GANDHI INSTITUTE OF TECHNOLOGY AND MANAGEMENT (GITAM)
(Deemed to be University)
VISAKHAPATNAM * HYDERABAD * BENGALURU

Accredited by NAAC with A^+ Grade

REGULATIONS AND SYLLABUS

OF

MASTER OF PHARMACY (M. Pharm. Pharmaceutics)

(w.e.f. 2021-22 admitted batch)

A University Committed to Excellence

MASTER OF PHARMACY (M. Pharm. Pharmaceutics)
REGULATIONS as per PCI
(w.e.f. 2021-2022 admitted batch)

1.0 ADMISSIONS

1.1 Admissions into the M. Pharmacy programme of GITAM University are governed by GITAM University admission regulations.

2.0 MINIMUM QUALIFICATION FOR ADMISSION

A Pass in the following examinations

2.1 B. Pharm. Degree examination of an Indian University established by law in India from an institution approved by Pharmacy Council of India (PCI) and has scored not less than 50 % of the maximum marks (aggregate of 4 years of B. Pharm.)

2.2 Every student, selected for admission to post graduate pharmacy programme 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.

2.3 Admissions into M. Pharm. will be based on the All India Entrance Test (GAT - PGP) conducted by GITAM University and the rule of reservation is followed wherever applicable.

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 PROGRAMME

The programme of study for M. Pharm. shall extend over a period of four semesters (two academic years).

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 less than 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 November/December to April/May 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. PROGRAMME/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/extracurricular 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.** These credits are divided into theory courses, practical, seminars, assignments, research work, discussions with the supervisor and journal club over the duration of four semesters. The credits are distributed semester-wise as shown in Table 8. 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 course of study for M. Pharm. specialization shall include semester wise theory & practical as given in Table –1 to 3. The number of hours to be devoted to each theory and practical course in any semester shall not be less than that shown in Table –1 to 3.

Table – 1: Course of study for M. Pharm. (Pharmaceutics)

Course Code	Course	Credit Hours	Credit Points	Hrs./wk	Marks
Semester I					
MPH 101T	Modern Pharmaceutical Analytical Techniques	4	4	4	100
MPH 102T	Drug Delivery Systems	4	4	4	100
MPH 103T	Modern Pharmaceutics	4	4	4	100
MPH 104T	Regulatory Affairs	4	4	4	100
MPH 105P	Pharmaceutics Practical – I	12	6	12	150
MPH 106P	Seminar/Assignment	7	4	7	100
	Total	35	26	35	650
Semester II					
MPH 201T	Molecular Pharmaceutics (Nano Technology and Targeted DDS)	4	4	4	100
MPH 202T	Advanced Biopharmaceutics & Pharmacokinetics	4	4	4	100
MPH 203T	Computer Aided Drug Delivery System	4	4	4	100
MPH 204T	Cosmetic and Cosmeceuticals	4	4	4	100
MPH 205P	Pharmaceutics Practical – II	12	6	12	150
MPH 206P	Seminar/Assignment	7	4	7	100
	Total	35	26	35	650

Table – 2: Course of study for M. Pharm. III Semester

Course Code	Course	Credit Hours	Credit points
MRM 301T	Research Methodology and Biostatistics*****	4	4

MPR 301T	Journal club	2	2
MPR 302T	Discussion/Presentation (Proposal presentation)	2	2
MPR 303P	Research Work (Proposed project work, Literature survey, Plan of work, Methodology)	28	14
Total		36	22

* Non University Exam

Table – 3: Course of study for M. Pharm. IV Semester

Course Code	Course	Credit Hours	Credit points
MPR 401T	Discussion/ Final Presentation (Presentation of work, communication skills, question and answers)	3	3
MPR 402P	Research work and colloquium (Objective(s) of the work done, Methodology adopted, Results & Discussions, Conclusions & Outcomes)	36	18
Total		39	21

Table – 4: Semester wise credits distribution

Semester	Credit points
I	26
II	26
III	22
IV	21
Total Credit Points	**95**

10. PROGRAMME 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.

11. EXAMINATIONS/ASSESSMENTS

The schemes for internal assessment and end semester examinations are given in Table –5 to 6.

