KAKATIYA UNIVERSITY, WARANGAL

SYLLUBUS FOR MASTER OF PHARMACY (M.PHARM)

TWO YEARS COURSE

From the academic year 2023-2024 onwards

PHARMACEUTICS

FACULTY OF PHARMACEUTICAL SCIENCES,
KAKATIYA UNIVERSITY NAAC A+ Grade, WARANGAL

Table of Contents

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 20203-24. The regulations framed are subject to modifications from time to time by the authorities of the Kakatiya 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 semestershall consist of not less than 90 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 75% attendance in individual courses considering theory and practical separately. The candidate shall complete the prescribed course satisfactorily to be eligible to appear for the respective examinations.

7. Program/Course credit structure

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

Credit assignment

Theory and Laboratory courses

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

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.	Pharmacy Practice	MPP
8.	Pharmacology	MPL
9.	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 Systems	4	4	4	100
MPH103T	Modern Pharmaceutics	4	4	4	100
MPH104T	IPR and Regulatory Affairs	4	4	4	100
MPH105P	Modern Pharmaceutical Analytical Techniques Practical	6	3	6	100
MPH106P	Pharmaceutics-I Practical	6	3	6	100
-	Seminar/Assignment	7	4	7	100
Total		35	26	35	700
Semester II					
MPH201T	Advanced Biopharmaceutics & Pharmacokinetics	4	4	4	100
MPH202T	Molecular Pharmaceutics (Nano technology &Targeted Drug Delivery Systems)	4	4	4	100
MPH203T	Pharmaceutical Production Technology	4	4	4	100
MPH204T	Cosmetic and Cosmeceuticals	4	4	4	100
MPH205P	Advanced BioPharmaceutics and Pharmaocokinetics Practical	6	3	6	100
MPH206P	Pharmaceutics-II Practical	6	3	6	100
-	Seminar/Assignment	7	4	7	100
	Total	35	26	35	700

Table – 11: Course of study for M. Pharm. III Semester (Common for All Specializations)

Course Code	Course	Credit Hours	Credit Points
MRM 301T	Research Methodology and Biostatistics	4	4
-	Journal club	1	1
-	Discussion / Presentation (Proposal Presentation)	2	2
-	Research Work	28	14
Total		35	21

Table – 12: 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 – 13: Semester wise credits distribution

Semester	Credit Points
I	26
II	26
III	21
IV	20
Co-curricular Activities (Attending Conference, Scientific Presentations and Other Scholarly Activities)	Minimum=02 Maximum=07*
Total Credit Points	Minimum=95 Maximum=100

*Credit Points for Co-curricular Activities

Table No-14 Guidelines for Awarding Credit Points for Co-Curricular Awards

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

Journal: The Editorial Board Out side 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 University from time to time.

1. **Program Committee**

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

2. The composition of the Programme Committee shall be as follows:

A teacher at the cadre of Professor shall be the Chairperson; One Teacher from each M.Pharm specialization and four student representatives (two from each academic year), nominated by the Head of the institution.

3. Duties of the Programme Committee:

i. Periodically reviewing the progress of the classes.
ii. Discussing the problems concerning curriculum, syllabus and the conduct of classes.
iii. Discussing with the course teachers on the nature and scope of assessment for the course and the same shall be announced to the students at the beginning of respective semesters.
iv. Communicating its recommendation to the Head of the institution on academic matters.
v. The Programme Committee shall meet at least twice in a semester preferably at the end of each sessional exam and before the end semester exam.

2. **Examinations/Assessments**

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

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 and the marks/grades shall be submitted to the university.

Note: In each semester Seminar -50marks and Assignment -50 marks (Non University exam/ Internal assessment)

Table No: 16- Schemes for Internal Assessment and End Semester (Pharmaceutics-MPH)

