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Course Structure and Syllabus

of

M.Pharm
(Industrial Pharmacy)

School of Pharmacy and Life Sciences

2024

COURSE STRUCTURE AND SYLLABI

M. Pharm (Industrial Pharmacy)

2024-25 Batch

Centurion UNIVERSITY

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School of Pharmacy and Life Sciences
CENTURION UNIVERSITY OF TECHNOLOGY & MANAGEMENT
Odisha-752050, India

Web Site: - www.cutm.ac.in

CENTURION UNIVERSITY OF TECHNOLOGY AND MANAGEMENT, ODISHA

CERTIFICATE

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This is to certify that the syllabus of the M. Pharm (Industrial Pharmacy) Programme of the School of Pharmacy and Life sciences is approved in the 14th Academic Council Meeting held on 22nd November 2024.

Dean
School of Pharmacy and Life Sciences
CUTM, Odisha

SCHOOL OF PHARMACY AND LIFE SCIENCES

SCHEME & SYLLABUS

M.PHARM (INDUSTRIAL PHARMACY)

FOR

Centurion UNIVERSITY

Shaping Lives...
Empowering Communities...

CENTURION UNIVERSITY OF TECHNOLOGY AND MANAGEMENTBHUBANESWAR, ODISHA

2024

VISION:

To be a globally recognized centre for Teaching, Research and Entrepreneurial Training in Pharmaceutical Sciences and to provide Healthcare services for Societal needs.

MISSION:

- To nurture young minds into knowledgeable, skillful and ethical professionals to serve for the society.
- To support research in diverse ways by launching partnerships and collaborations.
- To ensure affordable health care by developing pharmaceutical formulations using in house resources.
- To inculcate the mindset for entrepreneurship and innovativeness to enrich the healthcare system.

Programme Objectives:

1. To develop advanced knowledge and technical expertise in Pharmacy.
2. To cultivate research skills, innovations and professional practice in the Pharmaceutical industry.
3. To Nurture and support an inclination for higher education and entrepreneurship.

PROGRAMME OUTCOMES (POs):

At successfully completing the M. Pharm program, student should have achieved the following program outcomes mentioned below:

POs	
PO 1	**Pharmacy Knowledge:** Possess knowledge and comprehension of the core and basic knowledge associated with the profession of pharmacy, including biomedical sciences; pharmaceutical sciences; behavioral, social, and administrative pharmacy sciences; and manufacturing practices.
PO 2	**Planning Abilities:** Demonstrate effective planning abilities including time management, resource management, delegation skills and organizational skills. Develop and implement plans and organize work to meet deadlines.
PO 3	**Problem analysis:** Utilize the principles of scientific enquiry, thinking analytically, clearly and critically, while solving problems and making decisions during daily practice. Find, analyze, evaluate and apply information systematically and shall make defensible decisions.
PO 4	**Modern tool usage:** Learn, select, and apply appropriate methods and procedures, resources, and modern pharmacy-related computing tools with an understanding of the limitations.
PO 5	**Leadership skills:** Understand and consider the human reaction to change, motivation issues, leadership and team-building when planning changes required for fulfilment of practice, professional and societal responsibilities. Assume participatory roles as responsible citizens or leadership roles when appropriate to facilitate improvement in health and well-being.
PO 6	**Professional Identity:** Understand, analyze and communicate the value of their professional roles in society (e.g. health care professionals, promoters of health, educators, managers, employers, employees).
PO 7	**Pharmaceutical Ethics:** Honour personal values and apply ethical principles in professional and social contexts. Demonstrate behavior that recognizes cultural and personal variability in values, communication and lifestyles. Use ethical frameworks; apply ethical principles while making decisions and take responsibility for the outcomes associated with the decisions.
PO 8	**Communication:** Communicate effectively with the pharmacy community and with society at large, such as, being able to comprehend and write effective reports, make effective presentations and documentation, and give and receive clear instructions.

PO 9	**The Pharmacist and society:** Apply reasoning informed by the contextual knowledge to assess societal, health, safety and legal issues and the consequent responsibilities relevant to the professional pharmacy practice.
PO10	**Environment and sustainability:** Understand the impact of the professional pharmacy solutions in societal and environmental contexts, and demonstrate the knowledge of, and need for sustainable development.
PO11	**Entrepreneurship**: Develop entrepreneurship skills that support the growth of Pharmaceutical Industry / Pharmaceutical Services leading to economic development.
PO12	**Life-long learning:** Recognize the need for, and have the preparation and ability to engage in independent and life-long learning in the broadest context of technological change. Self-assess and use feedback effectively from others to identify learning needs and to satisfy these needs on an ongoing basis.

PSO (Program Specific Outcomes)

Sl No.	**Program Specific Outcomes**
PSO1	**Pharmaceutical Manufacturing and Process Optimization:** Proficiency in the design, development, and optimization of pharmaceutical manufacturing processes, ensuring quality control and scalability from laboratory to industrial scale.
PSO2	**Regulatory Compliance and Quality Assurance:** Ability to apply regulatory guidelines, Good Manufacturing Practices (GMP), and quality management systems to ensure the production of safe, effective, and high-quality pharmaceutical products.
PSO3	**Product Development and Formulation:** Expertise in the development, formulation, and characterization of drug delivery systems, including solid, liquid, and novel dosage forms, focusing on stability, bioavailability, and patient compliance.

CHAPTER – I: REGULATIONS

1. **Short Title and Commencement**

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

2. Minimum qualification for admission
A Pass in the following examinations

a) B. Pharm Degree examination of an Indian university established by law in India from an institution approved by Pharmacy Council of India and has scored not less than 55 % of the maximum marks (aggregate of 4 years of B.Pharm.)
b) Every student, selected for admission to post graduate pharmacy program in any PCI approved institution should have obtained registration with the State Pharmacy Council or should obtain the same within one month from the date of his/her admission, failing which the admission of the candidate shall be cancelled.