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 (*) in table 6 for which examinations shall be conducted by the subject experts at college level and the marks/grades shall be submitted to the University.

Table – 5: Schemes for internal assessments and end semester (Pharmaceutics – MPH)

Course code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
Semester I								
MPH 101T	Modern Pharmaceutical Analytical Techniques	10	15	1 Hr	25	75	3 Hr	100
MPH 102T	Drug Delivery Systems	10	15	1 Hr	25	75	3 Hr	100
MPH 103T	Modern Pharmaceutics	10	15	1 Hr	25	75	3 Hr	100
MPH 104T	Regulatory Affairs	10	15	1 Hr	25	75	3 Hr	100
MPH 105P	Pharmaceutics Practical – I	20	30	6 Hr	50	100	6 Hr	150
MPH 106P	Seminar/Assignment	-	-	-	-	100	-	100
Total								650
Semester II								
MPH 201T	Molecular Pharmaceutics (Nano Technology and Targeted DDS)	10	15	1 Hr	25	75	3 Hr	100
MPH 202T	Advanced Biopharmaceutics & Pharmacokinetics	10	15	1 Hr	25	75	3 Hr	100
MPH 203T	Computer Aided Drug Delivery System	10	15	1 Hr	25	75	3 Hr	100
MPH 204T	Cosmetic and Cosmeceuticals	10	15	1 Hr	25	75	3 Hr	100
MPH 205P	Pharmaceutics Practical – II	20	30	6 Hr	50	100	6 Hr	150
MPH 206P	Seminar/Assignment	-	-	-	-	100	-	100
Total								650

Table – 6: 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								
MRM 301T	Research Methodology and Biostatistics*	10	15	1 Hr	25	75	3 Hr	100
MPR 301T	Journal club	-	-	-	100	-	-	100
MPR 302T	Discussion/Presentation (Proposal presentation)	-	-	-	100	-	-	100
MPR 303P	Research Work (proposed project work, Literature survey, Plan of work, Methodology)	-	-	-	-	100	1 Hr	100
Total								400
Semester IV								
MPR 401T	Discussion/ Presentation (Presentation of work, communication skills, question and answers)	-	-	-	100	-	-	100
MPR 402P	Research Work and colloquium (Objective(s) of the work done, Methodology adopted, Results & Discussions, Conclusions & Outcomes)	-	-	-	-	100	1 Hr	100
Total								200

* Non University Examination

11.2. **Internal assessment: Continuous mode**

The marks allocated for Continuous mode of Internal Assessment shall be awarded as follows.

Table – 7: Scheme for awarding internal assessment: Continuous mode

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

Total	20

Table – 8: Guidelines for 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 **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 tables 5 – 6. 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 course including internal assessment.

13. CARRY FORWARD OF MARKS

In case a student fails to secure the minimum 50% in any Theory or Practical course as specified in 12, then he/she shall reappear for the end semester examination of that course. However his/her marks of the Internal Assessment shall be carried over and he/she shall be entitled for grade obtained by him/her on passing.

14. IMPROVEMENT OF INTERNAL ASSESSMENT

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

15. REEXAMINATION OF END SEMESTER EXAMINATIONS

Reexamination of end semester examination shall be conducted as per the schedule given in table 9. The exact dates of examinations shall be notified from time to time.

Table – 9: Tentative schedule of end semester examinations

Semester	For Regular candidates	For Failed Candidates
I and III	November/December	April/May
II and IV	April/May	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 II semesters till the III semester examinations. However, he/she shall not be eligible to attend the courses of IV semester until all the courses of I, II and III semesters are successfully completed. A student shall be eligible to get his/her CGPA upon successful completion of the courses of I to IV semesters within the stipulated time period as per the norms.

Note: Grade AB should be considered as failed and treated as one head for deciding ATKT. Such rules are also applicable for those students who fail to register for examination(s) of any course in any semester.

17. GRADING OF PERFORMANCES

17.1. Letter grades and grade points allocations:

Based on the performances, each student shall be awarded a final letter grade at the end of the semester for each course. The letter grades and their corresponding grade points are given in Table – 10.

Table – 10: 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:

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

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

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

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:

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

where C1, C2, C3, …. is the total number of credits for semester I, II, III,… and S1, S2, S3, …. 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).