Course Code	Course	Internal Assessment			End Semester Exams		Total Mar ks
		Sessional Exams		Tot al	Mar ks	Durati on	
		Mar ks	Durati on				
SEMESTER I							
MPH 101T	Modern Pharmaceuti cal Analytical Techniques	25	1.30 Hr	25	75	3Hrs	100
MPH 102T	Drug Delivery System	25	1.30 Hr	25	75	3Hrs	100
MPH 103T	Modern Pharmaceutics	25	1.30 Hr	25	75	3Hrs	100
MPH 104T	IPR and Regulatory Affair	25	1.30 Hr	25	75	3 Hrs	100
MPH 105P	Modern Pharmaceutical Analytical techniques	25	3 Hrs	25	75	4 Hrs	100
MPH 106P	Pharmaceutics-I	25	3 Hrs	25	75	4 Hrs	100
-	Seminar /Assignment	100	-	-		3Hrs	100
Total							700
SEMESTER II							
MPH 201T	Advanced Biopharmac eutics& Pharmacokinetics	25	1.30 Hr	25	75	3 Hrs	100
MPH 202T	Molecular Pharmaceuti cs(Nano Tech and Targeted DDS)	25	1.30 Hr	25	75	3 Hrs	100
MPH 203T	Pharmaceutical Production Technology	25	1.30 Hr	25	75	3 Hrs	100
MPH 204T	Cosmetic and Cosmeceutic Als	25	1.30 Hr	25	75	3 Hrs	100
MPH 205P	Pharmaceutics Practical III	25	3 Hrs	25	75	4 Hrs	100
MPH 206 P	Pharmaceutics Practical IV	25	3 Hrs	25	75	4 Hrs	100
	Seminar /Assignment	100				3Hrs	100
Total							700

Tables – 25: Schemes for internal assessments and end semester examinations (Semester III& IV)

Course Code	Course		Internal Assessment			End Semester Exams		Tota l Mark s
			Sessional Exams		Tot al	Mark s	Durati on	
			Mark s	Durati on				
SEMESTER III								
MRM30 1T	Research Methodology and Biostatistics		25	1.30 Hr	25	75	3 Hrs	100
-	Journal club		-	-	25	-	-	25
-	Discussion / Presentation (Proposal Presentation)		-	-	50	-	-	50
-	Research work		-	-	-	250	4 Hr	250
Total								425
SEMESTER IV								
-	Journal club	-	-	-	25	-	-	25
-	Discussion / Presentation (Proposal Presentation)	-	-	-	75	-	-	75
-	Research work and Colloquium	-	-	-	-	400	4 Hr	400
Total								500

Table – 26: 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. Re –Examination of End Semester Examinations

Reexamination of end semester examination shall be conducted as per the schedule given in table 28. The exact dates of examinations shall be notified from time to time.

Table – 27: 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 get his/her CGPA upon successful completion of the courses of I to IV semesters.

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 Performance

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 – 28.

Table – 28: 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 obtainedin 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, theSGPA 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 statusin case of F grade(s), till the course(s) is/are passed. When the course(s) is/are passedby obtaining a pass grade on subsequent examination(s) 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 C1, C2, C3,…. 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. 7.5 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 who fail in one or more courses during the M.Pharm program shall not be eligible for award of ranks. Moreover, the candidates should have completed the M. Pharm program in minimum prescribed number of years, (two years) for the award of Ranks

23. Duration of the completion of the Program of the 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.

24. Revaluation I Re totaling 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.

25. Readmission 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)
MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES
(MPH 101T) I SEMESTER

THEORY **60 HOURS**

Scope

This subject deals with various advanced analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are 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

UNIT- I **10HRS**

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.

b. IR spectroscopy: Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier - Transform IR Spectrometer, Factors affecting vibrational frequencies and Applications of IR spectroscopy

c. Spectroflourimetry: Theory of Fluorescence, Factors affecting fluorescence, Quenchers, Instrumentation and Applications of fluorescence spectrophotometer.

UNIT- II **8HRS**

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

UNIT- III **12 HRS**

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

UNIT- IV **10 HRS**

. 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

UNIT- V **10 HRS**

a) Immunological assays: RIA (Radio immuno assay), ELISA, Bioluminescence assays.

b) Thermal techniques: DSC, DTA, TGA, Principle, Instrumentation, factors affecting, advantages and disadvantages and Pharmaceutical applications.

UNIT- VI **8 HRS**

NMR Spectroscopy: Quantum numbers and their role in NMR, Principle, instrumentation, solvent requirements in NMR, Relaxation process, NMR signals in various compounds. Brief outline of FT-NMR and C^{13} NMR, applications of NMR Spectroscopy.

