugs of future. **12 Hours**

REFERENCES

1. Novel Drug Delivery Systems – Y.W. Chien. 2nd ed. (Revised and expanded). Marcel Dekker.
2. Controlled Drug Delivery: Concepts and Advances - S.P. Vyas & R.K. Khar. 1st ed. Vallabh Prakashan, New Delhi.
3. Controlled and Novel Drug Delivery - N.K. Jain. 1st ed. CBS Publishers, New Delhi, 1997.

DRUG DELIVERY SYSTEMS (MPH 202T)

Unit 1:

Sustained release (SR) and controlled release (CR) formulations: Introduction & basic concepts, advantages/disadvantages, factors influencing, physicochemical & biological approaches for SR/CR formulation, mechanism of drug delivery from SR/CR formulation. Polymers: introduction, definition, classification, properties and application. Dosage Forms for personalized medicine: Introduction, definition, pharmacogenetics, categories of patients for personalized medicines. Customized drug delivery systems, bioelectronic medicines, 3D printing of pharmaceuticals, tele pharmacy. **12 Hours**

Unit 2:

Rate controlled drug delivery systems: Principles & fundamentals, types, activation; Modulated drug delivery systems; mechanically activated, pH activated, enzyme activated, and osmotic activated drug delivery systems, feedback regulated drug delivery systems;

principles & fundamentals. **12 Hours**

Unit 3:

Gastro retentive drug delivery systems: Principle, concepts, advantages and disadvantages. Modulation of GI transit time, approaches to extend GI transit. Buccal drug delivery systems: Principle of mucoadhesion, advantages and disadvantages, mechanism of drug permeation, methods of formulation and evaluation. **12 Hours**

Unit 4:

Ocular drug delivery systems: Barriers of drug permeation, methods to overcome barriers. Transdermal drug delivery systems: Structure of skin and barriers, penetration enhancers, formulation and evaluation. **12 Hours**

Unit 5:

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

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

Medical devices: Materials and their requirements for manufacture of specialized medical devices-disposable hypodermic needles and syringes, prefilled syringes, drug eluting stents, orthopedic implants and intra ocular lenses. **12 Hours**

REFERENCES

1. Novel Drug Delivery Systems – Y.W. Chien. 2nd ed. (Revised and expanded). Marcel Dekker.
2. Controlled Drug Delivery Systems - J. R. Robinson & V.H.L. Lee. Marcel Dekker, Inc.
3. Encyclopedia of Controlled Delivery - Edith Mathiowitz. John Wiley and Sons, Inc.
4. Controlled Drug Delivery: Concepts and Advances - S.P. Vyas & R.K. Khar. 1st ed. Vallabh Prakashan, New Delhi.
5. Controlled and Novel Drug Delivery - N.K. Jain. 1st ed. CBS Publishers, New Delhi, 1997.

COMPUTER AIDED DRUG DEVELOPMENT (MPH 203T)

Unit 1:

Computers in pharmaceutical research and development: A general overview: History of computers in pharmaceutical research and development.

Statistical modeling in pharmaceutical research and development: Descriptive versus mechanistic non parametric and parametric modeling. Statistical parameters, estimation, confidence regions, nonlinearity at the optimum, sensitivity analysis, optimal design, population modeling. **12 Hours**

Unit 2:

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 3:

Computer-aided formulation development: Solid dosage forms, disperse systems such as suspensions, emulsions and micro emulsion drug carrier system with examples. Legal protection of innovative uses of computers in R&D, the ethics of computing in pharmaceutical research. Computers in clinical development: Clinical data collection and management, computers in market analysis. **12 Hours**

Unit 4:

Computer-aided biopharmaceutical characterization: Gastrointestinal absorption simulation. Introduction, theoretical background, model construction, parameter sensitivity analysis, virtual trial, fed vs. fasted state, in vitro dissolution and in vitro–in vivo correlation, biowaiver considerations

Computer simulations in pharmacokinetics and pharmacodynamics: Introduction. Computer simulation: Whole organism, isolated tissues, organs, cell, proteins and genes.

12 Hours

Unit 5:

Artificial intelligence (AI): Concepts and applications, robotics. Computational fluid dynamics: General overview and applications. Pharmaceutical automation, pharmaceutical applications, advantages and disadvantages. Current challenges and future directions.