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. programme shall not be eligible for award of ranks. Moreover, the candidates should have completed the M. Pharm. programme 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 PROGRAMME OF STUDY

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

25. REVALUATION/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 programme after break of study has to get the approval from the University by paying a condonation fee.

27. PROGRAMME EDUCATIONAL OBJECTIVES (PEO)

PEO1: To provide a comprehensive and advanced pharmaceutical education leading to M. Pharm. Degree.

PEO2: To integrate pharmacy knowledge and skills with pharmaceutical research.

PEO3: To develop pharmacists to contribute effectively in the social health care system.

PEO4: To provide hands on training through state of art infrastructure to inculcate research aptitude in pharmaceutical sciences.

PEO5: To inculcate leadership and entrepreneurship capabilities in future pharmacy professionals.

28. PROGRAM OUTCOMES (PO)

PO1: With the in-depth knowledge of novel drug delivery systems and selection of drugs and polymers for the development of drug & cosmeceutical products the graduates will excel in the field.

PO2: Knowledge on various preformulation elements, industrial management and GMP considerations, Pilot Plant Scale Up Techniques, Stability testing, sterilization and packaging of dosage forms, the graduate students are competent to meet the challenges of the industry.

PO3: Mastering the regulatory affairs, gain advanced knowledge and skills required to learn the concept of generic drugs 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 will make the graduates versatile pharmaceutical professionals..

PO4: Mastering the data analysis and interpretation skills with respect to dose calculations, dose adjustments and apply biopharmaceutics theories in practical problem solving and the pharmacokinetic models, bioequivalence and clinical pharmacokinetics make them competent to meet the challenges.

PO5: Required training is imparted on computer applications, Pharmacoinformatics, in drug development in Computational modeling, Preclinical development, clinical development, Artificial Intelligence.

PO6: Appreciable knowledge and exercise is imparted on Biostatistics and Research Methodology to make the students well versed with statistical analysis of the biological data.

29. PROGRAM SPECIFIC OUTCOMES (PSO)

PSO1: It helps in development of new medications, pharmaceutical formulations by using the latest technologies and processes.

PSO2: Professional Training to the students to work on drug compounds and develop new medications based on research. In this, students learn to test medications for efficiency and safety, oversee the production process to ensure medications are produced accurately, conduct clinical drug trials and evaluate the drug's effectiveness and to determine potential risks or side effects.

PSO3: Students are trained to collaborate with various pharmaceutical companies and a variety of health care professionals to ensure clinical drug trials are conducted safely as per regulatory guidelines for the testing of drugs.

PSO4: To create a talent pool by involving students in research projects and to make students undertake research projects under faculty guidance for publication and patenting and to foster ambitious desire among students to undertake higher studies and career growth.

SEMESTER – I

PHARMACEUTICS (MPH)

MPH 101T. MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES

Hours per week: 4L | End Examination: 75 Marks
Credit: 4 | Midsem: 25 Marks

Course Description: This course is designed to provide the student with basic information about various instrumental techniques covering spectroscopy, chromatography and thermal analysis. During the course the student will be learning the concepts and applications of various absorption (UV-Visible, IR) and emission (Spectrofluorimetry, Flame photometry) spectroscopic techniques along with X-ray crystallography, NMR and Mass spectroscopy. The student will also gain knowledge on the significance of various basic to complex chromatographic (TLC, HPLC, GC, Affinity chromatography) and electrophoresis (Gel, Moving boundary) techniques.

Course objectives: 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.

UNIT – I **12 Hrs**

a. UV-Visible spectroscopy: Introduction, Theory, laws, instrumentation associated with UV-Visible spectroscopy, choice of solvents and solvent effect and applications of UV-Visible spectroscopy, difference/ derivative spectroscopy.
b. IR spectroscopy: Theory, modes of molecular vibrations, sample handling, instrumentation of dispersive and Fourier Transform IR spectrometer, factors affecting vibrational frequencies and applications of IR spectroscopy, data interpretation.
c. Spectrofluorimetry: Theory of fluorescence, factors affecting fluorescence (characteristics of drugs that can be analyzed by fluorimetry), quenchers, instrumentation and applications of fluorescence spectrophotometer.
d. Flame emission spectroscopy and Atomic absorption spectroscopy: Principle, instrumentation, interferences and applications.