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

3. Duration of the program
The programs 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 Pharmacy Council of India, New Delhi.

4. Medium of instruction and examinations
Medium of instruction and examination shall be in English.

5. Working days in each semester
Each semester shall consist of not 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 December/January to May/June in every calendar year.

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

7. Program/Course credit structure
As per the philosophy of Credit Based Semester System, certain quantum of academic work viz. theory classes, practical classes, seminars, assignments, etc. are measured in terms of credits. On satisfactory completion of the courses, a candidate earns credits. The amount of credit associated with a course is dependent upon the number of hours of instruction per week in that course.

Similarly the credit associated with any of the other academic, co/extra- curricular activities is dependent upon the quantum of work expected to be put in for each of these activities per week/per activity.

7.1. Credit assignment

7.1.1. Theory and Laboratory courses

Courses are broadly classified as Theory and Practical. Theory courses consist of lecture (L) and Practical (P) courses consist of hours spent in the laboratory. Credits (C) for a course is dependent on the number of hours of instruction per week in that course, and is obtained by using a multiplier of one (1) for lecture and a multiplier of half (1/2) for practical (laboratory) hours. Thus, for example, a theory course having four lectures per week throughout the semester carries a credit of 4. Similarly, a practical having four laboratory hours per week throughout semester carries a credit of 2. The contact hours of seminars, assignments and research work shall be treated as that of practical courses for the purpose of calculating credits. i.e., the contact hours shall be multiplied by 1/2. Similarly, the contact hours of journal club, research work presentations and discussions with the supervisor shall be considered as theory course and multiplied by 1.

7.2. Minimum credit requirements

The minimum credit points required for the award of M. Pharm. degree is 95. However, based on the credit points earned by the students under the head of co-curricular activities, a student shall earn a maximum of 100 credit points. These credits are divided into Theory courses, Practical, Seminars, Assignments, Research work, Discussions with the supervisor, Journal club and Co-Curricular activities over the duration of four semesters. The credits 23 are distributed semester-wise as shown in Table 5. 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 specializations shall include Semester Wise Theory & Practical as given in Table – 1. 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.

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

Course Code	Course	Credit Hours	Credit Points	Hrs./wk	Marks
Semester I					
MIP101T	Modern Pharmaceutical Analytical Techniques	4	4	4	100
MIP102T	Pharmaceutical Formulation Development	4	4	4	100
MIP103T	Novel drug delivery systems	4	4	4	100

MIP104T	Intellectual Property Rights	4	4	4	100
MIP105 P	Industrial Pharmacy Practical I	12	6	12	150
MIP106 P	Seminar/Assignment	7	4	7	100
Total		**35**	**26**	**35**	**650**
Semester II					
MIP201T	Advanced Biopharmaceutics and Pharmacokinetics	4	4	4	100
MIP202T	Scale up and Technology Transfer	4	4	4	100
MIP203T	Pharmaceutical Production Technology	4	4	4	100
MIP204T	Entrepreneurship Management	4	4	4	100
MIP205 P	Industrial Pharmacy Practical II	12	6	12	150
MIP206 P	Seminar/Assignment	7	4	7	100
Total		**35**	**26**	**35**	**650**

Table – 2: Course of study for M. Pharm. III Semester
(Common for All Specializations)

Course Code	Course	Credit Hours	Credit Points
MRM301T	Research Methodology Biostatistics*	4	4
MIP302P	Journal Club	1	1
MIP303P	Discussion / Presentation(Proposal Presentation)	2	2
MIP304P	Research Work	28	14
Total		35	21

* Non University Exam

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

(Common for All Specializations)

Course Code	Course	Credit Hours	Credit Points
MIP401P	Journal Club	1	1
MIP402P	Research Work	31	16
MIP403P	Discussion / Final Presentation	3	3
Total		35	20

Table – 4: Semester wise credits distribution

Semester	Credit Points
I	26
II	26
III	21
IV	20
Co-curricular Activities	Minimum=02

(Attending Conference, Scientific Presentations and Other Scholarly Activities)	Maximum=07*
Total Credit Points	Minimum=95 Maximum=100*

Table – 5: Guidelines for Awarding Credit Points for Co-Curricular Activities

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

Note: International Conference: Held Outside India

International Journal: The Editorial Board outside India

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

10. Program Committee

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 – 6.

11.1. End semester examinations

The End Semester Examinations for each theory and practical course through semesters I to IVshall be conducted by the respective university except for the subject with asterix symbol (*) in table I and II for which examinations shall be conducted by the subject experts at college level and the marks/grades shall be submitted to the university.

Tables –6: Schemes for internal assessments and end semester (Industrial Pharmacy)

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
Semester I								
MIP101T	Modern Pharmaceutical Analytical Techniques	10	15	1 Hr	25	75	3 Hrs	100
MIP102T	Pharmaceutical Formulation Development	10	15	1 Hr	25	75	3 Hrs	100
MIP103T	Novel drug delivery systems	10	15	1 Hr	25	75	3Hrs	100
MIP104T	Intellectual Property Rights	10	15	1 Hr	25	75	3 Hrs	100
MIP105 P	Industrial Pharmacy Practical I	20	30	6 Hrs	50	100	6 Hrs	150
MIP106 P	Seminar/Assignment	-	-	-	-	-	-	-
Total								**650**

Semester II								
MIP201T	Advanced Biopharmaceutics and Pharmacokinetics	10	15	1 Hr	25	75	3 Hrs	100
MIP202T	Scale up and Technology Transfer	10	15	1 Hr	25	75	3 Hrs	100
MIP203T	Pharmaceutical Production Technology	10	15	1 Hr	25	75	3 Hrs	100
MIP204T	Entrepreneurship Management	10	15	1 Hr	25	75	3 Hrs	100
MIP205 P	Industrial Pharmacy Practical II	20	30	6 Hrs	50	100	6 Hrs	150
MIP206 P	Seminar/Assignment	-	-	-	-	-	-	100
Total								**650**