REFERENCE BOOKS:

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.
4. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi, 1997.
5. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis- Modern methods – Part B - J W Munson, Volume 11, Marcel Dekker Series

DRUG DELIVERY SYSTEMS
(MPH 102T)

THEORY **60 Hrs**

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..

UNIT- I **9 Hrs**

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 computation of desired release rate and dose for controlled release DDS, pharmacokinetic design for DDS – intermittent, zero order & first order release.

UNIT- II **9 Hrs**

Carriers for Drug Delivery: Polymers / co-polymers introduction, classification, characterization, polymerization techniques, application in CDDS / NDDS, biodegradable & natural polymers.

UNIT- III **9Hrs**

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

UNIT- IV **9 Hrs**

Study of Various DDS: Concepts, design, formulation & evaluation of controlled release oral DDS, GRDDS, Mucoadhesive and buccal DDS, colon specific, liquid sustained release systems, Ocular delivery systems.

UNIT- V **9 Hrs**

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

UNIT- VI **9 Hrs**

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

UNIT- VII **9 Hrs**

Personalized Medicine: Introduction, Definition, Pharmacogenetics, Categories of Patients for Personalized Medicines, Customized drug delivery systems, Bioelectronic Medicines, 3D printing of pharmaceuticals, Telepharmacy. 6 Hrs

REFERENCE BOOKS:

1. Y W. Chien, Novel Drug Delivery Systems, 2nd edition, revised and expanded, Marcel Dekker, Inc., New York, 1992.
2. Robinson, J. R., Lee V. H. L, Controlled Drug Delivery Systems, Marcel Dekker,Inc., New York, 1992.
3. Encyclopedia of controlled delivery, Editor- Edith Mathiowitz, Published by Wiley Interscience 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

MODERN PHARMACEUTICS
(MPH 103T)

THEORY **60 HRS**

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.

UNIT- I **14 Hrs**

a. Preformulation Concepts – Drug Excipient interactions - different methods, kinetics of stability, Stability testing. Theories of dispersion and pharmaceutical Dispersion (Emulsion and Suspension, SMEDDS) preparation and stability. Large and small volume parental – physiological and formulation consideration, Manufacturing and evaluation.

b. Optimization techniques in Pharmaceutical Formulation: Concept and parameters of optimization, Optimization techniques in pharmaceutical formulation and processing. Statistical design, Response surface method, Contour designs, Factorial designs and application in formulation

UNIT- II **10Hrs**

Validation : Introduction to Pharmaceutical Validation, Scope & merits and types of Validation, Validation and calibration of Master plan, ICH & WHO guidelines for calibration and validation of equipments(Tablet machine, Coating pan, auto clave, FBD, aseptic room), Validation of specific dosage form (solids and liquid). Government regulation, Manufacturing Process Model, DQ, IQ, OQ & PQ of facilities.

UNIT- III **10Hrs**

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 planning and control, Sales forecasting, budget and cost control, industrial and personal relationship. Concept of Total Quality Management.

UNIT- IV **10Hrs**

Compression, compaction and consolidation: Physics of tablet compression, Basic principles of interaction, compression and consolidation, effect of load, friction, distribution of forces in compaction, force volume relationship, Heckel plots, compaction profile, measurement of compression with strain gauge.

UNIT- V **10Hrs**

Dissolution testing: study of factors influencing dissolution, Dissolution data analysis mathematical models of drug release (Higuchi and Peppas)

UNIT- VI **6Hrs**

Linearity (Regression) Concept of significance, Standard deviation, standard error Chi square test, students T-test , ANOVA(one way and two way) test and P value.

REFERENCE BOOKS:

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.

IPR AND REGULATORY AFFAIRS
(MPH 104T)

THEORY **60 Hrs**

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
- To know the chemistry, manufacturing controls and their regulatory importance
- To learn the documentation requirements
- To learn the importance

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.

UNIT- I **10Hrs**

Drug product development: Active pharmaceutical ingredients, drug master file(DMF) and impurities. Generic product development: Introduction, Hatch-Waxman act and amendments, GUDUFA, ANDA (505j), ANDA approval process. New drug application (505B1 and 505B2). NDA approval process including IND. Scale up and post approval changes (SUPAC).Bioequivalence and Bioavailability, different types of studies for drug product approval.