UNIT – II **12 Hrs**

NMR spectroscopy: Quantum numbers and their role in NMR, principle, instrumentation, solvent requirement in NMR, relaxation process, NMR signals in various compounds, chemical shift, factors influencing chemical shift, spin-spin coupling, coupling constant, nuclear magnetic double resonance, brief outline of principles of FT-NMR and 13C NMR. Applications of NMR spectroscopy.

UNIT – III **12 Hrs**

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 – IV **12 Hrs**

Chromatography: Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution, isolation of drug from excipients, data interpretation and applications of the following:

a. Thin layer chromatography
b. High performance thin layer chromatography
c. Ion exchange chromatography
d. Column chromatography
e. Gas chromatography
f. High performance liquid chromatography
g. Ultra high performance liquid chromatography
h. Affinity chromatography
i. Gel chromatography

UNIT – V **12 Hrs**

a. Principle, instrumentation and applications of gel electrophoresis and moving boundary electrophoresis

b. X ray Crystallography: Production of X rays, different X ray methods, Bragg's law, rotating crystal technique, X ray powder technique, types of crystals and applications of X-ray diffraction

c. Thermal Techniques:

Differential Scanning Calorimetry (DSC): Principle, thermal transitions and instrumentation (Heat flux and power-compensation and designs), modulated DSC, hyper DSC, experimental parameters (sample preparation, experimental conditions, calibration, heating and cooling rates, resolution, source of errors) and their influence, advantage and disadvantages, pharmaceutical applications.

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

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

Course Outcomes: After completion of course student is able to know,

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

References

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, 6th 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 – A H Beckett and J B 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, Vol 11, Marcel. Dekker Series
8. Spectroscopy of Organic Compounds, 2nd edition, P.S/Kalsi, Wiley Eastern Ltd., Delhi.
9. Textbook of Pharmaceutical Analysis, K A Connors, 3rd edition, John Wiley & Sons, 1982.

MPH 102T. DRUG DELIVERY SYSTEMS

Hours per week: 4L | End Examination: 75 Marks
Credit: 4 | Midsem: 25 Marks

Course Description
Drug Delivery System is an important course for the M.Pharm (Pharmaceutics) students. It is a core course of pharmaceutics, which trains the students in different novel drug delivery system, and formulation strategies involved in it. This course includes principles, formulations, stability and production aspects of SR/CR formulation, Gastro-Retentive, ocular, transdermal, Protein and Peptide drug delivery systems. This course develops research approach in M.Pharm students specially in the area of formulation and development.

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

UNIT – I **12 Hrs**
SR/CR formulation: Introduction & basic concepts, advantages/ disadvantages, factors influencing, physicochemical & biological approaches for SR/CR formulation, mechanism of drug delivery from SR/CR formulation. 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.

UNIT – II **12 Hrs**
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.
Polymers: Introduction, definition, classification, properties and application

UNIT – III **12 Hrs**
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.

UNIT – IV **12 Hrs**
Occular Drug Delivery Systems: Barriers of drug permeation,
Methods to overcome barriers.
Transdermal Drug Delivery Systems: Structure of skin and barriers, penetration enhancers, Transdermal Drug Delivery Systems, formulation and evaluation.

UNIT – V **12 Hrs**
Protein and Peptide Delivery: Barriers for protein delivery.
Formulation and Evaluation of delivery systems of proteins and other macromolecules.
Vaccine delivery systems: Vaccines, uptake of antigens, single shot vaccines, mucosal and transdermal delivery of vaccines.

Course Outcomes: 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.

References

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

MPH 103T. MODERN PHARMACEUTICS

Hours per week: 4L — End Examination: 75 Marks
Credit: 4 — Midsem: 25 Marks

Course Description

Modern Pharmaceutics is an important course for the M.Pharm (Pharmaceutics) students. It is a core course of pharmaceutics, which trains the students different concepts related to Preformulation, Dissolution, Theories of dispersion, Large and small volume parenterals, Compression and Consolidation, cGMP & Industrial Management and different parameters related to validation and optimization techniques

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

UNIT – I **12 Hrs**

Preformation Concepts – Drug excipient interactions - different methods, kinetics of stability, stability testing.
Dissolution: Dissolution mechanisms, kinetic models for drug release - zero order, first order, Hixson Crowell's, Higuchi, Peppas, various compendial dissolution apparatus, dissolution profiles comparison- difference factor (f_1), similarity factor (f_2).