12 Hours

REFERENCES

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

PHARMACEUTICAL AND COSMETIC PRODUCT DEVELOPMENT (MPH 204T)

Unit 1:

Preformulation studies: Molecular optimization of APIs (drug substances), crystal morphology and variations, powder flow, structure modification, drug-excipient compatibility studies by TLC, DTA, DSC and TGA spectral studies, formulation additives: Study of different formulation additives, factors influencing their incorporation, role of formulation development and processing, new developments in excipient science. **12 Hours**

Unit 2:

Solubility: Importance, experimental determination, phase solubility analysis, pH-solubility profile, techniques to improve solubility of drugs and utilization of analytical methods – cosolvency, salt formation, complexation, solid dispersion, micellar solubilization and hydrotropy, methods of characterization. **12 Hours**

Unit 3:

Product stability: Mechanisms of degradation and protection, 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. **12 Hours**

Unit 4:

Herbal Cosmetics : Herbal ingredients used in Hair care, skin care and oral care. Review of guidelines for herbal cosmetics by private bodies like cosmos with respect to preservatives, emollients, foaming agents, emulsifiers and rheology modifiers. Challenges in formulating herbal cosmetics. **12 Hours**

Unit 5:

Cosmetics: Formulation, manufacturing and quality control methods of following cosmetic products. Hair care products - Shampoos, hair dyes, shaving products and depilatories. Dental hygiene products: Tooth paste, mouth washes. Skin care products: Hand cream, cleansing

cream, foundation creams. **12 Hours**

REFERENCES

1. Harry's Cosmeticology. 8th ed.
2. Poucher's Perfumes, Cosmetics & Soaps – Hilda Butler. 10th ed. Kluwer Academic Publishers.
3. Cosmetics - Formulation, Manufacture and Quality Control – P.P. Sharma. 4th ed.
4. Hand Book of Cosmetic Science and Technology - A.O. Barel, M. Paye & H.I. Maibach. 3rd ed.
5. Cosmetic and Toiletries Recent Suppliers' Catalogue.
6. CTFA Directory.

PHARMACEUTICS PRACTICAL – III (MPH 205P)

1. To perform in vitro dissolution profile of Controlled release or Sustained release marketed formulation.
2. Formulation and evaluation of sustained release matrix tablets.
3. Formulation and evaluation of osmotically controlled DDS.
4. Preparation and evaluation of Floating DDS- Hydro dynamically balanced DDS.
5. Formulation and evaluation of Muco-adhesive tablets.
6. Formulation and evaluation of transdermal patches.
7. To study the effect of temperature change, non solvent addition, incompatible polymer addition in micro capsule preparation.
8. Formulation and evaluation of microspheres.
9. Formulation and evaluation of liposomes or niosomes.
10. Demonstration statistical designing in formulation development through QBD approach.
11. Development and evaluation of Creams.
12. Development and evaluation of Shampoo and Tooth paste.
13. Effect of surfactant on the solubility of drugs.
14. Effect of pH on the solubility of drugs.
15. Stability testing of drugs in dosage forms at 25^0C/60% RH and 40^0C/75% RH and determine the shelf life.
16. Compatibility evaluation of drugs and excipients (DSC & FTIR).

Third Semester

RESEARCH METHODOLOGY & BIOSTATISTICS (MRM 301T)

(Note: Common Paper for all specializations)

Unit 1:

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. **12 Hours**

Unit 2:

Biostatistics: Definition, application, sample size, importance of sample size, factors influencing sample size, dropouts, statistical tests of significance, type of significance tests, parametric tests (students "t" test, ANOVA, Correlation coefficient, regression), non-parametric tests (Wilcoxan rank tests, analysis of variance, correlation, Chi-square test), null hypothesis, P values, degree of freedom, interpretation of P values. **12 Hours**

Unit 3:

Medical Research: History, values in medical ethics, autonomy, beneficence, non-maleficence, double effect, conflicts between autonomy and beneficence/non-malfeasance, 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. **12 Hours**

Unit 4:

CPCSEA guidelines for laboratory animal facility: Goals, veterinary care, quarantine, surveillance, diagnosis, treatment and control of disease, personal hygiene, location of animal facilities to laboratories, anesthesia, euthanasia, physical facilities, environment, animal husbandry, record keeping, SOPs, personnel and training, transport of lab animals. **12 Hours**

Unit 5:

Declaration of Helsinki: History, introduction, basic principles for all medical research, and additional principles for medical research combined with medical care. **12 Hours**

REFERENCES

1. Pharmaceutical Statistics: Practical and Clinical Applications - Stanford Bolton & Charles Bon. 5th ed. CRC Press.
2. Biostatistics: A Foundation for Analysis in the Health Sciences - Wayne W Daniel. 10th ed. John Wiley & Sons.
3. Introduction to Research in the Health Sciences - Stephen Polgar & Shane Thomas. 7th ed. Elsevier.
4. www.cpcsea.nic.in
5. www.wma.net