UNIT- II **10Hrs**

ICH- Guidelines of ICH – Q7 to Q11, M9. Clinical Trials. HIPPA – new, requirements to clinical study process, Parmacovigilance safety monitoring in clinical trials.

UNIT- III **10Hrs**

ANDA for generic drugs ways and means of US registration for foreign drugs. CMC, Post approval regulatory affairs. Regulation for combination products, medical devices & Biosimilars.

UNIT- IV **10Hrs**

Brief introduction to CDSCO, WHO, USFDA, EMEA, TGA, MHRA, MCC, ANVISA.

UNIT- V **10Hrs**

Definitions, Need for Patenting, Types of Patents, Conditions to be satisfied by an invention to be Patentable, introduction to patent and patent search. Parts of Patent. Filing of patents. The essential elements of patent. Guidelines for preparation of laboratory notebook, Non-obviousness in patent.

UNIT- VI **10Hrs**

Copy right, Trademark, Geographical indication acts, Patent litigation, 180 days market exclusivity and Doctrine of equivalents.

REFERENCE BOOKS

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

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES PRACTICALS (MPH 105P)

1. Analysis of pharmacopoeial compounds and their formulations by UV Vis spectrophotometer (Minimum 4 Experiments)
2. Simultaneous estimation of multi component containing formulations by UV/HPLC spectrophotometry (Minimum 4 Experiments)
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

PHARMACEUTICS- I PRACTICALS (MPH 106P)

1. To carry out preformulation studies of drugs, effect of surfactants and pH on the solubility of drugs, compatibility evaluation of drugs and excipients by DSC and FTIR .
2. Formulation and evaluation of SR/CR Tablets and compare In-Vitro dissolution profile of SR/CR Marketed formulation.
3. Formulation and evaluation osmotically controlled DDS
4. Preparation and evaluation of Floating DDS- hydro dynamically balanced DDS
5. Formulation and evaluation of Mucoadhesive tablets.
6. Formulation and evaluation of transdermal patches.
7. Stability studies of drugs in solutions and solid dosage forms according to ICH guidelines.
8. To study the effect of compressional force, particle size and binders on tablets disintegration time and dissolution of a tablet.
9. To study Micromeritic properties of powders and granulation.
10. Analysis of drug release from CR tablets, Higuchi, Peppas plot, zero order. Similarity factor determination
11. Preparation and evaluation of different polymeric membranes.
12. Validation of Tablet machine, coating pan, dryers, autoclave

SEMESTER-II
ADVANCED BIOPHARMACEUTICS & PHARMACOKINETICS (MPH 201T)

THEORY **60 Hrs**

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

UNIT- I **10Hrs**

Drug Absorption from the Gastrointestinal Tract: Gastrointestinal tract, Mechanism of drug absorption, Factors affecting drug absorption, pH–partition theory of drug absorption. Formulation and physicochemical factors: Dissolution rate, Dissolution process, Noyes–Whitney equation and drug dissolution, Factors affecting the dissolution rate. Gastrointestinal absorption: role of the dosage form: Solution (elixir, syrup and solution) as a dosage form ,Suspension as a dosage form, Capsule as a dosage form, Tablet as a dosage form ,Dissolution methods ,Formulation and processing factors, Correlation of in vivo data with in vitro dissolution data. Transport model: Permeability-Solubility-Charge State and the pH Partition Hypothesis, Properties of the Gastrointestinal Tract (GIT), pH Microclimate Intracellular pH Environment, Tight-Junction Complex.

UNIT- II **10Hrs**

Biopharmaceutic considerations in drug product design and In Vitro Performance: Introduction, biopharmaceutic factors affecting drug bioavailability, rate-limiting steps in drug absorption, physicochemical nature of the drug, formulation factors affecting drug product performance, in vitro: dissolution and drug release testing, compendial methods of dissolution, alternative methods of dissolution testing, meeting dissolution requirements, problems of variable control in dissolution testing performance of drug products. In vitro–in vivo correlation, dissolution profile comparisons.

UNIT- III **10Hrs**

Pharmacokinetics: Basic considerations, pharmacokinetic models, compartment modeling: one compartment model- IV bolus, IV infusion, extra-vascular. Multi compartment model: two compartment - model in brief.

