PCI

2016

THE MASTER OF PHARMACY (M. PHARM.)
COURSE REGULATION 2014

(BASED ON NOTIFICATION IN THE GAZETTE OF INDIA No. 362, DATED DECEMBER 11, 2014)

SCHEME AND SYLLABUS

PHARMACY COUNCIL OF INDIA
Combined Council's Building, Kotla Road,
Aiwan-E-Ghalib Marg, New Delhi-110 002.
Website : www.pci.nic.

COURSE STRUCTURE AND SYLLABUS
For
M. PHARM

MPH R 20 Regulations

(Applicable for batches admitted from 2020-2021)

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY: KAKINADA
KAKINADA - 533 003, Andhra Pradesh, India

ADITYA PHARMACY COLLEGE SURAMPALEM

PRINCIPAL
Aditya Pharmacy College
SURAMPALEM-533 437

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PHARMACY COUNCIL OF INDIA

NOTIFICATION

New Delhi, the 10th December, 2014

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

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

CHAPTER –I: REGULATIONS

1. Short Title and Commencement

These regulations shall be called as "The Revised Regulations for the Master of Pharmacy (M. Pharm.) Degree Program - Credit Based Semester System (CBSS) of the Pharmacy Council of India, New Delhi". They shall come into effect from the Academic Year 2016-17. The regulations framed are subject to modifications from time to time by the authorities of the university.

2. Minimum qualification for admission

A Pass in the following examinations

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

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

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

3. Duration of the program

The program of study for M.Pharm. shall extend over a period of four semesters (two academic years). The curricula and syllabi for the program shall be prescribed from time to time by 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 conducted from the month of June/July to November/December and the even semesters shall be conducted from the month of December/January to May/June in every calendar year.

6. Attendance and progress

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

7. Program/Course credit structure

As per the philosophy of Credit Based Semester System, certain quantum of academic work viz. theory classes, practical classes, seminars, assignments, etc. are measured in terms of credits. On satisfactory completion of the courses, a candidate earns credits. The amount of credit associated with a course is dependent upon the number of hours of instruction per week in that course. Similarly the credit associated with any of the other academic, co/extra- curricular activities is dependent upon the quantum of work expected to be put in for each of these activities per week/per activity.

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.

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
2.	Industrial Pharmacy	MIP
3.	Pharmaceutical Chemistry	MPC
4.	Pharmaceutical Analysis	MPA
5.	Pharmaceutical Quality Assurance	MQA
6.	Pharmaceutical Regulatory Affairs	MRA
7.	Pharmaceutical Biotechnology	MPB
8.	Pharmacy Practice	MPP
9.	Pharmacology	MPL
10.	Pharmacognosy	MPG

The course of study for M.Pharm specializations shall include Semester wise Theory & Practical as given in Table – 2 to 11. 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 to 11.

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 Tech and Targeted DDS)	4	4	4	100
MPH202T	Advanced Biopharmaceutics & Pharmacokinetics	4	4	4	100
MPH203T	Computer Aided Drug Delivery System	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 – 5: 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	Modern Bio-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 – 12: 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 Presentationsand Other Scholarly Activities)	Minimum=02 Maximum=07*
Total Credit Points	Minimum=95 Maximum=100*

*Credit Points for Co-curricular Activities

Table – 15: Guidelines for Awarding Credit Points for Co-curricular Activities

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

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

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

10. Program Committee

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

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 semester exam.

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)	10	15	1Hr	25	75	3Hr	100
MPH202T	Advanced Biopharmaceutics & Pharmacokinetics	10	15	1Hr	25	75	3Hr	100
MPH203T	Computer Aided Drug Delivery System	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

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)	10
Based on Practical Records, Regular viva voce, etc.	10
Total	20

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

Percentage of Attendance	Theory	Practical
95 – 100	8	10
90 – 94	6	7.5
85 – 89	4	5
80 – 84	2	2.5
Less than 80	0	0

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.programme if he/she secures at least 50% marks in that particular courseincluding 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

Reexamination of end semester examination shall be conducted as per the schedule given in table 29. The exact dates of examinations shall be notified from time to time.

Table – 29: Tentative schedule of end semester examinations

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

16. Allowed to keep terms (ATKT):

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

A student shall be eligible to carry forward all the courses of I and IIsemesters 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:

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

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

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

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 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:

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

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 undertake a project under the supervision of a teacher in Semester III to IV and submit a report. 4 copies of the project report shall be submitted (typed & bound copy not less than 75 pages).

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

Evaluation of Dissertation Book:

Objective(s) of the work done	50 Marks
Methodology adopted	150 Marks
Results and Discussions	250 Marks
Conclusions and Outcomes	50 Marks
Total	500 Marks

Evaluation of Presentation:

Presentation of work	100 Marks
Communication skills	50 Marks
Question and answer skills	100 Marks
Total	250 Marks

22. Award of Ranks

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

23. Award of degree

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

24. Duration for completion of the program of study

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

25. Revaluation I Retotaling of answer papers

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

26. Re-admission after break of study

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

PHARMACEUTICS (MPH)

SEMESTER - I

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES (MPH 101T)

Scope

This subject deals with various advanced analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are NMR, Mass spectrometer, IR, HPLC, GC etc.

Objectives

After completion of course student is able to know,

- Chemicals and Excipients
- The analysis of various drugs in single and combination dosage forms
- Theoretical and practical skills of the instruments

THEORY 60 HOURS

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. 11 Hrs
   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 IRspectroscopy
   c. Spectroflourimetry: Theory of Fluorescence, Factors affecting fluorescence, Quenchers, Instrumentation and Applications of fluorescence spectrophotometer.
   d. Flame emission spectroscopy and Atomic absorption spectroscopy: Principle, Instrumentation, Interferences and Applications.

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. 11 Hrs

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	11 Hrs
4	Chromatography: Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution and applications of the following: a) Paper chromatography b) Thin Layer chromatography c) Ion exchange chromatography d) Column chromatography e) Gas chromatography f) High Performance Liquid chromatography g) Affinity chromatography	11 Hrs
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 diffraction methods, Bragg's law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X- ray diffraction.	11 Hrs 5 Hrs
6	Immunological assays : RIA (Radio immuno assay), ELISA, Bioluminescence assays.	

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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.
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6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis- Modern methods – Part B - J W Munson, Volume 11, Marcel Dekker Series

DRUG DELIVERY SYSTEMS
(MPH 102T)

SCOPE

This course is designed to impart knowledge on the area of advances in novel drug delivery systems.

OBJECTIVES

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

- The various approaches for development of novel drug delivery systems.
- The criteria for selection of drugs and polymers for the development of delivering system
- The formulation and evaluation of Novel drug delivery systems..

THEORY 60 Hrs

1.	Sustained Release(SR) and Controlled Release (CR) formulations: Introduction & basic concepts, advantages/ disadvantages, factors influencing, Physicochemical & biological approaches for SR/CR formulation, Mechanism of Drug Delivery from SR/CR formulation. Polymers: introduction, definition, classification, properties and application Dosage Forms for Personalized Medicine: Introduction, Definition, Pharmacogenetics, Categories of Patients for Personalized Medicines: Customized drug delivery systems, Bioelectronic Medicines, 3D printing of pharmaceuticals, Telepharmacy.	10 Hrs
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.	10 Hrs
3	Gastro-Retentive Drug Delivery Systems: Principle, concepts advantages and disadvantages, Modulation of GI transit time approaches to extend GI transit. Buccal Drug Delivery Systems: Principle of muco adhesion, advantages and disadvantages, Mechanism of drug permeation, Methods of formulation and its evaluations.	10 Hrs
4	Occular Drug Delivery Systems: Barriers of drug permeation, Methods to overcome barriers.	06 Hrs

5	Transdermal Drug Delivery Systems: Structure of skin and barriers, Penetration enhancers, Transdermal Drug Delivery Systems, Formulation and evaluation.	10 Hrs
6	Protein and Peptide Delivery: Barriers for protein delivery. Formulation and Evaluation of delivery systems of proteins and other macromolecules.	08 Hrs
7	Vaccine delivery systems: Vaccines, uptake of antigens, single shot vaccines, mucosal and transdermal delivery of vaccines.	06 Hrs

REFERENCES

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

JOURNALS

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

ADITYA PHARMACY COLLEGE * SURAMPALEM *

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MODERN PHARMACEUTICS
(MPH 103T)

Scope

Course designed to impart advanced knowledge and skills required to learn various aspects and concepts at pharmaceutical industries

Objectives

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

- The elements of preformulation studies.
- The Active Pharmaceutical Ingredients and Generic drug Product development
- Industrial Management and GMP Considerations.
- Optimization Techniques & Pilot Plant Scale Up Techniques
- Stability Testing, sterilization process & packaging of dosage forms.