UNIT – II **12 Hrs**

Theories of dispersion and pharmaceutical dispersion (emulsion and suspension, SMEDDS) preparation and stability.

Large and small volume parenterals – physiological and formulation consideration, manufacturing and evaluation.

UNIT – III **12 Hrs**

Compression and Consolidation: Physics of tablet compression, consolidation, effect of friction, force distribution, force – volume distribution, Heckel plots, decompression, energy involved in compression

UNIT – IV **12 Hrs**

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.

UNIT – V **12 Hrs**

Validation: Introduction to Pharmaceutical Validation, Scope & merits of validation, validation and calibration of master plan, ICH & WHO guidelines for calibration and validation of equipment, validation of specific dosage form, types of validation. Government regulation, manufacturing process model, URS, DQ, IQ, OQ & PQ. of facilities.

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.

Course Outcomes: 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.

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.

MPH 104T. REGULATORY AFFAIRS

Hours per week: 4L | End Examination: 75 Marks
Credit: 4 | Midsem: 25 Marks

Course Description:

The course helps to provide a comprehensive education in the important aspects of Regulatory and Quality Compliance in the pharmaceutical industry. which trains the students in approval process of various regulatory filings in different countries, different phases of clinical trials and submitting regulatory documents, Pharmacovigilance and process of monitoring in clinical trials

Course objectives: 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

UNIT – I **12 Hrs**

Documentation in the 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.

UNIT – II **12 Hrs**

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

UNIT – III **12 Hrs**

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

UNIT – IV **12 Hrs**

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

UNIT – V **12 Hrs**

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.

Course Outcomes: 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 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
- Pharmacovigilance and process of monitoring in clinical trials.

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

MPH 105P. PHARMACEUTICS PRACTICALS – I

Hours per week: 12 End Examination: 100 Marks
Credit: 6 Midsem: 50 Marks

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 perform In-vitro dissolution profile of CR/ SR marketed formulation
8. Formulation and evaluation of sustained release matrix tablets
9. Formulation and evaluation osmotically controlled DDS
10. Preparation and evaluation of floating DDS- hydro dynamically balanced DDS
11. Formulation and evaluation of Mucoadhesive tablets.
12. Formulation and evaluation of transdermal patches.
13. To carry out preformulation studies of tablets.
14. To study the effect of compressional force on tablet disintegration time.
15. To study micromeritic properties of powders and granulation.
16. To study the effect of particle size on dissolution of a tablet.
17. To study the effect of binders on dissolution of a tablet.
18. To plot Heckal plot, Higuchi and peppas plot and determine similarity factors.

SEMESTER – II

MPH 201T. MOLECULAR PHARMACEUTICS

(NANO TECHNOLOGY & TARGETED DDS) (NTDS)

Hours per week: 4L — End Examination: 75 Marks
Credit: 4 — Midsem: 25 Marks

Course description: This course is designed to impart knowledge on the area of advances in novel drug delivery systems.It describes various approaches for development of novel drug delivery systems.The criteria for selection of drugs and polymers for the development of NTDS and the formulation and evaluation of novel drug delivery systems.Gives complete knowledge about Targeted Drug Delivery Systems and concepts events and biological process involved in drug targeting tumor targeting and brain specific delivery.

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

UNIT – I **12 Hrs**

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

UNIT – II **12 Hrs**

Targeting Methods: Introduction, preparation and evaluation.
Nano Particles & Liposomes: Types, preparation and evaluation.

UNIT – III **12 Hrs**

Micro Capsules/Micro Spheres: Types, preparation and evaluation, monoclonal antibodies; preparation and application, preparation and application of niosomes, aquasomes, phytosomes, electrosomes.