UNIT- IV **10Hrs**

Non-linear pharmacokinetics: cause of non-linearity, Michaelis – Menten equation, estimation of Kmax and Vmax. Noncompartmental Pharmacokinetics- statistical moment theory and physiological pharmacokinetic model. Altered pharmacokinetics in renal and hepatic diseases. Drug interactions: introduction, the effect of protein binding on interactions, the effect of tissue-binding on interactions, cytochrome p450-based drug interactions, and drug interactions linked to transporters.

UNIT- V **10Hrs**

Drug Product Performance, In Vivo: Bioavailability and Bioequivalence: drug product performance, purpose of bioavailability studies, relative and absolute availability. Methods for assessing bioavailability, bioequivalence studies, design and evaluation of bioequivalence studies, study designs, crossover study designs, evaluation of the data, bioequivalence example, study submission and drug review process. Biopharmaceutics classification system, methods. Permeability: In-vitro, in-situ and In-vivo methods. generic biologics (biosimilar drug products),clinical significance of bioequivalence studies, special concerns in bioavailability and bioequivalence studies, generic substitution.

UNIT- VI **10Hrs**

Application of Pharmacokinetics: Chrono Pharmacokinetics, Modified-Release Drug Products, Targeted Drug Delivery Systems and Biotechnological Products. Introduction to Pharmacokinetics and pharmacodynamics of biotechnology drugs Proteins and peptides, Monoclonal antibodies, Oligonucleotides, Vaccines (immunotherapy),Gene therapies.**10 Hrs**

REFERENCE BOOKS:

1. Biopharmaceutics and Clinical Pharmacokinetics by Milo Gibaldi, 4th edition,Philadelphia, Lea and Febiger, 1991
2. Biopharmaceutics and Pharmacokinetics, A. Treatise, D .M. Brahmankar and Sunil B. Jaiswal., VallabPrakashan, Pitampura, Delhi
3. Applied Biopharmaceutics and Pharmacokinetics by Shargel. Land YuABC, 2ndedition, Connecticut Appleton Century Crofts, 1985
4. Textbook of Biopharmaceutics and Pharmacokinetics, Dr. Shobha Rani R. Hiremath,Prism Book
5. Pharmacokinetics by Milo Gibaldi and D. Perrier, 2nd edition, Marcel Dekker Inc.,New York, 1982
6. Current Concepts in Pharmaceutical Sciences: Biopharmaceutics, Swarbrick. J, Leaand Febiger, Philadelphia, 1970

7. Clinical Pharmacokinetics, Concepts and Applications 3rd edition by MalcolmRowland and Thom~ N. Tozer, Lea and Febiger, Philadelphia, 1995
8. Dissolution, Bioavailability and Bioequivalence, Abdou. H.M, Mack PublishingCompany, Pennsylvania 1989
9. Biopharmaceutics and Clinical Pharmacokinetics, An Introduction, 4th edition,revised and expande by Robert. E. Notari, Marcel Dekker Inc, New York and Basel,1987.
10. Biopharmaceutics and Relevant Pharmacokinetics by John. G Wagner and M.Pemarowski, 1st edition, Drug Intelligence Publications, Hamilton, Illinois, 1971.
11. Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James. G.Boylan, Marcel Dekker Inc, New York, 1996.
12. Basic Pharmacokinetics,1 st edition,Sunil S JambhekarandPhilip J Breen,pharmaceutical press, RPS Publishing,2009.
13. Absorption and Drug Development- Solubility, Permeability, and Charge State, Alex Avdeef, John Wiley & Sons, Inc,2003.

MOLECULAR PHARMACEUTICS (NANO TECHNOLOGY & TARGETED DDS) (NTDS)
(MPH 202T)

THEORY **60 Hrs**

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.

UNIT- I **9Hrs**

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

UNIT- II **9Hrs**

Targeting Methods: introduction, types, preparation and evaluation of Nano Particles & Liposomes

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UNIT- III **9Hrs**

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

UNIT- IV **9Hrs**

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

UNIT- V **9Hrs**

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.

UNIT- VI **8Hrs**

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

UNIT- VII **7Hrs**

Study of commercial formulations DOXIL, RISPERDAL CONSTA, LUPRON DEPOT, INVEGA SUSTENNA, and LANCOME.