THEORY 60 HRS

1. a.	Preformation Concepts – Drug Excipient interactions - different methods, kinetics of stability, Stability testing. Theories of dispersion and pharmaceutical Dispersion (Emulsion and Suspension, SMEDDS) preparation and stability Large and small volume parental – physiological and formulation consideration, Manufacturing and evaluation.	10 Hrs
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	10 Hrs
2	Validation : Introduction to Pharmaceutical Validation, Scope & merits of Validation, Validation and calibration of Master plan, ICH & WHO guidelines for calibration and validation of equipments, Validation of specific dosage form, Types of validation. Government regulation, Manufacturing Process Model, URS, DQ, IQ, OQ & P.Q. of facilities.	10 Hrs
3	cGMP & Industrial Management: Objectives and policies of current good manufacturing practices, layout of buildings, services, equipments and their maintenance Production management: Production organization, , materials management, handling and transportation, inventory management and control, production and planning control, Sales forecasting, budget and cost control, industrial and personal relationship. Concept of Total Quality Management.	10 Hrs

4	Compression and compaction: Physics of tablet compression, compression, consolidation, effect of friction, distribution of forces, compaction profiles. Solubility.	10 Hrs
5	Study of consolidation parameters; Diffusion parameters, Dissolution parameters and Pharmacokinetic parameters, Heckel plots, Similarity factors – f2 and f1, Higuchi and Peppas plot, Linearity Concept of significance, Standard deviation, Chi square test, students T-test, ANOVA test.	10 Hrs

REFERENCES

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

REGULATORY AFFAIRS
(MPH 104T)

Scope

Course designed to impart advanced knowledge and skills required to learn the concept of generic drug and their development, various regulatory filings in different countries, different phases of clinical trials and submitting regulatory documents : filing process of IND, NDA and ANDA

- To know the approval process of
- To know the chemistry, manufacturing controls and their regulatory importance
- To learn the documentation requirements for
- To learn the importance and

Objectives:

Upon completion of the course, it is expected that the students will be able to understand

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

THEORY 60 Hrs

1. a. Documentation in Pharmaceutical industry: Master formula record, DMF (Drug Master File), distribution records. Generic drugs product development Introduction , Hatch- Waxman act and amendments, CFR (CODE OF FEDERAL REGULATION) ,drug product performance, in-vitro, ANDA regulatory approval process, NDA approval process, BE and drug product assessment, in –vivo, scale up process approval changes, post marketing surveillance, outsourcing BA and BE to CRO. — 12 Hrs

   b. Regulatory requirement for product approval: API, biologics, novel, therapies obtaining NDA, ANDA for generic drugs ways and means of US registration for foreign drugs — 12 Hrs

2	CMC, post approval regulatory affairs. Regulation for combination products and medical devices.CTD and ECTD format, industry and FDA liaison. ICH - Guidelines of ICH-Q, S E, M. Regulatory requirements of EU, MHRA, TGA and ROW countries.	12 Hrs
3	Non clinical drug development: Global submission of IND, NDA, ANDA. Investigation of medicinal products dossier, dossier (IMPD) and investigator brochure (IB).	12 Hrs
4	Clinical trials: Developing clinical trial protocols. Institutional review board/ independent ethics committee Formulation and working procedures informed Consent process and procedures. HIPAA- new, requirement to clinical study process, pharmacovigilance safety monitoring in clinical trials.	12 Hrs

REFERENCES

1. Generic Drug Product Development, Solid Oral Dosage forms, Leon Shargel and IsaderKaufer,Marcel Dekker series, Vol.143
2. The Pharmaceutical Regulatory Process, Second Edition Edited by Ira R. Berry and 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. Guidebook 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 Trials and 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.htm
10. https://www.tga.gov.au/tga-basics

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PHARMACEUTICS PRACTICAL - I

(MPH 105PA)

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

PHARMACEUTICS PRACTICAL - II

(MPH 105PB)

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

SEMESTER - II

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

(MPH 201T)

Scope

This course is designed to impart knowledge on the area of advances in novel drug delivery systems.

Objectives

Upon completion of the course student shall be able to understand

- The various approaches for development of novel drug delivery systems.
- The criteria for selection of drugs and polymers for the development of NTDS
- The formulation and evaluation of novel drug delivery systems.

THEORY		60 Hrs
1.	Targeted Drug Delivery Systems: Concepts, Events and biological process involved in drug targeting. Tumor targeting and Brain specific delivery.	12 Hrs
2	Targeting Methods: introduction preparation and evaluation. Nano Particles & Liposomes: Types, preparation and evaluation.	12 Hrs
3	Micro Capsules / Micro Spheres: Types, preparation and evaluation , Monoclonal Antibodies ; preparation and application, preparation and application of Niosomes, Aquasomes, Phytosomes, Electrosomes.	12 Hrs
4	Pulmonary Drug Delivery Systems : Aerosols, propellents, ContainersTypes, preparation and evaluation, Intra Nasal Route Delivery systems; Types, preparation and evaluation.	12 Hrs
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 nonviral gene transfer). Liposomal gene delivery systems. Biodistribution and Pharmacokinetics. knowledge of therapeutic antisense molecules and aptamers as drugs of future.	12 Hrs

REFERENCES

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

ADVANCED BIOPHARMACEUTICS & PHARMACOKINETICS
(MPH 202T)

Scope

This course is designed to impart knowledge and skills necessary for dose calculations, dose adjustments and to apply biopharmaceutics theories in practical problem solving. Basic theoretical discussions of the principles of biopharmaceutics and pharmacokinetics are provided to help the students' to clarify the concepts.

Objectives

Upon completion of this course it is expected that students will be able understand,

- The basic concepts in biopharmaceutics and pharmacokinetics.
- The use raw data and derive the pharmacokinetic models and parameters the best describe the process of drug absorption, distribution, metabolism and elimination.
- The critical evaluation of biopharmaceutic studies involving drug product equivalency.
- The design and evaluation of dosage regimens of the drugs using pharmacokinetic and biopharmaceutic parameters.
- The potential clinical pharmacokinetic problems and application of basics of pharmacokinetic

THEORY	60 Hrs
1. Drug Absorption from the Gastrointestinal Tract: Gastrointestinal tract, Mechanism of drug absorption, Factors affecting drug absorption, pH–partition theory of drug absorption. Formuulation and physicochemical factors: Dissolution rate, Dissolution process, Noyes–Whitney equation and drug dissolution, Factors affecting the dissolution rate. Gastrointestinal absorption: role of the dosage form: Solution (elixir, syrup and solution) as a dosage form ,Suspension as a dosage form, Capsule as a dosage form, Tablet as a dosage form ,Dissolution methods ,Formulation and processing factors, Correlation of in vivo data with in vitro dissolution data.Transport model: Permeability-Solubility-Charge State and the pH Partition Hypothesis, Properties of the Gastrointestinal Tract (GIT), pH Microclimate Intracellular pH Environment, Tight-Junction Complex.	12 Hrs
2 Biopharmaceutic considerations in drug product design and In Vitro Drug Product Performance: Introduction, biopharmaceutic factors affecting drug bioavailability, rate-limiting steps in drug absorption, physicochemical nature of the drug formulation factors affecting drug product performance, in vitro: dissolution and drug release testing, compendial methods of dissolution, alternative methods of dissolution testing,meeting dissolution requirements,problems of variable control in dissolution testingperformance of drug products. In vitro–in vivo correlation, dissolution profile comparisons, drug product stability, considerations in the design of a drug product.	12 Hrs
3 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 of k_{max} and v_{max}. 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.	12 Hrs

4	Drug Product Performance, In Vivo: Bioavailability and Bioequivalence: drug product performance, purpose of bioavailability studies, relative and absolute availability. methods for assessing bioavailability, bioequivalence studies, design and evaluation of bioequivalence studies, study designs, crossover study designs, evaluation of the data, bioequivalence example, study submission and drug review process. biopharmaceutics classification system, methods. Permeability: In-vitro, in-situ and In-vivo methods.generic biologics (biosimilar drug products),clinical significance of bioequivalence studies, special concerns in bioavailability and bioequivalence studies, generic substitution.	12 Hrs
5	Application of Pharmacokinetics: Modified-Release Drug Products, Targeted Drug Delivery Systems and Biotechnological Products. Introduction to Pharmacokinetics and pharmacodynamic, drug interactions. Pharmacokinetics and pharmacodynamics of biotechnology drugs. Introduction, Proteins and peptides, Monoclonal antibodies, Oligonucleotides, Vaccines (immunotherapy), Genetherapies.	12 Hrs

REFERENCES

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

COMPUTER AIDED DRUG DEVELOPMENT
(MPH 203T)

Scope

This course is designed to impart knowledge and skills necessary for computer Applications in pharmaceutical research and development who want to understand the application of computers across the entire drug research and development process. Basic theoretical discussions of the principles of more integrated and coherent use of computerized information (informatics) in the drug development process are provided to help the students to clarify the concepts.

Objectives

Upon completion of this course it is expected that students will be able to understand,

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

THEORY 60 Hrs

1. a. Computers in Pharmaceutical Research and Development: A General Overview: History of Computers in Pharmaceutical Research and Development. Statistical modeling in Pharmaceutical research and development: Descriptive versus Mechanistic Modeling, Statistical Parameters, Estimation, Confidence Regions, Nonlinearity at the Optimum, Sensitivity Analysis, Optimal Design, Population Modeling — 12 Hrs

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

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 Hrs

3	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	12 Hrs
4	a. Computer-aided biopharmaceutical characterization: Gastrointestinal absorption simulation. Introduction, Theoretical background, Model construction, Parameter sensitivity analysis, Virtual trial, Fed vs. fasted state, In vitro dissolution and in vitro- in vivo correlation, Biowaiver considerations b. Computer Simulations in Pharmacokinetics and Pharmacodynamics: Introduction, Computer Simulation: Whole Organism, Isolated Tissues, Organs, Cell, Proteins and Genes. c. Computers in Clinical Development: Clinical Data Collection and Management, Regulation of Computer Systems	12 Hrs
5	Artificial Intelligence (AI), Robotics and Computational fluid dynamics: General overview, Pharmaceutical Automation, Pharmaceutical applications, Advantages and Disadvantages. Current Challenges and Future Directions.	12 Hrs

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.

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ADITYA PHARMACY COLLEGE * SURAMPALEM *

FORMULATION DEVELOPMENT OF PHARMACEUTICAL AND COSMETIC PRODUCTS
(MPH204T)

Scope

This course is designed to impart knowledge and skills necessary to train the students on par with the routine of Industrial activities in R&D and F&D.

Objectives

On completion of this course it is expected that students will be able to understand-
The scheduled activities in a Pharmaceutical firm.
The pre formulation studies of pilot batches of pharmaceutical industry. The significance of dissolution and product stability

THEORY 60 Hrs

1. Preformulation Studies: 12 Hrs
   Molecular optimization of APIs (drug substances), crystal morphology and variations, powder flow, structure modification, drug-excipient compatibility studies, methods of determination.

2. Formulation Additives: 12 Hrs
   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.

3. Solubility & Dissolution: 12 Hrs
   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. Biorelevent media, in-vitro and in-vivo correlations, levels of correlations.