Tables – 7: Schemes for internal assessments and end semester examinations (Semester III& IV)

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
Semester III								
MRM301T	Research Methodology and Biostatistics*	10	15	1 Hr	25	75	3 Hrs	100
MIP302 P	Journal Club	-	-	-	25	-	-	25
MIP303 P	Discussion / Presentation (Proposal Presentation)	-	-	-	50	-	-	50
MIP304 P	Research work	-	-	-	-	350	-	350

Semester IV								
MIP401P	Journal club	-	-	-	25	-	-	25
MIP402P	Discussion / Presentation (Proposal Presentation)	-	-	-	75	-	-	75
MIP403P	Research work and Colloquium	-	-	-	-	400	1 Hr	400
Total								**500**
Total								**525**

*Non University Examination

11.2. Internal assessment: Continuous mode

The marks allocated for Continuous mode of Internal Assessment shall be awarded as per the scheme given below.

Table – 8: Scheme for awarding internal assessment: Continuous mode

Theory	
Attendance (Refer Table – 10)	8
Student – Teacher interaction	2
Total	10
Practical	
Attendance (Refer Table – 10)	10
Based on Practical Records, Regular viva voce, etc.	10
Total	20

Table – 9: 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 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 10. The exact dates of examinations shall be notified from time to time.

Table – 10: Tentative schedule of end semester examinations

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

16. Allowed to keep terms (ATKT):

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

A student shall be eligible to carry forward all the courses of I and 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 –11.

Table – 11: Letter grades and grade points equivalent to Percentage of marks and performances

Percentage of Marks Obtained	Letter Grade	Grade Point	Performance
90.00 – 100	0	10	Outstanding
80.00 – 89.99	A	9	Excellent
70.00 – 79.99	B	8	Good
60.00 – 69.99	C	7	Fair
50.00 – 59.99	D	6	Average
Less than 50	F	0	Fail
Absent	AB	0	Fail

A learner who remains absent for any end semester examination shall be assigned a letter grade of AB and a corresponding grade point of zero. He/she should reappear for the said evaluation/examination in due course.

18. The Semester grade point average (SGPA)

The performance of a student in a semester is indicated by a number called 'Semester Grade Point Average' (SGPA). The SGPA is the weighted average of the grade points obtained in all the courses by the student during the semester. For example, if a student takes five courses (Theory/Practical) in a semester with credits C1, C2, C3 and C4 and the student' s grade points in these courses are G1, G2, G3 and G4, respectively, and then students' SGPA is equal to:

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

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

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

19. Cumulative Grade Point Average (CGPA)

The CGPA is calculated with the SGPA of all the IV semesters to two decimal points and is indicated in final grade report card/final transcript showing the grades of all IV semesters and their courses. The CGPA shall reflect the failed status in case of F grade(s), till the course(s) is/are passed. When the course(s) is/are passed by obtaining a pass grade on subsequent examination(s) the CGPA shall only reflect the new grade and not the fail grades earned earlier. The CGPA is calculated as:

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

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). 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. Award of degree

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

24. Duration for completion of the program of study

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

25. Revaluation I Retotaling of answer papers

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

26. Re-admission after break of study

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

CHAPTER - II: SYLLABUS

SEMESTER-I

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES (MIP101T)

Course Objective:

- To get fundamental knowledge of advanced analytical instrumental techniques for identification, characterization and quantification of drugs
- To handle instruments like NMR, Mass spectrometer, IR, HPLC, GC, etc.
- To perform analysis of elemental impurities

Course Outcomes: On completion of this course, the successful students should be able to:

CO	Statements	Cos & POs Mapping
CO-1	***Analyze*** various drugs in single and combination dosage forms.	PO1, PO2, PO3, PO11, PO12
CO-2	***Analyze*** Chemicals and Excipients	PO1, PO2, PO3, PO11, PO12
CO-3	***Explain*** general principles and theory of spectroscopy	PO1, PO2, PO3, PO4,PO11,PO12
CO-4	***Describe*** various separation techniques by employing chromatographic methods.	PO1, PO2, PO3, PO4,PO11,PO12
CO-5	***Understand*** basic principles of biological tests and immunoassay.	PO1, PO2, PO3, PO11, PO12

THEORY **60 Hours**

11 Hrs

1. a. UV-Visible spectroscopy: Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV- Visible spectroscopy.
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. Spectro flourimetry: Theory of Fluorescence, Factors affecting fluorescence, Quenchers, Instrumentation and Applications of fluorescence spectrophotometer.
d. Flame emission spectroscopy and Atomic absorption spectroscopy: Principle, Instrumentation, Interferences and Applications.

11 Hrs

2.NMR spectroscopy: Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in

various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and 13C NMR. Applications of NMR spectroscopy

11 Hrs

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

11 Hrs

4.Chromatography: Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution and applications of the following:
a) Paper chromatography b) Thin Layer chromatography c) Ion exchange chromatography d) Column chromatography e) Gas chromatography f) High Performance Liquid chromatography g) Affinity chromatography

11 Hrs

5. a. Electrophoresis: Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following:
a) Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresis d) Zone electrophoresis e) Moving boundary electrophoresis f) Iso electric focusing
b. X ray Crystallography: Production of X rays, Different X ray diffraction methods, Bragg‘ s law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X-ray diffraction.

5 Hrs

6. a. Potentiometry: Principle, working, Ion selective Electrodes and Application of potentiometry.

b. Thermal Techniques: Principle, thermal transitions and Instrumentation (Heat flux and power-compensation and designs), Modulated DSC, Hyper DSC, experimental parameters (sample preparation, experimental conditions, calibration, heating and cooling rates, resolution, source of errors) and their influence, advantage and disadvantages, pharmaceutical applications.

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

d. TGA: Principle, instrumentation, factors affecting results, advantage and disadvantages, pharmaceutical applications.