REFERENCE BOOKS

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).

PHARMACEUTICAL PRODUCTION TECHNOLOGY
(MPH 203T)

THEORY **60 HRS**

Scope

This course is designed to impart knowledge and skills necessary to train the students to be on par with the routine of Industrial activities in Production

Objectives

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

- Handle the scheduled activities in a Pharmaceutical firm.
- Manage the production of large batches of pharmaceutical formulations.

UNIT- I **10Hrs**

a) Improved Tablet Production: Tablet production process, unit operation improvements, granulation and pelletization equipments, continuous and batch mixing, rapid mixing granulators, rota granulators, spheronizers and marumerisers, and other specialized granulation and drying equipments. Problems encountered.

b) Coating Technology: Process, equipments, particle coating, fluidized bed coating, application techniques. Problems encountered.

UNIT- II **9Hrs**

Parenteral Production: Plant layout, design area planning & environmental control, wall and floor treatment, fixtures and machineries, change rooms, personnel flow, utilities & utilities equipment location, engineering and maintenance.

UNIT- III **9Hrs**

Lyophilization & Spray drying Technology: Principles, process, freeze-drying and spray drying equipments.

UNIT- IV **9Hrs**

Capsule Production: Production process, advances in capsule manufacturing and filling machines for hard and soft gelatin capsules. Layout and problems encountered.

UNIT- V **9Hrs**

Disperse Systems Production: Production processes, applications of mixers, mills, disperse equipments including fine solids dispersion, problems encountered.

UNIT- VI **7Hrs**

Packaging Technology: Types of packaging materials, machinery (strip and blister), labeling, package printing for different dosage forms.

UNIT- VII **7Hrs**

Air Handling Systems: Study of AHUs, humidity & temperature control, air filtration systems, dust collectors. Water Treatment Process: Techniques and maintenance – RO, DM, ultra – filtration, WFI.

REFERENCE BOOKS:

1. The Theory & Practice of Industrial Pharmacy, L. Lachman, Varghese Publ, Bombay.
2. Modern Pharmaceutics by Banker, Vol 72, Marcel Dekker, NY.
3. Pharmaceutical Dosage Forms, Vol 1, 2, 3 by Lachman, Lieberman, Marcel Dekker, NY.
4. Pharmaceutical Dosage Forms, Parentral medications, Vol 1, 2 by K.E. Avis, Marcel Dekker, NY.
5. Pharmaceutical Production Facilities, design and applications, by G.C. Cole, Taylor and Francis.
6. Dispersed System Vol 1, 2, 3 by Lachman, Lieberman, Marcel Dekker, NY.
7. Product design and testing of polymeric materials by N.P. Chezerisionoff.
8. Pharmaceutical Project Management, T.Kennedy, Vol 86, Marcel Dekker, NY.
9. Packaging Pharmaceutical and Health Care, H.Lockhard.
10. Quality Control of Packaging Materials in Pharmaceutical Industy, .Kharburn, Marcel Dekker, NY.
11. Freeze drying / Lyophilization of Pharmaceuticals & Biological Products, L. Ray, Vol 96, Marcel Dekker, NY.
12. Tablet Machine Instrumentation In Pharmaceuticals, PR Watt, Ellis Horwoods, UK.

COSMETICS AND COSMECEUTICALS
(MPH 204T)

THEORY **60 Hrs**

Scope

This course is designed to impart knowledge and skills necessary for the fundamental need for cosmetic and cosmeceutical products.

Objectives

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

- Key ingredients used in cosmetics and cosmeceuticals.
- Key building blocks for various formulations.
- Current technologies in the market
- Various key ingredients and basic science to develop cosmetics and cosmeceuticals
- Scientific knowledge to develop cosmetics and cosmeceuticals with desired Safety, stability, and efficacy.

UNIT- I **10Hrs**

Cosmetics – Regulatory: Definition of cosmetic products as per Indian regulation. Indian regulatory requirements for labeling of cosmetics Regulatory provisions relating to import of cosmetics. Misbranded and spurious cosmetics. Regulatory provisions relating to manufacture of cosmetics – Conditions for obtaining license, prohibition of manufacture and sale of certain cosmetics, loan license, offences and penalties.