UNIT – IV **12 Hrs**

Pulmonary Drug Delivery Systems: Aerosols, propellents, container types, preparation and evaluation

Intra Nasal Route Delivery systems; Types, preparation and evaluation.

UNIT –V **12 Hrs**

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 the future.

Course Outcomes: 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.

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, New Delhi, First edition 1997 (reprint in 2001).

MPH 202T. ADVANCED BIOPHARMACEUTICS & PHARMACOKINETICS

Hours per week: 4L End Examination: 75 Marks
Credit: 4 Midsem: 25 Marks

Course description: This course is designed to impart knowledge and skills necessary for dose calculations, dose adjustments and to apply biopharmaceutics theories in practical problem solving.The basic concepts in biopharmaceutics and pharmacokinetics and the use of raw data and derive the pharmacokinetic models and parameters the best describe the process of drug absorption, distribution, metabolism and elimination.This course also describes about the critical evaluation of biopharmaceutical studies involving drug product equivalency. This subject also describes potential clinical pharmacokinetic problems and application of basics of pharmacokinetics.

Course objectives: 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.

UNIT – I **12 Hrs**

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 **12 Hrs**

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

UNIT – III **12 Hrs**

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 kmax and vmax.
Drug interactions: introduction, the effect of protein-binding interactions, the effect of tissue-binding interactions, cytochrome p450-based drug interactions, drug interactions linked to transporters.

UNIT – IV **12 Hrs**

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 – V **12 Hrs**

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), gene therapies.

Course Outcomes: 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 biopharmaceutical 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

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, Lea and Febiger, Philadelphia, 1970
7. Clinical Pharmacokinetics, Concepts and Applications 3rd edition by Malcolm Rowland and Thom~ N. Tozer, Lea and Febiger, Philadelphia, 1995
8. Dissolution, Bioavailability and Bioequivalence, Abdou. H.M, Mack PublishingCompany, Pennsylvania 1989
9. Biopharmaceutics and Clinical Pharmacokinetics, An Introduction, 4th edition, revised and expanded 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, 1st edition, Sunil S Jambhekarand Philip J Breen, Pharmaceutical press, RPS Publishing, 2009.
13. Absorption and Drug Development - Solubility, Permeability and Charge State, Alex Avdeef, John Wiley & Sons, Inc, 2003.

MPH 203T. COMPUTER AIDED DRUG DEVELOPMENT

Hours per week: 4L — End Examination: 75 Marks
Credit: 4 — Midsem: 25 Marks

Course description: This course is designed to impart knowledge about computers in pharmaceutical research and development.Usage of computational modeling of drug disposition and computers in preclinical development. Different optimization techniques in pharmaceutical formulation and usage of computers in market analysis and clinical development.Recent advances in Artificial intelligence (AI) and robotics in pharmaceutical research and development .

Course objectives: 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.

UNIT – I **12 Hrs**

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.

b. Quality-by-Design in pharmaceutical development: Introduction, ICH Q8 guideline, regulatory and industry views on QbD, scientifically based QbD - examples of application.

UNIT – II **12 Hrs**

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.

UNIT – III **12 Hrs**

Computer-aided formulation development: Concept of optimization, optimization parameters, factorial design, optimization technology & screening design. Computers in pharmaceutical formulation: development of pharmaceutical emulsions, microemulsion drug carriers. Legal protection of innovative uses of computers in R&D, the ethics of computing in pharmaceutical research, computers in market analysis.

UNIT – IV **12 Hrs**

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

UNIT – V **12 Hrs**

Artificial Intelligence (AI), Robotics and Computational fluid dynamics: General overview, pharmaceutical automation, pharmaceutical applications, advantages and disadvantages. current challenges and future directions.

Course Outcomes: 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)

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.

MPH 204T. COSMETICS AND COSMECEUTICALS

Hours per week: 4L — End Examination: 75 Marks
Credit: 4 — Midsem: 25 Marks

Course description: This course describes the fundamental need for cosmetic and cosmeceutical products.This course describes the key ingredients used in cosmetics and cosmeceuticals and key building blocks for various formulations.Recent technologies in the market for designing of cosmetics and cosmeceuticals and various key ingredients and basic science to develop cosmetics and cosmeceuticals.It also describes the scientific knowledge to develop stable, safe and effective cosmetics and cosmeceuticals.