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5. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.
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PHARMACEUTICAL FORMULATION DEVELOPMENT (MIP102T)

Course Objective:

- To impart knowledge and skills necessary to train the students on par with the routine of Industrial activities in R&D and F&D.
- To get knowledge on pre-formulation studies of pilot batches of pharmaceutical industries
- To improve product stability through dissolution testing

Course Outcomes: On completion of this course, the successful students should be able to:

CO	Statements	Cos & POs Mapping
CO-1	***Recall*** the significance of preformulation studies in pharmaceutical formulation development.	PO1, PO2, PO3,PO4,PO6, PO11, PO12
CO-2	***Illustrate*** various formulation additives and understand the factors influencing their incorporation and new developments in excipient science.	PO1, PO2, PO3, PO4, PO6, PO11, PO12
CO-3	***Outline*** the importance of solubility studies and examine different techniques to improve the solubility of poorly aqueous soluble drugs.	PO1, PO2,PO3,PO4,PO6, PO11, PO12
CO-4	***Perceive*** the theories, dissolution mechanism, in vitro dissolution testing models, and factors influencing dissolution in vitro and in-vivo correlation.	PO1, PO2,PO3,PO4,PO6, PO11, PO12
CO-5	***Elaborate*** on the drug degradation mechanisms, factors influencing drug stability, and stability testing of drugs and pharmaceuticals as per ICH guidelines.	PO1,PO2,PO3,PO4,PO6,PO7 PO11, PO12

THEORY **60 Hours**

12 rs

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

12 Hrs

2.Formulation Additives: Study of different formulation additives, factors influencing their incorporation, role of formulation development and processing, new developments in excipient science. Design of experiments – factorial design for product and process development.

12 Hrs

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

12 Hrs

4.Dissolution: Theories, mechanisms of dissolution, in-vitro dissolution testing models– sink and non-sink. Factors influencing dissolution and intrinsic dissolution studies. Dissolution test apparatus – designs, dissolution testing for conventional and controlled release products. Data handling and correction factor. Biorelevent media, in-vitro and in-vivo correlations, levels of correlations.

12 Hrs

5.Product Stability: Degradation kinetics, mechanisms, stability testing of drugs and pharmaceuticals, factors influencing-media effects and pH effects, accelerated stability studies, interpretation of kinetic data (API & tablets). Solid state stability and shelf life assignment. Stability protocols, reports and ICH guidelines.

REFERENCES

1. Lachman L, Lieberman HA, Kanig JL. The Theory and Practice of Industrial Pharmacy, 3rd ed., Varghese Publishers, Mumbai 1991.
2. Sinko PJ. Martin's physical pharmacy and pharmaceutical sciences, 5th ed., B.I. Publications Pvt. Ltd, Noida, 2006.
3. Lieberman HA, Lachman L, Schwartz JB. Pharmaceutical dosage forms: tablets Vol. I-III, 2nd ed., CBS Publishers & distributors, New Delhi, 2005.
4. Conners KA. A Text book of pharmaceutical analysi Wells JI. Pharmaceutical preformulation: Thephysicochemical properties of drug substances. Ellis Horwood Ltd., England, 1998.
5. Yalkowsky SH. Techniques of solubilization of drugs. Vol-12. Marcel Dekker Inc., New York, 1981
6. Dressman J, Kramer J. Pharmaceutical dissolution testing. Saurah printer pvt. Ltd., New Delhi,2005.
7. Sethi PD. Quantitative analysis of drugs in pharmaceutical formulations, 3rd ed., CBS publications, New Delhi, 2008.
8. Carstensen JT, Rhodes CT. Drug stability principles and practices, 3rd ed.,CBS Publishers & distributors, New Delhi, 2005.
9. Yoshioka S, Stella VJ. Stability of drugs and dosage forms, Springer (India) Pvt. Ltd., New Delhi, 2006.
10. Banker GS, Rhodes CT. Modern Pharmaceutics, 4th ed., Marcel Dekker Inc, New York, 2005.
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12. Mazzo DJ. International stability testing. Eastern Press Pvt. Ltd., Bangalore, 1999. 13. Beckett AH, Stenlake JB. Practical pharmaceutical chemistry, Part I & II., 4th ed.,CBS Publishers & distributors, New Delhi, 2004.
13. Indian Pharmacopoeia. Controller of Publication. Delhi, 1996.
14. British Pharmacopoeia. British Pharmacopoeia Commission Office, London, 2008.
15. United States Pharmacopoeia. United States Pharmacopeial Convention, Inc, USA, 2003.
16. Encyclopaedia of Pharm. Technology, Vol I – III.
17. Wells J. I. Pharmaceutical Preformulation: The physicochemical properties of drug substances, Ellis Horwood Ltd. England, 1988.

NOVEL DRUG DELIVERY SYSTEMS (MIP103 T)

Course Objective:

- To impart skilled knowledge and skills necessary to train the students in novel drug delivery systems.
- To formulate and evaluate various novel drug delivery systems
- To understand new trends for Personalized Medicine

Course Outcomes: On completion of this course, the successful students should be able to:

CO	Statements	Cos & POs Mapping
CO-1	***Study*** rate controlled drug delivery systems and various polymers used	PO1,PO2,PO3, PO12
CO-2	***Explain*** the basic concepts in formulating and evaluating various drug delivery systems.	PO1,PO2,PO3, PO4,PO12
CO-3	***Design and Evaluate*** the transdermal drug delivery system and topical delivery systems.	PO1,PO2,PO3, PO4,PO12
CO-4	***Categorize*** the formulation and evaluation concepts of cosmetics for skin, hair, nails and eyes.	PO1,PO2,PO3, PO4,PO12
CO-5	***Appraise*** the events involved in drug targeting and elaborate the concepts of protein, peptide drug delivery, recombinant DNA technology and new trends in personalized medicine.	PO1,PO2,PO3, PO4,PO12

THEORY **60 Hours**

12 Hrs

1.Concept & Models for NDDS: Classification of rate-controlled drug delivery systems (DDS), rate programmed release, activation modulated & feedback regulated DDS, effect of system parameters in controlled drug delivery, computation of desired release rate and dose for controlled release DDS, pharmacokinetic design for DDS – intermittent, zero order & first order release.