4. Product Stability: 12 Hrs
   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.

5. Cosmetics: 12 Hrs
   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, 3rd ed., Varghese Publishers, Mumbai 1991.
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. I-III, 2nded., CBS Publishers & distributors, New Delhi, 2005.
4. Conners KA. A Text book of pharmaceutical analysis Wells JI. Pharmaceutical preformulation: The physicochemical properties of drug substances. Ellis Horwood Ltd., England, 1998.
5. Yalkowsky SH. Techniques of solubilization of drugs. Vol-12. Marcel Dekker Inc., New York, 1981
6. Dressman J, Kramer J. Pharmaceutical dissolution testing. Saurah printer pvt. Ltd., New Delhi,2005.
7. Sethi PD. Quantitative analysis of drugs in pharmaceutical formulations, 3rd ed., CBS publications, New Delhi, 2008.
8. Carstensen JT, Rhodes CT. Drug stability principles and practices, 3rd ed., CBS Publishers & distributors, New Delhi, 2005.
9. Yoshioka S, Stella VJ. Stability of drugs and dosage forms, Springer (India) Pvt. Ltd., New Delhi, 2006.
10. Banker GS, Rhodes CT. Modern Pharmaceutics, 4th ed., Marcel Dekker Inc, New York, 2005.
11. W. Grimm - Stability testing of drug products.
12. Mazzo DJ. International stability testing. Eastern Press Pvt. Ltd., Bangalore,1999.13. Beckett AH, Stenlake JB. Practical pharmaceutical chemistry, Part I & II., 4th ed., CBS Publishers & distributors, New Delhi, 2004.
13. Indian Pharmacopoeia. Controller of Publication. Delhi, 1996.
14. British Pharmacopoeia. British Pharmacopoeia Commission Office, London, 2008.
15. United States Pharmacopoeia. United States Pharmacopeial Convention, Inc, USA, 2003.
16. Encyclopaedia of Pharm. Technology, Vol I – III.
17. Wells J. I. Pharmaceutical Preformulation : The physicochemical properties of drug substances, Ellis Horwood Ltd. England, 1988.
18. Harry's Cosmeticology. 8th edition.
19. Poucher's perfume cosmetics and Soaps,10th edition.
20. Cosmetics - Formulation, Manufacture and quality control, PP.Sharma,4th edition
21. Handbook of cosmetic science and Technology A.O.Barel, M.Paye and H.I. Maibach. 3 rd edition

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PHARMACEUTICS PRACTICAL - III
(MPH 205PA)

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
4. Formulation and evaluation of liposomes/niosomes
5. Formulation and evaluation of spherules
6. Improvement of dissolution characteristics of slightly soluble drug by Solid dispersion technique.
7. Comparison of dissolution of two different marketed products /brands
8. Protein binding studies of a highly protein bound drug & poorly protein bound drug
9. Bioavailability studies of Paracetamol in animals.
10. Pharmacokinetic and IVIVC data analysis by Winnoline^{R} software
11. In vitro cell studies for permeability and metabolism

PHARMACEUTICS PRACTICAL - IV
(MPH 205PB)

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

Semester III

MRM 301T - Research Methodology & Biostatistics

UNIT – I

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

UNIT – II

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

UNIT – III

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

UNIT – IV

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

UNIT – V

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

R-13 Technology
16-17

ACADEMIC REGULATIONS COURSE STRUCTURE AND DETAILED SYLLABUS

For
M.PHARMACY
Pharmaceutical Technology

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY KAKINADA
KAKINADA - 533 003, Andhra Pradesh, India

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JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY: KAKINADA
KAKINADA - 533 003, Andhra Pradesh, India

ACADEMIC REGULATIONS R13 FOR M. Tech (REGULAR) DEGREE COURSE

Applicable for the students of M. Tech (Regular) Course from the Academic Year 2013-14 onwards

The M. Tech Degree of Jawaharlal Nehru Technological University Kakinada shall be conferred on candidates who are admitted to the program and who fulfil all the requirements for the award of the Degree.

1.0 ELIGIBILITY FOR ADMISSIONS

Admission to the above program shall be made subject to eligibility, qualification and specialization as prescribed by the University from time to time.

Admissions shall be made on the basis of merit/rank obtained by the candidates at the qualifying Entrance Test conducted by the University or on the basis of any other order of merit as approved by the University, subject to reservations as laid down by the Govt. from time to time.

2.0 AWARD OF M. Tech DEGREE

2.1 A student shall be declared eligible for the award of the M. Tech Degree, if he pursues a course of study in not less than two and not more than four academic years.
2.2 The student shall register for all 80 credits and secure all the 80 credits.
2.3 The minimum instruction days in each semester are 90.

3.0 A. COURSES OF STUDY

The following specializations are offered at present for the M. Tech course of study.

1. M.Tech- Structural Engineering
2. M.Tech- Transportation Engineering
3. M.Tech- Infrastructure Engineering & Management
4. ME- Soil Mechanics and Foundation Engineering
5. M.Tech- Power Electronics
6. M.Tech- Power & Industrial Drives
7. M.Tech- Power Electronics & Electrical Drives
8. M.Tech- Power System Control & Automation
9. M.Tech- Power Electronics & Drives
10. M.Tech- Power Systems
11. M.Tech- Power Systems Engineering
12. M.Tech- High Voltage Engineering
13. M.Tech- Power Electronics and Power Systems
14. M.Tech- Power System and Control
15. M.Tech- Power Electronics & Systems
16. M.Tech- Electrical Machines and Drives
17. M.Tech- Advanced Power Systems
18. M.Tech- Power Systems with Emphasis on High Voltage Engineering
19. M.Tech- Control Engineering
20. M.Tech- Instrumentation & Control
21. M.Tech- Control Systems
22. M.Tech- Thermal Engineering
23. M.Tech- CAD/CAM
24. M.Tech- Machine Design
25. M.Tech- Computer Aided Design and Manufacture
26. M.Tech- Advanced Manufacturing Systems
27. M.Tech- Systems and Signal Processing

28. M.Tech- Digital Electronics and Communication Systems
29. M.Tech- Electronics & Communications Engineering
30. M.Tech- Communication Systems
31. M.Tech- Communication Engineering & Signal Processing
32. M.Tech- Microwave and Communication Engineering
33. M.Tech- Telematics
34. M.Tech- Digital Systems & Computer Electronics
35. M.Tech- Embedded System
36. M.Tech- VLSI
37. M.Tech- VLSI Design
38. M.Tech- VLSI System Design
39. M.Tech- Embedded System & VLSI Design
40. M.Tech- VLSI & Embedded System
41. M.Tech- VLSI Design & Embedded Systems
42. M.Tech- Computer Science & Engineering
43. M.Tech- Computer Science
44. M.Tech- Computer Science & Technology
45. M.Tech- Image Processing
46. M.Tech- Digital Image Processing
47. M.Tech- Computers & Communication
48. M.Tech- Computers & Communication Engineering
49. M.Tech- Computer Networks
50. M.Tech- Computer Networks & Information Security
51. M.Tech- Information Technology
52. M.Tech- Software Engineering
53. M.Tech- Neural Networks
54. M.Tech- Chemical Engineering
55. M.Tech- Biotechnology
56. M.Tech- Nano Technology
57. M.Tech- Remote Sensing
58. M.Tech- Food Processing
59. M.Tech- Avionics

and any other course as approved by AICTE/ University from time to time.

ADITYA PHARMACY COLLEGE SURAMPALEM

PRINCIPAL
Aditya Pharmacy College
SURAMPALEM-533 437

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY: KAKINADA
KAKINADA - 533 003, Andhra Pradesh, India

3.0 B. Departments offering M. Tech Programmes with specializations are noted below:

Civil Engg.	1. M.Tech- Structural Engineering 2. M.Tech- Transportation Engineering 3. M.Tech- Infrastructure Engineering & Management 4. ME- Soil Mechanics and Foundation Engineering
EEE	1. M.Tech- Power Electronics 2. M.Tech- Power & Industrial Drives 3. M.Tech- Power Electronics & Electrical Drives 4. M.Tech- Power System Control & Automation 5. M.Tech- Power Electronics & Drives 6. M.Tech- Power Systems 7. M.Tech- Power Systems Engineering 8. M.Tech- High Voltage Engineering 9. M.Tech- Power Electronics and Power Systems 10. M.Tech- Power System and Control 11. M.Tech- Power Electronics & Systems 12. M.Tech- Electrical Machines and Drives 13. M.Tech- Advanced Power Systems 14. M.Tech- Power Systems with Emphasis on High Voltage Engineering 15. M.Tech- Control Engineering 16. M.Tech- Instrumentation & Control 17. M.Tech- Control Systems
ME	1. M.Tech- Thermal Engineering 2. M.Tech- CAD/CAM 3. M.Tech- Machine Design 4. M.Tech- Computer Aided Design and Manufacture 5. M.Tech- Advanced Manufacturing Systems
ECE	1. M.Tech- Systems and Signal Processing 2. M.Tech- Digital Electronics and Communication Systems 3. M.Tech- Electronics & Communications Engineering 4. M.Tech- Communication Systems 5. M.Tech- Communication Engineering & Signal Processing 6. M.Tech- Microwave and Communication Engineering 7. M.Tech- Telematics 8. M.Tech- Digital Systems & Computer Electronics 9. M.Tech- Embedded System 10. M.Tech- VLSI 11. M.Tech- VLSI Design 12. M.Tech- VLSI System Design 13. M.Tech- Embedded System & VLSI Design 14. M.Tech- VLSI & Embedded System 15. M.Tech- VLSI Design & Embedded Systems 16. M.Tech- Image Processing 17. M.Tech- Digital Image Processing 18. M.Tech- Computers & Communication 19. M.Tech- Computers & Communication Engineering
CSE	1. M.Tech- Computer Science & Engineering 2. M.Tech- Computer Science 3. M.Tech- Computer Science & Technology 4. M.Tech- Computer Networks

	5. M.Tech- Computer Networks & Information Security 6. M.Tech- Information Technology 7. M.Tech- Software Engineering 8. M.Tech- Neural Networks
Others	1. M.Tech- Chemical Engineering 2. M.Tech- Biotechnology 3. M.Tech- Nano Technology 4. M.Tech- Remote Sensing 5. M.Tech- Food Processing 6. M.Tech- Avionics

4.0 ATTENDANCE

4.1 A student shall be eligible to write University examinations if he acquires a minimum of 75% of attendance in aggregate of all the subjects.