UNIT- II **10Hrs**

Cosmetics - Biological aspects: Structure of skin relating to problems like dry skin, acne, pigmentation, prickly heat, wrinkles and body odor. Structure of hair and hair growth cycle. Common problems associated with oral cavity. Cleansing and care needs for face, eye lids, lips, hands, feet, nail, scalp, neck, body and under-arm.

UNIT- III **10Hrs**

Formulation Building blocks: Building blocks for different product formulations of cosmetics/cosmeceuticals. Surfactants – Classification and application. Emollients, rheological additives: classification and application. Antimicrobial used as preservatives, their merits and demerits. Factors affecting microbial preservative efficacy. Building blocks for formulation of a moisturizing cream, vanishing cream, cold cream, shampoo and toothpaste. Soaps and syndet bars.

UNIT- IV **10Hrs**

Perfumes; Classification of perfumes. Perfume ingredients listed as allergens in EU regulation. Controversial ingredients: Parabens, formaldehyde liberators, dioxane.

UNIT- V **10Hrs**

Design of cosmeceutical products: Sun protection, sunscreens classification and regulatory aspects. Addressing dry skin, acne, pigmentation, prickly heat, wrinkles, body odor, dandruff, dental cavities, bleeding gums, mouth odor and sensitive teeth through cosmeceutical formulations.

UNIT- VI **10Hrs**

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

REFERENCE BOOKS

1. Harry's Cosmeticology. 8th edition.
2. Poucher'sperfumecosmeticsandSoaps,10th edition.
3. Cosmetics - Formulation, Manufacture and quality control, PP.Sharma,4th edition
4. Handbook of cosmetic science and Technology A.O.Barel, M.Paye and H.I. Maibach. 3 rd edition
5. Cosmetic and Toiletries recent suppliers catalogue.
6. CTFA directory.

ADVANCED BIOPHARMACEUTICS AND PHARMACOKINETICS PRACTICALS (MPH205P)

1. Improvement of dissolution characteristics of slightly soluble drug by Solid dispersion technique.
2. Comparison of dissolution of two different marketed products /brands
3. Comparison of diffusion studies of two different marketed products /brands
4. Protein binding studies of a highly protein bound drug & poorly protein bound drug
5. Calculation of all Pharmacokinetic parameters from the I.V. Bolus Data.
6. Calculation of all Pharmacokinetic parameters from the Urinary Data of I.V. Bolus Injection.
7. Calculation of all Pharmacokinetic parameters from the I.V. Infusion Data.
8. Calculation of all Pharmacokinetic parameters from the Extravascular Data – Residual Method.
9. Calculation of all Pharmacokinetic parameters from the Extravascular Data – Wagner Nelson method
10. Bioavailability studies of Paracetamol (Animal).

PHARMACEUTICS-II PRACTICALS (MPH206P)

1. Formulation and evaluation of tablets
2. Formulation and evaluation of capsules
3. Formulation and evaluation of injections
4. Formulation and evaluation of emulsion
5. Formulation and evaluation of suspension.
6. Formulation and evaluation of enteric coating tablets.
7. Preparation and evaluation of a freeze dried formulation.
8. Preparation and evaluation of a spray dried formulation.
9. To study the effect of temperature change , non solvent addition, incompatible polymer addition in microcapsules preparation
10. Preparation and evaluation of Alginate beads
11. Formulation and evaluation of gelatin /albumin microspheres
12. Formulation and evaluation of liposomes/niosomes
13. Formulation and evaluation of spherules
14. To address Dry skin, acne, blemish, Wrinkles, bleeding gums and dandruff
15. Formulation and Evaluation of cosmetic products pertaining to skin, hair and teeth.

Semester III

MRM 301T - Research Methodology & Biostatistics

(Common to all specializations)

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. 10 Hrs

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. 10 Hrs

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. 10 hrs

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. 10 hrs

UNIT – V

Declaration of Helsinki: History, introduction, basic principles for all medical research, and additional principles for medical research combined with medical care. 10 hrs

Reference Books

1. Philip Kotler and Kevin Lane Keller : Marketing Management , Prentice Hall of India , NewDelhi.
2. Arun Kumar , Meenakshi : Marketing Management ,Vikas Publishing, india