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

12 Hrs

2. Study of Various DDS: Concepts, design, formulation & evaluation of controlled release oral DDS, Mucoadhesive DDS (buccal, nasal, pulmonary) Pulsatile, colon specific, liquid sustained release systems, Ocular delivery systems.

08 Hrs

3.Transdermal Drug Delivery Systems: Theory, design, formulation & evaluation including iontophoresis and other latest developments in skin delivery systems.

04 Hrs

4.Sub-Micron Cosmeceuticals: Biology, formulation science and evaluation of various cosmetics for skin, hair, nail, eye etc and it' s regulatory aspects.

12 Hrs

5. a. Targeted Drug Delivery Systems: Importance, concept, biological process and events involved in drug targeting, design, formulation & evaluation, methods in drug targeting – nanoparticles, liposomes, niosomes, pharmacosomes, resealed erythrocytes, microspheres, magnetic microspheres. Specialized pharmaceutical emulsions – multiple emulsions, micro-emulsions.

04 Hrs

b. Protein / Peptide Drug Delivery Systems: Concepts, delivery techniques, formulation, stability
testing, causes of protein destabilization, stabilization methods.

06 Hrs

c. Biotechnology in Drug Delivery Systems: Brief review of major areas-recombinant DNA technology, monoclonal antibodies, gene therapy.

06 Hrs

e. New trends for Personalized Medicine: Introduction, Definition, Pharmacogenetics, Categories of Patients for Personalized Medicines: Customized drug delivery systems, Bioelectronic Medicines, 3D printing of pharmaceuticals, Tele pharmacy.

REFERENCES

1. Novel Drug Delivery System, Y.W. Chein, Vol 50, Marcel Dekker, NY.
2. Controlled Drug Delivery Systems, Robinson, Vol 29, Marcel Dekker, NY.
3. Transdermal Controlled Systemic Medications, YW Chein, Vol 31, Marcel Dekker, NY.
4. Bioadhesive DDS, E. Mathiowitz, Vol 98, Marcel Dekker, NY.
5. Nasal System Drug Delivery, K.S.E. Su, Vol 39, Marcel Dekker, NY.
6. Drug Delivery Devices, Vol 32, P Tyle Marcel Dekker, NY.
7. Polymers for Controlled Drug Delivery, P.J. Tarcha, CRC Press.
8. Pharmaceutical Biotechnology, Vyas, CBS, Delhi.
9. Biotechnology of Industrial Antibiotics, E.J. Vandamme, Marcel Dekker, NY.
10. Protein Formulation & Delivery, E.J. McNally, Vol 99, Marcel Dekker, NY.
11. Drug Targeting, M.H. Rubinstein, John Wiley, NY.

INTELLECTUAL PROPERTY RIGHTS (MIP104T)

Course Objective:

- To assist in the Regulatory Audit process.
- To establish regulatory guidelines for drug and drug products
- To learn the Regulatory requirements for contract research organization

Course Outcomes: On completion of this course, the successful students should be able to:

CO	Statements	Cos & POs Mapping
CO-1	***Explain*** *the* patent, its types, different parts, essential elements and filling process.	PO1,PO2,PO3, PO5,PO6,PO7,PO12
CO-2	***Discuss*** the role of GATT, TRIPS and WIPO in patenting.	PO1,PO2,PO3, PO5,PO6,PO7,PO12
CO-3	***Identify*** the major bodies regulating Indian pharmaceutical sector, IPR's and their types.	PO1,PO2,PO3, PO5,PO6,PO7,PO12
CO-4	***Classify*** the organisation and functions of CDSCO, WHO and USFDA	PO1,PO2,PO3, PO5,PO6,PO7,PO12
CO-5	***Discuss*** the regulatory requirements for contract research organization and regulations of Biosimilars.	PO1,PO2,PO3, PO5,PO6,PO7,PO12

THEORY **60 Hours**

12 Hrs

1.Definition, need for patenting, Types of Patents, Conditions to be satisfied by an invention to be patentable, Introduction to patent search. Parts of patents. Filling of patents. The essential elements of patent; Guidelines for preparation of laboratory note book, Non-obviousness in Patent.

12 Hrs

2. Role of GATT, TRIPS, and WIPO

12 Hrs

3. Brief introduction to Trademark protection and WHO Patents. IPR's and its types, Major bodies regulating Indian Pharmaceutical sector.

12 Hrs

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

12 Hrs

4. **Regulatory requirements** for contract research organization. Regulations for Biosimilars.

REFERENCES:

1. Pharmaceutical Process Validation: By Fra R. Berry and Robert A. Nash, Vol 57, 2nd Edition.
2. Applied Production and Operation Management by Evans, Anderson and Williams.
3. GMP for pharmaceuticals Material Management by K.K. Ahuja Published by CBS publishers.
4. ISO 9000-Norms and explanations.
5. GMP for pharmaceuticals- Willing S.H. Marcel and Dekker.