4.2 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.

4.3 Shortage of Attendance below 65% in aggregate shall not be condoned.

4.4 Students whose shortage of attendance is not condoned in any semester are not eligible to write their end semester examination of that class.

4.5 A prescribed fee shall be payable towards condonation of shortage of attendance.

4.6 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 readmission into that semester when offered next. If any candidate fulfills the attendance requirement in the present semester, he shall not be eligible for readmission into the same class.

5.0 EVALUATION

The performance of the candidate in each semester shall be evaluated subject-wise, with a maximum of 100 marks for theory and 100 marks for practicals, on the basis of Internal Evaluation and End Semester Examination.

5.1 For the theory subjects 60 marks shall be awarded based on the performance in the End Semester Examination and 40 marks shall be awarded based on the Internal Evaluation. The internal evaluation shall be made based on the **average** of the marks secured in the two Mid Term-Examinations conducted-one in the middle of the Semester and the other immediately after the completion of instruction. Each mid term examination shall be conducted for a total duration of 120 minutes with 4 questions (without choice) each question for 10 marks. End semester examination is conducted for 60 marks for 5 questions to be answered out of 8 questions.

5.2 For practical subjects, 60 marks shall be awarded based on the performance in the End Semester Examinations and 40 marks shall be awarded based on the day-to-day performance as Internal Marks.

5.3 There shall be two seminar presentations during III semester and IV semester. For seminar, a student under the supervision of a faculty member, shall collect the literature on a topic and critically review the literature and submit it to the department in a report form and shall make an oral presentation before the Project Review Committee consisting of Head of the Department, Supervisor and two other senior faculty members of the department. For each Seminar there will be only internal evaluation of 50 marks. A candidate has to secure a minimum of 50% of marks to be declared successful.

5.4 A candidate shall be deemed to have secured the minimum academic requirement in a subject if he secures a minimum of 40% of marks in the End semester Examination and a minimum aggregate of 50% of the total marks in the End Semester Examination and Internal Evaluation taken together.

5.5 In case the candidate does not secure the minimum academic requirement in any subject (as specified in 5.4) he has to reappear for the End semester Examination in that subject. A candidate shall be given one chance to re-register for each subject provided the internal marks secured by a candidate are less than 50% and has failed in the end examination. In such a case, the candidate must re-register for the subject(s) and secure the required minimum attendance. The candidate's attendance in the re-registered subject(s) shall be calculated separately to decide upon his eligibility for writing the end examination in those subject(s). In the event of the student taking another chance, his internal marks and end examination marks obtained in the previous attempt stand cancelled. For re-registration the

candidates have to apply to the University through the college by paying the requisite fees and get approval from the University before the start of the semester in which re-registration is required.

5.6 In case the candidate secures less than the required attendance in any re registered subject (s), he shall not be permitted to write the End Examination in that subject. He shall again re-register the subject when next offered.

5.7 Laboratory examination for M. Tech. courses must be conducted with two Examiners, one of them being the Laboratory Class Teacher or teacher of the respective college and the second examiner shall be appointed by the university from the panel of examiners submitted by the respective college.

6.0 EVALUATION OF PROJECT/DISSERTATION WORK

Every candidate shall be required to submit a thesis or dissertation on a topic approved by the Project Review Committee.

6.1 A Project Review Committee (PRC) shall be constituted with Head of the Department and two other senior faculty members.

6.2 Registration of Project Work: A candidate is permitted to register for the project work after satisfying the attendance requirement of all the subjects, both theory and practical.

6.3 After satisfying 6.2, a candidate has to submit, in consultation with his project supervisor, the title, objective and plan of action of his project work for approval. The student can initiate the Project work, only after obtaining the approval from the Project Review Committee (PRC).

6.4 If a candidate wishes to change his supervisor or topic of the project, he can do so with the approval of the Project Review Committee (PRC). However, the Project Review Committee (PRC) shall examine whether or not the change of topic/supervisor leads to a major change of his initial plans of project proposal. If yes, his date of registration for the project work starts from the date of change of Supervisor or topic as the case may be.

6.5 A candidate shall submit his status report in two stages at least with a gap of 3 months between them.

6.6 The work on the project shall be initiated at the beginning of the II year and the duration of the project is two semesters. A candidate is permitted to submit Project Thesis only after successful completion of theory and practical course with the approval of PRC not earlier than 40 weeks from the date of registration of the project work. The candidate has to pass all the theory and practical subjects before submission of the Thesis.

6.7 Three copies of the Project Thesis certified by the supervisor shall be submitted to the College/School/Institute.

6.8 The thesis shall be adjudicated by one examiner selected by the University. For this, the Principal of the College shall submit a panel of 5 examiners, eminent in that field, with the help of the guide concerned and head of the department.

6.9 If the report of the examiner is not favourable, the candidate shall revise and resubmit the Thesis, in the time frame as decided by the PRC. If the report of the examiner is unfavorable again, the thesis shall be summarily rejected. The candidate has to re-register for the project and complete the project within the stipulated time after taking the approval from the University.

6.10 If the report of the examiner is favourable, Viva-Voce examination shall be conducted by a board consisting of the Supervisor, Head of the Department and the examiner who adjudicated the Thesis. The Board shall jointly report the candidate's work as one of the following:

A. Excellent
B. Good
C. Satisfactory
D. Unsatisfactory

The Head of the Department shall coordinate and make arrangements for the conduct of Viva-Voce examination.

6.11 If the report of the Viva-Voce is unsatisfactory, the candidate shall retake the Viva-Voce examination only after three months. If he fails to get a satisfactory report at the second Viva-Voce examination, the candidate has to re-register for the project and complete the project within the stipulated time after taking the approval from the University.

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7.0 AWARD OF DEGREE AND CLASS

After a student has satisfied the requirements prescribed for the completion of the program and is eligible for the award of M. Tech. Degree he shall be placed in one of the following four classes:

Class Awarded	% of marks to be secured
First Class with Distinction	70% and above (Without any Supplementary Appearance)
First Class	Below 70% but not less than 60%
	70% and above (With any Supplementary Appearance)
Second Class	Below 60% but not less than 50%

The marks in internal evaluation and end examination shall be shown separately in the memorandum of marks.

8.0 WITHHOLDING OF RESULTS

If the student has not paid the dues, if any, to the university or if any case of indiscipline is pending against him, the result of the student will be withheld. His degree will be withheld in such cases.

8.0 TRANSITORY REGULATIONS (for R09)

9.1 Discontinued or detained candidates are eligible for re-admission into same or equivalent subjects at a time as and when offered.

9.2 The candidate who fails in any subject will be given two chances to pass the same subject; otherwise, he has to identify an equivalent subject as per R13 academic regulations.

10. GENERAL

10.1 Wherever the words "he", "him", "his", occur in the regulations, they include "she", "her", "hers".

10.2 The academic regulation should be read as a whole for the purpose of any interpretation.

10.3 In the case of any doubt or ambiguity in the interpretation of the above rules, the decision of the Vice-Chancellor is final.

10.4 The University may change or amend the academic regulations or syllabi at any time and the changes or amendments made shall be applicable to all the students with effect from the dates notified by the University.

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MALPRACTICES RULES

DISCIPLINARY ACTION FOR / IMPROPER CONDUCT IN EXAMINATIONS

	Nature of Malpractices/Improper conduct	Punishment
	If the candidate:	
1. (a)	Possesses or keeps accessible in examination hall, any paper, note book, programmable calculators, Cell phones, pager, palm computers or any other form of material concerned with or related to the subject of the examination (theory or practical) in which he is appearing but has not made use of (material shall include any marks on the body of the candidate which can be used as an aid in the subject of the examination)	Expulsion from the examination hall and cancellation of the performance in that subject only.
(b)	Gives assistance or guidance or receives it from any other candidate orally or by any other body language methods or communicates through cell phones with any candidate or persons in or outside the exam hall in respect of any matter.	Expulsion from the examination hall and cancellation of the performance in that subject only of all the candidates involved. In case of an outsider, he will be handed over to the police and a case is registered against him.
2.	Has copied in the examination hall from any paper, book, programmable calculators, palm computers or any other form of material relevant to the subject of the examination (theory or practical) in which the candidate is appearing.	Expulsion from the examination hall and cancellation of the performance in that subject and all other subjects the candidate has already appeared including practical examinations and project work and shall not be permitted to appear for the remaining examinations of the subjects of that Semester/year. The Hall Ticket of the candidate is to be cancelled and sent to the University.
3.	Impersonates any other candidate in connection with the examination.	The candidate who has impersonated shall be expelled from examination hall. The candidate is also debarred and forfeits the seat. The performance of the original candidate who has been impersonated, shall be cancelled in all the subjects of the examination (including practicals and project work) already appeared and shall not be allowed to appear for examinations of the remaining subjects of that semester/year. The candidate is also debarred for two consecutive semesters from class work and all University examinations. The continuation of the course by the candidate is subject to the academic regulations in connection with forfeiture of seat. If the imposter is an outsider, he will be handed over to the police and a case is registered against him.
4.	Smuggles in the Answer book or additional sheet or takes out or arranges to send out the question paper during the examination or answer book or additional sheet, during or after the examination.	Expulsion from the examination hall and cancellation of performance in that subject and all the other subjects the candidate has already appeared including practical examinations and project work and shall not be permitted for the remaining examinations of the subjects of that semester/year. The candidate is also debarred for two consecutive semesters from class work and all University examinations. The continuation of the course by the candidate is subject to the academic regulations in connection with forfeiture of seat.
5.	Uses objectionable, abusive or offensive language in the answer paper or in letters to the examiners or writes to the examiner requesting him to award pass marks.	Cancellation of the performance in that subject.