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

UNIT – I **12 Hrs**

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, offenses and penalties.

UNIT – II **12 Hrs**

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 **12 Hrs**

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

UNIT – IV **12 Hrs**

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

UNIT – V **12 Hrs**

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.

Course Outcomes: 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.

References

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

MPH 205P. PHARMACEUTICS PRACTICALS – II

Hours per week: 12 End Examination: 100 Marks
Credit: 6 Midsem: 50 Marks

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® software.
11. In vitro cell studies for permeability and metabolism
12. DoE using Design Expert® Software
13. Formulation data analysis using Design Expert® Software
14. Quality-by-Design in pharmaceutical development
15. Computer simulations in pharmacokinetics and pharmacodynamics
16. Computational modeling of drug disposition
17. To develop clinical data collection manual
18. To carry out sensitivity analysis, and population modeling.
19. Development and evaluation of creams.
20. Development and evaluation of shampoo and toothpaste base.
21. To incorporate herbal and chemical actives to develop products.
22. To address dry skin, acne, blemish, wrinkles, bleeding gums and dandruff.

- The concept of calibration, qualification and validation.

1. Qualification of pharmaceutical testing equipment (Dissolution testing apparatus, friability apparatus, disintegration tester)
2. Check list for bulk pharmaceutical chemicals vendors
3. Check list for tableting production.
4. Check list for sterile production area
5. Check list for water for injection.
6. Design of plant layout: Sterile and non-sterile
7. Case study on application of QbD
8. Case study on application of PAT

SEMESTER – III

MRM 301T. RESEARCH METHODOLOGY & BIOSTATISTICS

Hours per week: 4L — End Examination: 75 Marks
Credit: 4 — Midsem: 25 Marks

Course Description: This introductory course of research methodologies and biostatistics will give students an overview of the many study designs and statistical tests that are used in the medical industry to answer research issues. This course focuses on the CPCSEA guidelines and prerequisites for performing animal experiments, categorising research projects, developing a study, experimental design, measuring and interpreting data, and conducting ethical research.

Course objectives: Impart knowledge on statistical principles that can be applied to design experiments and help in the interpretation of the results.

UNIT – I **12 Hrs**

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 **12 Hrs**

Biostatistics: Definition, application, sample size, importance of sample size, factors influencing sample size, dropouts.

Measures of central tendency: Computation of means, median and mode from grouped and ungrouped data. Measure of dispersion: Computation of variance, standard deviation, standard error and their coefficients.

UNIT – III **12 Hrs**

Regression and correlation: Method of least squares, Correlation Coefficient, rank correlation and multiple regressions.

Probability rules: Binomial, poison and normal distribution.

UNIT – IV **12 Hrs**

Tests of significance: Testing hypotheses- principle and applications of Z, t-, F- ratio and chi-square tests in pharmaceutical and medical research. Analysis of Variance: 1-way, 2-way and 3-way classification. Non-parametric tests: Sign test, Wilcoxon signed rank test, Wilcoxon rank sum test, Kruskal Wallis test, run test and median tests.

UNIT – V **12 Hrs**

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.

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

Course Outcomes: Upon completion of the course the student is able to select appropriate statistical methods required for a particular research design and develop appropriate research hypothesis for a research project. Develop appropriate framework for research studies. Gain knowledge regarding CPCSEA guidelines and prerequisites for conducting animal experiments.

References

1. Santosh Gupta: "Research Methodology and Statistical Techniques", Deep & Deep Publication, 2001

2. C. R. Kothari: "Research Methodology – Methods & Techniques", 2nd edition, Wishwa Prakashan, 2000.

3. K. P. C. Swain:"A Text book of Research Methodology", 1st edition, Kalyani Publishers, 2007.

4. "Research Methodology and Statistical Techniques" Indira Gandhi National Open University.

5. M. N. Ghosh: "Fundamentals of Experimental Pharmacology", 2nd edition, Scientific Book Agency, Calcutta, India, 1984.

6. H. G. Vogel: "Drug Discovery and Evaluation-Pharmacological Assays", 2nd edition, Springer Verlag, Berlin, Germany, 2002.