INDUSTRIAL PHARMACY PRACTICAL – I (MIP105P)

Course Objective:

- To examine the formulation techniques
- To understand the characteristic futures of basic excipients used for various sustained, controlled drug delivery systems and cosmetics.
- To test the prepared modified drug delivery systems

Course Outcomes: On completion of this course, the successful students should be able to:

CO	Statements	Cos & POs Mapping
CO-1	***Recall*** *the basic principles of analytical techniques and their instrumentation used for drug analysis. .*	PO1,PO2,PO3, PO4,PO6,PO11,PO12
CO-2	***Use*** various analytical instruments for the estimation of drugs in various formulations.	PO1,PO2,PO3, PO4,PO6,PO12
CO-3	***Prepare*** various sustained/controlled drug delivery systems and cosmetic preparations to examine the formulation techniques.	PO1,PO2,PO3, PO4,PO6,PO12
CO-4	***Evaluate*** the drug and excipients compatibility and drug release from various formulations.	PO1,PO2,PO3, PO4,PO6,PO12
CO-5	***Describe*** the characteristic futures of basic excipients used for various sustained, controlled drug delivery systems and cosmetics.	PO1,PO2,PO3, PO4,PO6,PO12

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 / GC
4. Estimation of riboflavin/quinine sulphate by fluorimetry
5. Estimation of sodium/potassium by flame photometry
6. Effect of surfactants on the solubility of drugs.
7. Effect of pH on the solubility of drugs.
8. Stability testing of solution and solid dosage forms for photo degradation.
9. Stability studies of drugs in dosage forms at 25^{o}C,60% RH and 40^{o}C, 75% RH.
10. Compatibility evaluation of drugs and excipients (DSC & FTIR).

11. Preparation and evaluation of different polymeric membranes.
12. Formulation and evaluation of sustained release oral matrix tablet/ oral reservoir system.
13. Formulation and evaluation of microspheres / microcapsules.
14. Formulation and evaluation of transdermal drug delivery systems.
15. Design and evaluation of face wash, body- wash, creams, lotions, shampoo, toothpaste, lipstick.
16. Electrophoresis of protein solution.
17. Preparation and evaluation of Liposome delivery system.

SEMESTER-II

ADVANCED BIOPHARMACEUTICS & PHARMACOKINETICS (MIP201T)

Course Objective:

- To impart knowledge and skills necessary for dose calculations, dose adjustments
- To learn and apply Biopharmaceutics theories in practical problem solving.
- To determine the bioavailability testing protocol of a drug

Course Outcomes: On completion of this course, the successful students should be able to:

CO	Statements	Cos & POs Mapping
CO-1	***Understand*** the basic concepts of absorption, distribution, metabolism and excretion of drugs.	PO1,PO2,PO3, PO12
CO-2	***Determine*** the bioavailability testing protocol of a drug and compare the bioequivalence among marketed products.	PO1,PO2,PO3, PO12
CO-3	***Apply*** the pharmacokinetic models for the determination of pharmacokinetic parameters.	PO1,PO2,PO3, PO12
CO-4	***Explain*** the drug product performance in in-vitro, in-vivo and insitu models.	PO1,PO2,PO3, PO4,PO12
CO-5	***Predict and compute*** the pharmacokinetics for the determination of pharmacokinetic and pharmacodynamic drug interactions.	PO1,PO2,PO3, PO12

THEORY **60 Hours**

12 Hrs

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

12 Hrs

2.Biopharmaceutic Considerations in Drug Product Design and In Vitro Drug Product Performance: Introduction, Biopharmaceutic Factors Affecting Drug Bioavailability, Rate-Limiting Steps in Drug Absorption, Physicochemical Nature of the Drug Formulation Factors Affecting Drug Product Performance, In Vitro: Dissolution and Drug Release Testing, Compendial Methods of Dissolution, Alternative Methods of Dissolution Testing, Meeting Dissolution Requirements, Problems of Variable Control in Dissolution Testing Performance of Drug

Products: In Vitro– In Vivo Correlation, Dissolution Profile Comparisons, Drug Product Stability, Considerations in the Design of a Drug Product.

12 Hrs

3.Pharmacokinetics: Basic considerations, Pharmacokinetic models, Compartment modeling: One compartment model- IV bolus, IV infusion, Extra-vascular; Multi Compartment model: Two compartment - model in brief, Non-Linear Pharmacokinetics: Cause of non-linearity, Michaelis – Menten equation, Estimation 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.

12 Hrs

4.Drug Product Performance, In Vivo: Bioavailability and Bioequivalence: Drug Product Performance, Purpose of Bioavailability Studies, Relative and Absolute Availability, , Methods for Assessing Bioavailability, Bioequivalence Studies, Design and Evaluation of Bioequivalence Studies, Study Designs, Crossover Study Designs, Evaluation of the Data, Bioequivalence Example, Study Submission and Drug Review Process, The Biopharmaceutics Classification System, Generic Biologics (Biosimilar Drug Products),Clinical Significance of Bioequivalence Studies, Special Concerns in Bioavailability and Bioequivalence Studies, Generic Substitution.

12 Hrs

5.Application of Pharmacokinetics: Modified-Release Drug Products, Targeted Drug Delivery Systems and Biotechnological Products. Relationship between Pharmacokinetics including Pharmacodynamics: Generation of a pharmacokinetic– pharmacodynamic (PKPD) equation, Pharmacokinetic and pharmacodynamic, interactions. Pharmacokinetics and pharmacodynamics of biotechnology drugs: Introduction, Proteins and peptides, Monoclonal antibodies, Oligonucleotides, Vaccines (immunotherapy), Gene therapies

REFERENCES

1. Biopharmaceutics and Clinical Pharmacokinetics by Milo Gibaldi, 4th edition, Philadelphia, Lea and Febiger, 1991
2. Biopharmaceutics and Pharmacokinetics, A. Treatise, D .M. Brahmankar and Sunil B.J aiswal., Vallab Prakashan, Pitampura, Delhi
3. Applied Biopharmaceutics and Pharmacokinetics by Shargel. Land YuABC, 2nd edition, Connecticut Appleton Century Crofts, 1985
4. Textbook of Biopharmaceutics and Pharmacokinetics, Dr. Shobha Rani R. Hiremath, Prism Book
5. Pharmacokinetics by Milo Gibaldi and D. Perrier, 2nd edition, Marcel Dekker Inc., New York, 1982
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 Publishing Company, 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 Jambhekar and Philip J Breen, pharmaceutical press, RPS Publishing,2009.
13. Absorption and Drug Development- Solubility, Permeability, and Charge State, Alex Avdeef, John Wiley & Sons, Inc, 2003.