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6.	Refuses to obey the orders of the Chief Superintendent/Assistant – Superintendent / any officer on duty or misbehaves or creates disturbance of any kind in and around the examination hall or organizes a walk out or instigates others to walk out, or threatens the officer-in charge or any person on duty in or outside the examination hall of any injury to his person or to any of his relations whether by words, either spoken or written or by signs or by visible representation, assaults the officer-in-charge, or any person on duty in or outside the examination hall or any of his relations, or indulges in any other act of misconduct or mischief which result in damage to or destruction of property in the examination hall or any part of the College campus or engages in any other act which in the opinion of the officer on duty amounts to use of unfair means or misconduct or has the tendency to disrupt the orderly conduct of the examination.	In case of students of the college, they shall be expelled from examination halls and cancellation of their performance in that subject and all other subjects the candidate(s) has (have) already appeared and shall not be permitted to appear for the remaining examinations of the subjects of that semester/year. The candidates also are debarred and forfeit their seats. In case of outsiders, they will be handed over to the police and a police case is registered against them.
7.	Leaves the exam hall taking away answer script or intentionally tears of the script or any part thereof inside or outside the examination hall.	Expulsion from the examination hall and cancellation of performance in that subject and all the other subjects the candidate has already appeared including practical examinations and project work and shall not be permitted for the remaining examinations of the subjects of that semester/year. The candidate is also debarred for two consecutive semesters from class work and all University examinations. The continuation of the course by the candidate is subject to the academic regulations in connection with forfeiture of seat.
8.	Possess any lethal weapon or firearm in the examination hall.	Expulsion from the examination hall and cancellation of the performance in that subject and all other subjects the candidate has already appeared including practical examinations and project work and shall not be permitted for the remaining examinations of the subjects of that semester/year. The candidate is also debarred and forfeits the seat.
9.	If student of the college, who is not a candidate for the particular examination or any person not connected with the college indulges in any malpractice or improper conduct mentioned in clause 6 to 8.	Student of the colleges expulsion from the examination hall and cancellation of the performance in that subject and all other subjects the candidate has already appeared including practical examinations and project work and shall not be permitted for the remaining examinations of the subjects of that semester/year. The candidate is also debarred and forfeits the seat. Person(s) who do not belong to the College will be handed over to police and, a police case will be registered against them.
10.	Comes in a drunken condition to the examination hall.	Expulsion from the examination hall and cancellation of the performance in that subject and all other subjects the candidate has already appeared including practical examinations and project work and shall not be permitted for the remaining examinations of the subjects of that semester/year.
11.	Copying detected on the basis of internal evidence, such as, during valuation or during special scrutiny.	Cancellation of the performance in that subject and all other subjects the candidate has appeared including practical examinations and project work of that semester/year examinations.
12.	If any malpractice is detected which is not covered in the above clauses 1 to 11 shall be reported to the University for further action to award suitable punishment.	

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Malpractices identified by squad or special invigilators

1. Punishments to the candidates as per the above guidelines.
2. Punishment for institutions : (if the squad reports that the college is also involved in encouraging malpractices)
   - (i) A show cause notice shall be issued to the college.
   - (ii) Impose a suitable fine on the college.
   - (iii) Shifting the examination centre from the college to another college for a specific period of not less than one year.

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JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY: KAKINADA
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For Constituent Colleges and Affiliated Colleges of JNTUK

Ragging

Prohibition of ragging in educational institutions Act 26 of 1997

Salient Features

- ⇨ Ragging within or outside any educational institution is prohibited.
- ⇨ Ragging means doing an act which causes or is likely to cause Insult or Annoyance of Fear or Apprehension or Threat or Intimidation or outrage of modesty or Injury to a student

	Imprisonment upto		Fine Upto
Teasing, Embarrassing and Humiliation	6 Months	+	Rs. 1,000/-
Assaulting or Using Criminal force or Criminal intimidation	1 Year	+	Rs. 2,000/-
Wrongfully restraining or confining or causing hurt	2 Years	+	Rs. 5,000/-
Causing grievous hurt, kidnapping or Abducts or rape or committing unnatural offence	5 Years	+	Rs. 10,000/-
Causing death or abetting suicide	10 Months	+	Rs. 50,000/-

In Case of Emergency CALL TOLL FREE NO. : 1800 - 425 - 1288

LET US MAKE JNTUK A RAGGING FREE UNIVERSITY

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Ragging

ABSOLUTELY NO TO RAGGING

1. Ragging is prohibited as per Act 26 of A.P. Legislative Assembly, 1997.
2. Ragging entails heavy fines and/or imprisonment.
3. Ragging invokes suspension and dismissal from the College.
4. Outsiders are prohibited from entering the College and Hostel without permission.
5. Girl students must be in their hostel rooms by 7.00 p.m.
6. All the students must carry their Identity Cards and show them when demanded
7. The Principal and the Wardens may visit the Hostels and inspect the rooms any time.

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M.PHARMACY

PHARMACEUTICAL TECHNOLOGY

I SEMESTER

Paper 101	-	Modern Analytical Techniques
Paper 102	-	Research Methodologies
Paper 103	-	Biopharmaceutics & Pharmacokinetics
Paper 104	-	Advanced Physical Pharmaceutics
Paper 105	-	Biopharmaceutics & Pharmacokinetics - LAB
Paper 106	-	Advanced Physical Pharmaceutics - LAB
Paper 107	-	Seminar

II SEMESTER

Paper 201	-	Advanced Pharmaceutical Technology - I
Paper 202	-	Advances In Drug Delivery Systems
Paper 203	-	Advanced Pharmaceutical Technology - II
Paper 204	-	Drug Regulatory Affairs
Paper 205	-	Advanced Pharmaceutical Technology - LAB
Paper 206	-	Advances In Drug Delivery Systems - LAB
Paper 207	-	Seminar

III SEMESTER

Paper 301	-	Seminar-I
Paper 302	-	Project Work – I

IV SEMESTER

Paper 401	-	Seminar-II
Paper 402	-	Project Work – II
Paper 403	-	Comprehensive Viva Voce

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SCHEME OF INSTRUCTIONS AND EVALUATION

PHARMACEUTICAL TECHNOLOGY

I SEMESTER							
Paper No.	Title of the Paper	Evaluation / Marks				Total	Credits
		Theory		Practical			
		Mid Examination	University End Examination	Mid Examination	University End Examination		
Paper – 101	Modern Analytical Techniques	40	60			100	3
Paper – 102	Research Methodologies	40	60			100	3
Paper – 103	Biopharmaceutics & Pharcokinetics	40	60			100	3
Paper – 104	Advanced Physical Pharmaceutics	40	60			100	3
Paper – 105	Biopharmaceutics & Pharcokinetics			40	60	100	2
Paper – 106	Advanced Physical Pharmaceutics			40	60	100	2
Paper – 107	Seminar					100	2
	TOTAL					700	18

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II SEMESTER							
Paper No.	Title of the Paper	Evaluation / Marks				Total	Credits
		Theory		Practical			
		Mid Examination	University End Examination	Mid Examination	University End Examination		
Paper – 201	Advanced Pharmaceutical Technology - I	40	60			100	3
Paper –202	Advances in Drug Delivery Systems	40	60			100	3
Paper – 203	Advanced Pharmaceutical Technology - II	40	60			100	3
Paper – 204	Drug Regulatory affairs	40	60			100	3
Paper – 205	Advanced Pharmaceutical Technology			40	60	100	2
Paper – 206	Advances in Drug Delivery Systems			40	60	100	2
Paper – 207	Seminar					100	2
	TOTAL					700	18

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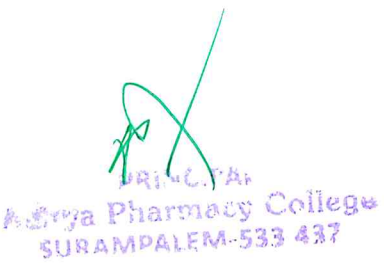
III SEMESTER			
Paper No.		Marks	Credits
Paper - 301	Seminar – I	50	2
Paper - 302	Project work – I	100	14
	Total	150	16

IV SEMESTER			
Paper No.		Marks	Credits
Paper - 401	Seminar – II	50	2
Paper – 402	Project work – II	100	14
Paper - 403	Comprehensive Viva Voce	100	4
	Total	250	20
Grand Total (Four Semesters)		1800	72



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M.PHARM (PHARMACEUTICS)

I-I	**MODERN ANALYTICAL TECHNIQUES**	**L / P / Credits**
	(Paper Common for all Specializations)	**-- / -- / 3**

Principles, instrumentation and applications of the following Instruments and Chromatography techniques

Unit- I

i. UV- Visible spectrophotometry
ii. Infrared spectroscopy
iii. Spectrofluorimetry

Unit- II

i. NMR spectroscopy
ii. Electron Spin Resonance spectroscopy
iii. Atomic Emission spectroscopy

Unit- III

i. HPLC
ii. HPTLC
iii. Exclusion chromatography
iv. Super critical fluid chromatography

Unit- IV

i. Mass Spectroscopy including LCMS & GCMS
ii. GLC

Unit- V

i. Phase Emission spectroscopy
ii. X-Ray diffractometry
iii. Optical Rotatory Diffusion
iv. Vapour phase chromatography
v. Affinity chromatography
vi. Ion-exchange chromatography

TEXT BOOKS

1. Practical Pharmaceutical Chemistry Vol. 1 &II by Beckett & Stenlake.
2. Instrumental Methods of Analysis by Scog and West.
3. Instrumental Methods of Analysis by B.K.Sharma
4. Vogel's text book of Quantitative Chemical Analysis.
5. Instrumental methods of Analysis by Willard & Merrit.
6. A text book of Pharmaceutical Analysis by K. A. Conners.