SCALE UP AND TECHNOLOGY TRANSFER (MIP202 T)

Course Objective:

- To understand the key requirements for designing pilot plants and scaling up pharmaceutical manufacturing processes to deal with industry
- To introduce the concepts, procedures, and documentation required for validating pharmaceutical processes,
- To familiarise students with the importance of equipment qualification and process validation in ensuring the reliability

Course Outcomes: On completion of this course, the successful students should be able to:

CO	Statements	Cos & POs Mapping
CO-1	***Design*** pilot plants for various dosage forms and apply scale-up principles for successful technology transfer from R&D to full-scale production	PO1,PO2,PO3,PO12
CO-2	***Conduct*** validation of pharmaceutical processes, including analytical, cleaning, and vendor qualification, while maintaining proper documentation	PO1,PO2,PO3,PO4,PO5,PO12
CO-3	***Understan***d the procedures for equipment qualification (IQ, OQ, PQ) and perform validation for key pharmaceutical manufacturing equipment.	PO1,PO2,PO3, PO11,PO12
CO-4	***Validate*** critical pharmaceutical manufacturing processes, ensuring consistency in quality, compliance, and operational standards.	PO1,PO2,PO3,PO12
CO-5	***Identify*** and mitigate industrial safety hazards and design safety systems to control risks and ensure environmental compliance in pharmaceutical manufacturing.	PO1,PO2,PO3,PO12

THEORY **60 Hours**

12 Hrs

1.Pilot plant design: Basic requirements for design, facility, equipment selection, for tablets, capsules, liquid orals, parenteral and semisolid preparations.

Scale up:

Importance, Technology transfer from R & D to pilot plant to plant scale, process scale up for tablets, capsules, liquid orals, semisolids, parentral, NDDS products – stress on formula,

equipment's, product uniformity, stability, raw materials, physical layout, input, in-process and finished product specifications, problems encountered during transfer of technology.

12 Hrs

2.Validation: General concepts, types, procedures & protocols, documentation, VMF. Analytical method validation, cleaning validation and vender qualification.

12 Hrs

3.Equipment Qualification: Importance, IQ, OQ, PQ for equipment's – autoclave, DHS, membrane filter, rapid mixer granulator, cone blender, FBD, tablet compression machine, liquid filling and sealing machine. Aseptic room validation.

12 Hrs

4.Process validation: Importance, validation of mixing, granulation, drying, compression, tablet coating, liquid filling and sealing, sterilization, water process systems, environmental control.

12 Hrs

5.Industrial safety: Hazards – fire, mechanical, electrical, chemical and pharmaceutical, Monitoring & prevention systems, industrial effluent testing & treatment. Control of environmental pollution.

REFERENCES

1. Pharmaceutical process validation, JR Berry, Nash, Vol 57, Marcel Dekker, NY.
2. Pharmaceutical Production facilities, design and applications, by GC Cole, Taylor and Francis.
3. Pharmaceutical project management, T.Kennedy, Vol 86, Marcel Dekker, NY.
4. The theory & Practice of Industrial Pharmacy, L.Lachman, H.A.Lieberman, Varghese Publ. Bombay.
5. Tablet machine instruments in pharmaceuticals, PR Watt, John Wiloy.
6. Pharmaceutical dosage forms, Tablets, Vol 1, 2, 3 by Lachman, Lieberman, Marcel Dekker, NY.
7. Pharmaceutical dosage forms, Parentral medications, Vol 1, 2 by K.E. Avis, Marcel Dekker, NY.
8. Dispersed system Vol 1, 2, 3 by Lachman, Lieberman, Marcel Dekker, NY.
9. Subrahmanyam, CVS, Pharmaceutical production and Management, 2007, Vallabh Prakashan, Dehli.

PHARMACEUTICAL PRODUCTION TECHNOLOGY (MIP203 T)

Course Objective:

- To impart knowledge and skills necessary to train the students to be on par with the routine of Industrial activities in Production.
- To recall the tablet production process, selection of equipment and problems encountered with coating.
- To get skill on air handling systems.

Course Outcomes: On completion of this course, the successful students should be able to:

CO	Statements	Cos & POs Mapping
CO-1	***Recall*** the tablet production process, selection of equipment and problems encountered with coating.	PO1,PO2,PO3,PO4,PO12
CO-2	***Explain*** the production of parenteral, controls and maintenance of aseptic area.	PO1,PO2,PO3,PO4,PO12
CO-3	***Utilize*** the process of freeze drying and spray drying dosage form development.	PO1,PO2,PO3,PO4,PO12
CO-4	***Assess*** the production process of capsules and dispersed systems	PO1,PO2,PO3,PO4,PO12
CO-5	***Elaborate*** air handling systems and processing of water for Pharmaceutical use.	PO1,PO2,PO3,PO4,PO12

THEORY **60 Hours**

12 Hrs

1.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.

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

12 Hrs

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

12 Hrs

3. Lyophilization & Spray drying Technology: Principles, process, freeze-drying and spray drying equipment's.

12 Hrs

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

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

Packaging Technology: Types of packaging materials, machinery, labeling, package printing for different dosage forms.

12 Hrs

5.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.

REFERENCES

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.

ENTREPRENEURSHIP MANAGEMENT (MIP204 T)

Course Objective:

- To provide an understanding of the conceptual framework of entrepreneurship
- To explore the dynamics of entrepreneurial motivation and competencies, and guide the development of key entrepreneurial traits
- To equip students with the skills and knowledge necessary to launch and organize a successful enterprise

Course Outcomes: On completion of this course, the successful students should be able to:

CO	Statements	Cos & POs Mapping
CO-1	***Define*** enterprise, types of enterprises, government policies and schemes for enterprise development.	PO1,PO2,PO3,PO7,PO11PO12
CO-2	***Outline*** the process entrepreneurship development, interpersonal skills, creativity and factors affecting entrepreneur.	PO1,PO2,PO3,PO7,PO11PO12
CO-3	***Plan*** for launching an enterprise, its organization and SWOT analysis.	PO1,PO2,PO3,PO5,PO11,PO12
CO-4	***Appraise*** the performance, assessment of growth, networking and profitability of an enterprise and analyze the resources, raw materials, manpower, market and quality control of an enterprise.	PO1,PO2,PO3,PO7,PO11PO12
CO-5	***Design*** new enterprise, project proposal, resources and implementation.	PO1,PO2,PO3,PO5,PO7,PO11PO12

THEORY **60 Hours**

12 Hrs

1.Conceptual Frame Work: Concept need and process in entrepreneurship development. Role of enterprise in national and global economy. Types of enterprise – Merits and Demerits. Government policies and schemes for enterprise development. Institutional support in enterprise development and management.

12 Hrs

2.Entrepreneur: Entrepreneurial motivation – dynamics of motivation. Entrepreneurial competency – Concepts. Developing Entrepreneurial competencies - requirements and understanding the process of entrepreneurship development, self-awareness, interpersonal skills, creativity, assertiveness, achievement, factors affecting entrepreneur role.

12 Hrs

3.Launching and Organizing an Enterprise: Environment scanning – Information, sources, schemes of assistance, problems. Enterprise selection, market assessment, enterprise feasibility study, SWOT Analysis. Resource mobilization - finance, technology, raw material, site and manpower. Costing and marketing management and quality control. Feedback, monitoring and evaluation.

12 Hrs

4.Growth Strategies and Networking: Performance appraisal and assessment. Profitability and control measures, demands and challenges. Need for diversification. Future Growth – Techniques of expansion and diversification, vision strategies. Concept and dynamics. Methods, Joint venture, co-ordination and feasibility study.

12 Hrs

5. Preparing Project Proposal to Start on New Enterprise Project work – Feasibility report; Planning, resource mobilization and implementation.

REFERENCES

1. Akhauri, M.M.P. (1990): Entrepreneurship for Women in India, NIESBUD, New Delhi.
2. Hisrich, R.D & Brush, C.G. (1996) The Women Entrepreneurs, D.C. Health & Co., Toranto.
3. Hisrich, R.D. and Peters, M.P. (1995): Entrepreneurship – Starting, Developing and Managing a New Enterprise, Richard D., Inwin, INC, USA.
4. Meredith, G.G. etal (1982): Practice of Entrepreneurship, ILO, Geneva.
5. Patel, V.C. (1987): Women Entrepreneurship – Developing New Entrepreneurs, Ahmedabad EDII.

INDUSTRIAL PHARMACY PRACTICAL – II (MIP205P)

Course Objective:

- To understand and apply techniques like solid dispersion for improving the dissolution characteristics of poorly soluble drugs.
- To develop skills in conducting bioavailability studies using animal models
- To gain hands-on experience in the formulation, preparation, and evaluation of various pharmaceutical dosage forms

Course Outcomes: On completion of this course, the successful students should be able to:

CO	Statements	Cos & POs Mapping
CO-1	***Apply*** the solid dispersion technique to enhance the dissolution rate of slightly soluble drugs and evaluate the improvements in drug release profiles..	PO1,PO2,PO3,PO4,PO12
CO-2	***Compare*** the dissolution characteristics of two different marketed products or brands, assessing their bioequivalence and performance in vitro.	PO1,PO2,PO3,PO4,PO12
CO-3	***Perform*** protein binding studies on highly and poorly protein-bound drugs, interpreting the effects on drug pharmacokinetics and therapeutic action.	PO1,PO2,PO3,PO4,PO12
CO-4	***Conduct*** animal-based bioavailability studies for drugs like Paracetamol, perform pharmacokinetic analysis, and utilize software like WinNonLin® to analyze and interpret IVIVC data.	PO1,PO2,PO3,PO4,PO12
CO-5	***Develop and evaluate*** various pharmaceutical dosage forms based on quality control parameters like dissolution, stability, and drug release, ensuring their safety.	PO1,PO2,PO3,PO4,PO12

1. Improvement of dissolution characteristics of slightly soluble drug by Solid dispersion technique.
2. Comparison of dissolution of two different marketed products /brands
3. Protein binding studies of a highly protein bound drug & poorly protein bound drug
4. Bioavailability studies of Paracetamol (Animal).
5. Pharmacokinetic and IVIVC data analysis by WinnolineR software
6. In vitro cell studies for permeability and metabolism
7. Formulation and evaluation of tablets
8. Formulation and evaluation of capsules
9. Formulation and evaluation of injections
10. Formulation and evaluation of emulsion
11. Formulation and evaluation of suspension.
12. Formulation and evaluation of enteric coating tablets.
13. Preparation and evaluation of a freeze dried formulation.
14. Preparation and evaluation of a spray dried formulation.

SEMESTER-III

RESEARCH METHODOLOGY & BIOSTATISTICS (MRM301 T)

Course Objective:

- To provide value addition and current requirement in clinical research and pharmacovigilance
- To conceptualizing, designing, conducting, managing and reporting of clinical trials.
- To develop drug safety data in Pre-clinical and clinical phases of Drug development and post-market surveillance.

Course Outcomes: On completion of this course, the successful students should be able to:

CO	Statements	Cos & POs Mapping
CO-1	***Explain*** the regulatory requirements for conducting clinical trial	PO1, PO2,PO3, PO7, PO12
CO-2	***Demonstrate*** the types of clinical trial designs	PO1, PO2,PO3, PO7, PO12
CO-3	***Execute*** safety monitoring, reporting and close-out activities	PO1, PO2,PO3, PO7, PO12
CO-4	***Describe*** the principles of Pharmacovigilance	PO1, PO2,PO3, PO7, PO12
CO-5	***Perform*** the adverse drug reaction reporting systems and communication in Pharmacovigilance	PO1, PO2,PO3, PO7, PO12

THEORY **60 Hours**

12 Hrs

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

12Hrs

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

12 Hrs

3.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.

12 Hrs

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

12 Hrs

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

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