REFERENCE BOOKS

1. I.P.
2. B.P.
3. U.S.P.
4. Remington's Pharmaceutical Sciences.
5. Spectroscopy b Silversterin

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I-I	RESEARCH METHODOLOGIES (Paper common for all Specializations)	L / P / Credits -- / -- / 3

UNIT I

Statistical Methods:

Chance Variation – Probability Distribution - Normal Distribution – Sampling Distribution Error and its significance-Measures of Error- Control of Error in Experimental Investigations – Problem Solving.

UNIT II

Correlation and Regression., Multiple Regression - Problem Solving

UNIT III

Tests of Significance: Principles, t-test, z-test, F-ratio test, Chi-square test, Non-parametric tests- their applications in pharmacy research with examples – Problem Solving.

UNIT IV

Design of Experiments

Criteria of a good design with examples.

Principles- Randomization, replication and local control.

Study of CRD, RBD, LSD and factorial designs- their applications in Pharmacy research with examples – Problem Solving.

UNIT V

Analysis of Variance (ANOVA) – one way, two way and three way – principles and applications in pharmacy research- Problem Solving

Optimisation Techniques : Optimisation Techniques based on Factorial Experiments - Problem Solving.

Text & Referrence Books :

1. Fundamentals of Biostatistics by Khan & Khanum,Third Revised Edition, Ukaaz Publications, Hyderabad
2. Theory & Practice of Industrial Pharmacy by Leon Lachman and Others
3. Remingtons Practice of Pharmaceutical sciences, (Latest Edition)
4. Principles of Biostatistics by Marcello Pagnano, Published by Brooks/Cole, (Saurabh Printers Pvt. Ltd)

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I-I BIOPHARMACEUTICS & PHARMACOKINETICS L / P / Credits
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UNIT - I

Bio-availability Bioequivalence and Therapeutic equivalence: Designing of bioavailability studies and interpretation of results.

Physicochemical properties affecting bioavailability, pH-partition theory, dissolution, surface area adsorption, complexion, polymorphism and techniques of enhancing dissolution rate.

Formulation factors affecting bioavailability of drugs in dosage forms of Tablets, capsules, parenterals, liquid orals and topical dosage forms.

UNIT - II

Basic concepts of Pharmacokinetics: Compartmental models: One, Two and non-compartmental approaches to Pharmacokinetics. Recent trends, merits and limitations of these approaches. Application of these models to determine the various pharmacokinetic parameters pertaining to:

a) Absorption: (wherever applicable) absorption rate constant, Absorption half time, lag time and extent of absorption, AUC.
b) Distribution: Apparent volume of distribution and its determination.
c) Metabolism: Metabolic rate constant
d) Elimination: Over all apparent elimination rate constant and half life under the following conditions:
    i. Intravenous bolus injection.
    ii. Intravenous infusion.

UNIT - III

Elimination: Over all apparent elimination rate constant and half life under the following conditions:

i. Single dose oral administration.
ii. Multiple dose injections.
iii. Multiple dosage oral administration

Non invasive methods of estimating Pharmacokinetic parameters with emphasis on salivary and urinary compartments.

Concept of clearance: Organ clearance, total clearance, hepatic clearance, lung clearance and renal clearance.

UNIT - IV

Non-linear Pharmacokinetics: Concepts of linear and non linear pharmacokinetics, Michaelis - Menton kinetics characteristics. Basic kinetic parameters, possible causes of non induction, non linear binding, non linearity of pharmacological responses.

Time dependent pharmacokinetics: Introduction, classification, physiologically induced time dependency: Chronopharmacokinetics, chemically induced dependency.

Drug Metabolism - sites of metabolism, factors affecting drug metabolism (genetic, species and environmental).

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UNIT - V

Clinical pharmacokinetics: Altered kinetics in pregnancy, child birth, infants and geriatrics. Kinetics in GI disease, malabsorption syndrome, Liver, cardiac, renal and pulmonary disease states.

Drug interactions: Kinetics of drug interaction, study of drug-drug interactions mediated through absorption, distribution, metabolism and elimination, mechanisms of interaction and consequence. Influence of alcohol, smoking, food and beverages on drug action.

REFERENCES:

1. Biopharmaceutics and clinical Pharmacokinetics by Milo Gibaldi.
2. Remington's Pharmaceutical Sciences by Mack publishing company, Pennsylvania.
3. Pharmacokinetics by Milo Gibaldi, Donald Perrier; Marcel Dekker, Inc.
4. Handbook of clinical Pharmacokinetics by Milo Gibaldi and Laurie Prescott by ADIS Health Science Press.
5. Biopharmaceutics and Pharmacokinetics by Robert E. Notari.
6. Biopharmaceutics by Swarbrick.
7. Biopharmaceuties and Pharmacokinetics- A Treatise by D.M.Brahmankar and Sunil B.Jaiswal., Vallabh Prakashan Pitampura, Delhi.
8. Clinical Pharmacokinetics, Concepts and Applications by Malcolm Rowland and Thomas N.Tozer. Lea and Febiger, Philadelphia, 1995.
9. Dissolution, Bioavailability and Bioequivalence by Abdou. H.M., Mack Publishing Company, Pennsylvania, 1989.
10. Biopharmaceutics and Clinical Pharmacokinetics- An introduction; 4th edition, Revised and expanded By Robert. E. Notari, Marcel Dekker Inc, New York and Basel, 1987.
11. Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James. C.Boylan. Marcel Dekker Inc, New York, 1996.

PRINCIPAL
Aditya Pharmacy College
SURAMPALEM-533 437

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY: KAKINADA
KAKINADA - 533 003, Andhra Pradesh, India

I-I ADVANCED PHYSICAL PHARMACEUTICS L / P / Credits
-- / -- / 3

UNIT – I

Particle science and powder technology: Crystal structure, Amorphous state, Polymorphism, particle size distribution, particle size analysis methods. Solid dispersions/solid solutions.
Physics of tablet compression: Compression, consolidation strength of granules, compression and consolidation under high loads, effect of friction, distribution of forces in compaction, force volume relationships, Heckel plots, compaction profiles, energy involved in compaction, strength of tablet, crushing strength, friability, lamination, instrumentation of tablet machines.

UNIT - II

Dissolution and solubility: Solubility and solubilisation of non electrolytes, solubilisation by the use of surfactants, cosolvents, complexation, drug derivatisation and solid state manipulation, dissolution rates of solids in liquids, measurement of dissolution rates
Theories on stability of disperse systems: Adsorption, wetting, crystal growth mechanisms, physical stability of suspensions and emulsions, stability testing of emulsions and suspension and release of drugs from suspensions and emulsion formulations. Biopharmaceutical aspects of disperse systems.

UNIT - III

Rheology: Theoretical consideration, instrumentation, rheological properties of disperse systems and semi solids.
Polymer science: Properties of polymers, thermodynamics of polymer solution, phase separation, polymers in solid state, applications of polymers in pharmaceutical formulations

UNIT - IV

Kinetics and drug stability: stability calculations, rate equation, Complex order Kinetics, kinetics of some decompositions, strategy of stability testing, methods of stabilization, methods of accelerated stability testing in dosage forms, Freeze-Thaw methods, centrifugal methods, temperature and humidity control, Physical stability testing of pharmaceutical products.

Unit – V

Physical properties, instrumental analysis of drug molecules, Differential Thermal Analysis, Differential Scanning Calorimetry, Diffusive Reflective Spectrophotometry, X-Ray Diffraction Analysis.

REFERENCES:

1. Physical Pharmacy; By Alfred martin
2. Remington's Pharmaceutical Sciences.
3. Theory and Practice of Industrial Pharmacy By Lachmann and Libermann.
4. Pharmaceutical Preformulations; By J.J. Wells.
5. Modern Pharmaceutics; By Gillbert and S. Banker.
6. Instrumental Methods of Chemical Analysis – B. K. Sharma - 9th Edition.
7. Principles of Instrumental Analysis by Donglas A. Skoog, James, J. Leary, 4th Edition.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY: KAKINADA
KAKINADA - 533 003, Andhra Pradesh, India

I-I	**BIO PHARMACEUTICS & PHARMACOKINETICS LAB**	**L / P / Credits** -- / -- / 2

(Experiments based on Theory)

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY: KAKINADA
KAKINADA - 533 003, Andhra Pradesh, India

I-I	ADVANCED PHYSICAL PHARMACEUTICS LAB	L / P / Credits
		-- / -- / 2

(Experiments based on theory)

Courses - R-13
16-17

M.PHARMACY

PHARMACEUTICS

I SEMESTER

Paper 101	-	Modern Analytical Techniques
Paper 102	-	Research Methodologies
Paper 103	-	Biopharmaceutics & Pharmacokinetics
Paper 104	-	Advanced Physical Pharmaceutics
Paper 105	-	Biopharmaceutics & Pharmacokinetics - LAB
Paper 106	-	Advanced Physical Pharmaceutics - LAB
Paper 107	-	Seminar

II SEMESTER

Paper 201	-	Advanced Pharmaceutical Technology
Paper 202	-	Advances In Drug Delivery Systems
Paper 203	-	Industrial Pharmacy
Paper 204	-	Drug Regulatory Affairs
Paper 205	-	Advanced Pharmaceutical Technology - LAB
Paper 206	-	Advances In Drug Delivery Systems - LAB
Paper 207	-	Seminar

III SEMESTER

Paper 301	-	Project Seminar-I (On the proposed project work with aims and objectives) - 50 Marks
Paper 302	-	Project work - I

IV SEMESTER

Paper 401	-	Project Seminar-II (On the experimentation and results of the project work) – 50 Marks
Paper 402	-	Project work - II

ADITYA PHARMACY COLLEGE SURAMPALEM

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SURAMPALEM-533 437

SCHEME OF INSTRUCTIONS AND EVALUATION

PHARMACEUTICS

FIRST SEMESTER

Paper No.	Title of the Paper	Evaluation / Marks				Total	Credits
		Theory		Practical			
		Mid Examination	University End Examination	Mid Examination	University End Examination		
Paper – 101	Modern Analytical Techniques	40	60			100	3
Paper – 102	Research Methodologies	40	60			100	3
Paper – 103	Biopharmaceutics & Pharcokinetics	40	60			100	3
Paper – 104	Advanced Physical Pharmaceutics	40	60			100	3
Paper – 105	Biopharmaceutics & Pharcokinetics			40	60	100	2
Paper – 106	Advanced Physical Pharmaceutics			40	60	100	2
Paper – 107	Seminar					100	2
	TOTAL					700	18

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SECOND SEMESTER

Paper No.	Title of the Paper	Evaluation / Marks				Total	Credits
		Theory		Practical			
		Mid Examination	University End Examination	Mid Examination	University End Examination		
Paper – 201	Advanced Pharmaceutical Technology	40	60			100	3
Paper –202	Advances in Drug Delivery Systems	40	60			100	3
Paper – 203	Industrial Pharmacy	40	60			100	3
Paper – 204	Drug Regulatory affairs	40	60			100	3
Paper – 205	Advanced Pharmaceutical Technology			40	60	100	2
Paper – 206	Advances in Drug Delivery Systems			40	60	100	2
Paper – 207	Seminar					100	2
	TOTAL					700	18

ADITYA PHARMACY COLLEGE SURAMPALEM

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THIRD AND FOURTH SEMESTERS

Paper No.	III Semester	Total	Credits ***
Paper - 301	Project Seminar – I (On the proposed project work with aims and objectives)	50	2
Paper - 302	Project work - I	----	20
	Total	50	22

Paper No.	IV Semester	Total	Credits ***
Paper - 401	Project Seminar – II (On the Completed project work)	50	2
Paper - 402	Project work - II	---	20
	TOTAL MARKS	50	22
	GRAND TOTAL FOR THE COURSE	1500	80

M.PHARM (PHARMACEUTICS)

I Semester

PAPPER 101 - MODERN ANALYTICAL TECHNIQUES
(Paper Common for all Specializations)

Principles, instrumentation and applications of the following Instruments and Chromatography techniques

Unit- I

i. UV- Visible spectrophotometry
ii. Infrared spectroscopy
iii. Spectrofluorimetry

Unit- II

i. NMR spectroscopy
ii. Electron Spin Resonance spectroscopy
iii. Atomic Emission spectroscopy

Unit- III

i. HPLC
ii. HPTLC
iii. Exclusion chromatography
iv. Super critical fluid chromatography

Unit- IV

i. Mass Spectroscopy including LCMS & GCMS
ii. GLC

Unit- V

i. Plasma Emission spectroscopy
ii. X-Ray diffractometry
iii. Optical Rotatory Diffusion
iv. Vapor phase chromatography
v. Affinity chromatography
vi. Ion-exchange chromatography

TEXT BOOKS

1. Practical Pharmaceutical Chemistry Vol. 1 &II by Beckett & Stenlake.
2. Instrumental Methods of Analysis by Scog and West.
3. Instrumental Methods of Analysis by B.K.Sharma
4. Vogel's text book of Quantitative Chemical Analysis.
5. Instrumental methods of Analysis by Willard & Merrit.
6. A text book of Pharmaceutical Analysis by K. A. Conners.

REFERENCE BOOKS

1. I.P.
2. B.P.
3. U.S.P.
4. Remington's Pharmaceutical Sciences.
5. Spectroscopy b Silversterin

PAPER 102 -RESEARCH METHODOLOGIES
(Paper common for all Specializations)

UNIT I

Statistical Methods:

Chance Variation – Probability Distribution - Normal Distribution – Sampling Distribution

Error and its significance-Measures of Error- Control of Error in Experimental Investigations – Problem Solving.

UNIT II

Correlation and Regression., Multiple Regression - Problem Solving

UNIT III

Tests of Significance: Principles, t-test, z-test, F-ratio test, Chi-square test, Non-parametric tests- their applications in pharmacy research with examples – Problem Solving

UNIT IV

Design of Experiments

Criteria of a good design with examples.

Principles- Randomization, replication and local control.

Study of CRD, RBD, LSD and factorial designs- their applications in Pharmacy research with examples – Problem Solving

UNIT V

Analysis of Variance (ANOVA) – one way, two way and three way – principles and applications in pharmacy research- Problem Solving

Optimisation Techniques : Optimisation Techniques based on Factorial Experiments - Problem Solving.

Text & Referrence Books :

1. Fundamentals of Biostatistics by Khan & Khanum,Third Revised Edition, Ukaaz Publications, Hyderabad
2. Theory & Practice of Industrial Pharmacy by Leon Lachman and Others
3. Remingtons Practice of Pharmaceutical sciences, (Latest Edition)
4. Principles of Biostatistics by Marcello Pagnano, Published by Brooks/Cole, (Saurabh Printers Pvt. Ltd)

PAPER 103 - BI0PHARMACEUTICS & PHARMACOKINETICS

Unit - I

Bio-availability Bioequivalence and Therapeutic equivalence: Designing of bioavailability studies and interpretation of results.

Physicochemical properties affecting bioavailability, pH-partition theory, dissolution, surface area adsorption, complexion, polymorphism and techniques of enhancing dissolution rate.

Formulation factors affecting bioavailability of drugs in dosage forms of Tablets, capsules, parenterals, liquid orals and topical dosage forms.

Unit - II

Basic concepts of Pharmacokinetics: Compartmental models: One, Two and non-compartmental approaches to Pharmacokinetics. Recent trends, merits and limitations of these approaches. Application of these models to determine the various pharmacokinetic parameters pertaining to:

a) Absorption: (wherever applicable) absorption rate constant, Absorption half time, lag time and extent of absorption, AUC.

b) Distribution: Apparent volume of distribution and its determination.

c) Metabolism: Metabolic rate constant

d) Elimination: Over all apparent elimination rate constant and half life under the following conditions:

i. Intravenous bolus injection.

ii. Intravenous infusion.

Unit - III

Elimination: Over all apparent elimination rate constant and half life under the following conditions:

i. Single dose oral administration.

ii. Multiple dose injections.

iii. Multiple dosage oral administration

Non invasive methods of estimating Pharmacokinetic parameters with emphasis on salivary and urinary compartments.

Concept of clearance: Organ clearance, total clearance, hepatic clearance, lung clearance and renal clearance.

Unit - IV

Non-linear Pharmacokinetics: Concepts of linear and non linear pharmacokinetics, Michaelis - Menton kinetics characteristics. Basic kinetic parameters, possible causes of non induction, non linear binding, non linearity of pharmacological responses.

Time dependent pharmacokinetics: Introduction, classification, physiologically induced time dependency: Chronopharmacokinetics, chemically induced dependency.

Drug Metabolism - sites of metabolism, factors affecting drug metabolism (genetic, species and environmental).

Unit - V

Clinical pharmacokinetics: Altered kinetics in pregnancy, child birth, infants and geriatrics. Kinetics in GI disease, malabsorption syndrome, Liver, cardiac, renal and pulmonary disease states.

Drug interactions: Kinetics of drug interaction, study of drug-drug interactions mediated through absorption, distribution, metabolism and elimination, mechanisms of interaction and consequence. Influence of alcohol, smoking, food and beverages on drug action.

References:

1. Biopharmaceutics and clinical Pharmacokinetics by Milo Gibaldi.
2. Remington's Pharmaceutical Sciences by Mack publishing company, Pennsylvania.
3. Pharmacokinetics by Milo Gibaldi, Donald Perrier; Marcel Dekker, Inc.
4. Handbook of clinical Pharmacokinetics by Milo Gibaldi and Laurie Prescott by ADIS Health Science Press.
5. Biopharmaceutics and Pharmacokinetics by Robert E. Notari.
6. Biopharmaceutics by Swarbrick.
7. Biopharmaceuties and Pharmacokinetics- A Treatise by D.M.Brahmankar and Sunil B.Jaiswal., Vallabh Prakashan Pitampura, Delhi.
8. Clinical Pharmacokinetics, Concepts and Applications by Malcolm Rowland and Thomas N.Tozer. Lea and Febiger, Philadelphia, 1995.
9. Dissolution, Bioavailability and Bioequivalence by Abdou. H.M., Mack Publishing Company, Pennsylvania, 1989.
10. Biopharmaceutics and Clinical Pharmacokinetics- An introduction; 4th edition, Revised and expanded By Robert. E. Notari, Marcel Dekker Inc, New York and Basel, 1987.
11. Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James. C.Boylan. Marcel Dekker Inc, New York, 1996.

PAPER 104 - ADVANCED PHYSICAL PHARMACEUTICS

Unit – I

Particle science and powder technology: Crystal structure, Amorphous state, Polymorphism, particle size distribution, particle size analysis methods. Solid dispersions/solid solutions.
Physics of tablet compression: Compression, consolidation strength of granules, compression and consolidation under high loads, effect of friction, distribution of forces in compaction, force volume relationships, Heckel plots, compaction profiles, energy involved in compaction, strength of tablet, crushing strength, friability, lamination, instrumentation of tablet machines.

Unit - II

Dissolution and solubility: Solubility and solubilisation of non electrolytes, solubilisation by the use of surfactants, cosolvents, complexation, drug derivatisation and solid state manipulation, dissolution rates of solids in liquids, measurement of dissolution rates
Theories on stability of disperse systems: Adsorption, wetting, crystal growth mechanisms, physical stability of suspensions and emulsions, stability testing of emulsions and suspension and release of drugs from suspensions and emulsion formulations. Biopharmaceutical aspects of disperse systems.

Unit - III

Rheology: Theoretical consideration, instrumentation, rheological properties of disperse systems and semi solids.
Polymer science: Properties of polymers, thermodynamics of polymer solution, phase separation, polymers in solid state, applications of polymers in pharmaceutical formulations

Unit - IV

Kinetics and drug stability: stability calculations, rate equation, Complex order Kinetics, kinetics of some decompositions, strategy of stability testing, methods of stabilization, methods of accelerated stability testing in dosage forms, Freeze-Thaw methods, centrifugal methods, temperature and humidity control, Physical stability testing of pharmaceutical products.

Unit – V

Physical properties, instrumental analysis of drug molecules, Differential Thermal Analysis, Differential Scanning Calorimetry, Diffusive Reflective Spectrophotometry, X-Ray Diffraction Analysis.

References:

1. Physical Pharmacy; By Alfred martin
2. Remington's Pharmaceutical Sciences.
3. Theory and Practice of Industrial Pharmacy By Lachmann and Libermann.
4. Pharmaceutical Preformulations; By J.J. Wells.
5. Modern Pharmaceutics; By Gillbert and S. Banker.
6. Instrumental Methods of Chemical Analysis – B. K. Sharma - 9th Edition.
7. Principles of Instrumental Analysis by Donglas A. Skoog, James, J. Leary, 4th Edition.

PAPER 105 - BIO PHARMACEUTICS & PHARMACOKINETICS LAB
(Experiments based on Theory)

PAPER 106 - ADVANCED PHYSICAL PHARMACEUTICS LAB
(Experiments based on theory)

II SEMESTER

PAPER 201 - ADVANCED PHARMACEUTICAL TECHNOLOGY

UNIT- I

Preformulation studies: Goal of preformulation, preformulation parameters, Methodology, Solid state properties, Solubility & partition coefficient, Drug-Excipient compatibility.

UNIT- II

Formulation Development of Solid dosage forms:

Improved production techniques for tablets: New materials, processess, equipments improvements, high shear mixers, compression machines, coating machines, Coating techniques in tablet technology for product development, Physics of tablet compression and computerization for in process quality control of tablets.

Formulation Development of Powder dosage forms:

Formulation development and manufacture of powder dosage from for internal and external use including inhalation dosage forms.

UNIT- III

Formulation Development of Liquid and Semi-solid dosage forms:

Recent advances in formulation aspects and manufacturing of monophasic dosage forms, recent advances in formulation aspect and manufacturing of suspensions and semi-solid dosage forms.

UNIT- IV

Formulation Development of Parenteral dosage forms:

Advances in materials & production techniques, filling machines, sterilizers & aseptic processing

Formulation Development of Aerosols:

Advances in propellants, metered dose inhaler designs, dry powder inhalers, selection of containers & formulation aspects in aerosol formulation, Manufacture & quality control.

UNIT- V

Aseptic processing operation:

Introduction, Contamination control, Microbial environmental monitoring, Microbiological testing of water, Microbiological air testing, Characterization of aseptic process, Media and incubation condition, Theoretical evaluation of aseptic operations.

References:

1. Theory and Practice of Industrial Pharmacy by Lachmann and Libermann.
2. Modern Pharmaceutics by Gillbert and S. Banker.
3. Remington's Pharmaceutical Sciences.
4. Pharmaceutical Preformulations by J.J. Wells.
5. Advances in Pharmaceutical Sciences Vol. 1-5 by H.S. Bean & A.H. Beckett.

PAPER 202 - ADVANCES IN DRUG DELIVERY SYSTEMS

UNIT- I

1. Fundamentals of controlled drug delivery systems, use of polymers in controlled drug delivery, pharmacokinetic and pharmacodynamic basis of controlled drug delivery. Design, fabrication, evaluation and applications of the following controlled release systems.
   a) Controlled release oral drug delivery systems
   b) Parenteral controlled release drug delivery systems
   c) Implantable therapeutic systems

UNIT- II

   d) Transdermal therapeutic systems and Iontophoresis
   e) Ocular and intrauterine delivery systems
   f) Bioadhesive drug delivery systems
   g) Proteins and peptide drug delivery

UNIT- III

Biochemical and molecular biology approaches to controlled drug delivery
a) Micro particulate drug carriers; Liposomes, Niosomes, Microspheres, Nanoparticles and Resealed erythrocytes.
b) Monocional antibodies

UNIT- IV

Drug targeting to particular organs:
a) Drug delivery to respiratory system
b) Problems of drug delivery to the brain and targeting to brain
c) Drug delivery to eye
d) Drug targeting in Neoplastic diseases

UNIT- V

Drug carrier systems targeted to widely dispersed cells
a) Delivery to Macrophages
b) Delivery to lymphoid cells of immune network
c) Delivery to lysosomal storage diseases

References:

1. Encyclopedia of controlled delivery; by Edith Mathiowitz, Published by Wiley Interscience Publication, John Wiley and sons, Inc, New York / Chichester / Weinheim.
2. Controlled and Novel Drug Delivery by N.K.Jain, CBS Publishers and Distributors, New Delhi, First edition, 1997 (reprint in 2001).
3. Controlled Drug Delivery - Concepts and Advances by S.P.Vyas and R.K.Khar, Vallabh Prakashan, New Delhi, First edition, 2002.
4. Remington's Pharmaceutical Sciences.
5. Novel drug delivery system by Y.M.Chien, Marcel Dekker, Inc.
6. Controlled Drug Delivery - Fundamentals and Applications, 2nd edition by Joseph R.Robinson and Vincent H.L.Lee.
7. Pharmaceutical Dosage forms, disperse system: Volume 1, by Herbert A.Libermann et.al, Marcel Dekker, Inc.
8. Pharmaceutical Dosage forms: Tablets Volume II, Herbert A.Libermann et.al, Marcer Dekker, Inc.
9. Bentley's Textbook of Pharmaceutics by E.A.Rawline, ELBS Publications.
10. Microencapsulation and Related Drug Process by Patric B.Deasy.

PAPER 203 - INDUSTRIAL PHARMACY

UNIT- I

A detailed study involving machinery and theory of pharmaceutical unit operations like Milling, Mixing, Filtration, Drying and Sterilization.

UNIT- II

Materials of construction of pharmaceutical equipment and packaging materials.

Study of the principles, production techniques and scale up techniques in the large scale production of tablets, capsules, emulsions, suspensions, sterile products, Semisolids and liquid pharmaceuticals, ophthalmic products.

UNIT- III

Production Management: Production organization, objectives and policies, good manufacturing practices, layout of buildings, services, equipment and their maintenance, materials management, handling and transportation, inventory management and control, production and planning control. Sales forecasting, budget and cost control, industrial and personal relationship.

UNIT- IV

Quality control, Process and Dosage form: Process control, control of manufacturing process, statistical quality control, control charts of automated process control, dosage form control, testing programme and method, product identification system, adulteration and misbranding , drug information profile.

UNIT- V

Process Validation: Regulatory basis, Validation of solid dosage forms, sterile products, liquid dosage forms. Process validation of raw materials, Validation of analytical methods, Equipment and Process.

References:

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

PAPER 204 - DRUG REGULATORY AFFAIRS
(Paper Common for all Specializations)

Unit - I

Formulation development: Regulatory requirements involved in the preformulation studies, solid, liquid and semi-solid dosage forms, controlled release preparations, injections, ocular preparations as per the European community, United States and Indian regulatory authorities

Unit - II

Manufacturing: Regulatory requirements as per European community, United States and Indian regulatory authorities for manufacturing information, manufacturing formula, process, validation of manufacturing process, equipment, documentation, inspection requirement of regulatory guidelines for active ingredients, data requirement for new drug, International aspects of Excipients, approval as per guidelines of all the territories. Regulatory guidelines for packaging materials, test and evaluation of packaging materials, biological test, elastometer test, microbiological test and evaluation of closures.

Unit - III

Stability testing: Scientific and technical background to the design of stability testing regulatory requirements as per European community, United States and Indian regulatory authorities for testing of new active substances, bulk active drug substances, dosage form in their final packaging. Extension of shelf-life after authorization of drug international harmonization and current guidelines. Regulatory affairs in respect of residual solvents as per the ICH guidelines, analytical method validation, pharmacokinetic and toxicokinetic validation.

Biopharmaceutics: Different testing parameters and standards as per regulatory requirements of European community, United States and Indian regulatory authorities with respect to factors related to formulation, dosage form, manufacturing process, stability and storage.

Unit - IV

Preclinical aspects of Biopharmaceutics: Current guidelines and developments as per regulatory requirements of European community, United States and Indian regulatory authorities in respect of clinical bioavailability , study design, presentation documentation and statistical analysis

Clinical pharmacology and Pharmacodynamics: Regulatory guidelines as per European community, United States and Indian regulatory authorities on clinical study design, documentation, presentation and interpretation. Clinical trials: Definition, phase I, phase II, phase III and phase IV studies, design documentation, presentation and interpretation, statistical analysis of clinical data and factorial design.

Unit - V

Intellectual property rights and patents: Introduction, purpose, international scenario and Indian scenario, guidelines as per European community, United States and Indian regulatory authorities, documentation, presentation and application, procedure for obtaining and writing a patent and patenting rules and regulations

References:

1. Quality Assurance Guide by Organization of Pharmaceutical producers of India.
2. Drug formulation manual by D.P.S. Kohli and D.H.Shah. Eastern publishers, New Delhi.
3. How to practice GMPs by P.P.Sharma. Vandhana Publications, Agra.
4. Pharmaceutical Process Validation by Fra. R. Berry and Robert A. Nash.
5. Pharmaceutical Preformulations by J.J. Wells.
6. Applied production and operations management by Evans, Anderson, Sweeney and Williams.
7. Basic Principles of Clinical Research and Methodology by Gupta.
8. Biopharmaceutics and Clinical Pharmacokinetics-An introduction; 4th edition, Revised and expanded by Robert. E. Notari, Marcel Dekker Inc, New York and Basel, 1987

CEU 205 - **ADVANCED PHARMACEUTICAL TECHNOLOGY LAB**
(Experiments Based on Theory)

CEU206 - **ADVANCES IN DRUG DELIVERY SYSTEMS LAB**
(Experiments Based on Theory)