MANIPAL
ACADEMY of HIGHER EDUCATION
(Deemed to be University under Section 3 of the UGC Act, 1956)

Academic Program Regulations – 2017

Based on PCI Notification in the Gazette of India, No 362, dated 11 December, 2014

Program Title: MPharm (Master of Pharmacy)

CBCS (Choice Based Credit System)

Specialization: Industrial Pharmacy

Manipal College of Pharmaceutical Sciences
Manipal Academy of Higher Education
Manipal-576 104, Karnataka, India

MANIPAL
ACADEMY of HIGHER EDUCATION
(Institution of Eminence Deemed to be University)

July 1, 2023

Academic Program Regulations – 2017 : MPharm, CBCS – Approval

The Master of Pharmacy (MPharm) program, CBCS of Manipal Academy of Higher Education being offered at Manipal College of Pharmaceutical Sciences under the title "Academic Program Regulations – 2017: MPharm, CBCS" has been duly approved by the Academic Council of Manipal Academy of Higher Education.

REGISTRAR

MANIPAL ACADEMY OF HIGHER EDUCATION * INSTITUTION OF EMINENCE DEEMED TO BE UNIVERSITY * MANIPAL - 576 104

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PHARMACY COUNCIL OF INDIA

NOTIFICATION

New Delhi, the 10th December, 2014

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

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

CHAPTER I: REGULATIONS

1. Short title and commencement

These regulations shall be called as "Master of Pharmacy (MPharm) Degree Program-Regulations - Choice Based Credit System (CBCS). The program regulations are based on the PCI notification in the Gazette of India, No. 362, dated 11 December 2014.

They shall come into effect from the academic year 2017-18. The regulations framed are subject to modifications from time to time by the authorities of the Manipal Academy of Higher Education.

2. Minimum qualification for admission

A pass in the following examinations

a) BPharm 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 BPharm).
b) Every student, selected for admission to postgraduate 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.
c) Any foreign pharmacy degree approved by the Pharmacy Council of India.

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

3. Duration of the program

The program of study for MPharm 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 Manipal Academy of Higher Education based on the inputs from Pharmacy Council of India, New Delhi.

4. Medium of instruction and examination

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 July/August to November/December and the even semesters shall be conducted for the month of December/January to May/June in an academic year.

6. Attendance and progress

A candidate is required to put in at least 80% attendance in individual courses considering the 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 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-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 tutorial (T). Practical (P) courses consist of hours spent in the laboratory. Credits (C) for a course are 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/tutorial and a multiplier of half (½) 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 the semester carries a credit of 2. The contact hours of seminars, and research work and journal club shall be treated as that of practical courses for the purpose of calculating credits, i.e., the contact hours shall be multiplied by ½.

7.2. Minimum credit requirements

The minimum credit points required for the award of MPharm degree is 95. However, based on the credit points earned by the students under the heads of co-curricular activities and choice based inter/multidisciplinary courses, a student shall earn a maximum of 100 credit points. These credits are divided into theory courses, practical, seminars, research work, journal club and co-curricular activities over the duration of four semesters. The credits are distributed semester-wise as shown in Table 14. Courses generally progress in sequence, building competencies and their positioning indicate 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 the respective courses.

9. Course work of study

The specializations in MPharm program are given in Table 1.

Table 1. List of MPharm specializations and their codes

S. No.	Specialization	Code
1	Pharmaceutics	MPH
2	Industrial Pharmacy	MIP
3	Pharmaceutical Chemistry	MPC
4	Pharmaceutical Analysis	MPA
5	Pharmaceutical Quality Assurance	MQA
6	Pharmaceutical Regulatory Affairs	MRA
7	Pharmaceutical Biotechnology	MPB
8	Pharmacy Practice	MPP
9	Pharmacology	MPL
10	Pharmacognosy	MPG

The course work of MPharm specializations shall include semester wise theory and practical as given in Table 2 to 13. The number of hours to be devoted to each theory lectures (L), tutorials (T) and practical (P) course in any semester shall not be less than that shown in Table 2 to 13.

Table 2. Course work of MPharm – Pharmaceutics (MPH) specialization						
Course Code	**Course Title**	**Credit hours/week**			**Credit Points**	**Marks**
		Lecture (L)	**Tutorial (T)**	**Practical (P)**		
Semester I						
PQA-MPH101T	Modern Pharmaceutical Analytical Techniques	4	--	--	4	100
PCE-MPH102T	Drug Delivery Systems	4	1	--	5	100
PCE-MPH103T	Modern Pharmaceutics	4	1	--	5	100
PRM-MPH104T	Regulatory Affairs	4	1	--	5	100
PCE-MPH105P	Pharmaceutics Practical I	--	--	12	6	150
PCE-MPH106S	Seminar*	--	--	2	1	100
	Total	**16**	**3**	**14**	**26**	**650**
Semester II						
PCE-MPH201T	Molecular Pharmaceutics (Nano Tech and Targeted DDS)	4	1	--	5	100
PCE-MPH202T	Advanced Biopharmaceutics and Pharmacokinetics	4	1	--	5	100
PCE-MPH203T	Computer Aided Drug Delivery Systems	4	1	--	5	100
PCE-MPH204T	Cosmetic and Cosmeceuticals	4	1	--	5	100
PCE-MPH205P	Pharmaceutics Practical II	--	--	12	6	150
PCE-MPH206S	Seminar*	--	--	2	1	100
	Total	**16**	**4**	**14**	**27**	**650**
* No end-semester examination. Only continuous mode						

Table 3. Course work of MPharm –Industrial Pharmacy (MIP) specialization						
Course Code	**Course Title**	**Credit hours/week**			**Credit Points**	**Marks**
		Lecture (L)	**Tutorial (T)**	**Practical (P)**		
Semester I						
PQA-MIP101T	Modern Pharmaceutical Analytical Techniques	4	--	--	4	100
PCE-MIP102T	Pharmaceutical Formulation Development	4	1	--	5	100
PCE-MIP103T	Novel Drug Delivery Systems	4	1	--	5	100
PRM-MIP104T	Intellectual Property Rights	4	1	--	5	100
PCE-MIP105P	Industrial Pharmacy Practical I	--	--	12	6	150
PCE-MIP106S	Seminar*	--	--	2	1	100
	Total	**16**	**3**	**14**	**26**	**650**
Semester II						
PCE-MIP201T	Advanced Biopharmaceutics and Pharmacokinetics	4	1	--	5	100
PCE-MIP202T	Scale-up and Technology Transfer	4	1	--	5	100
PCE-MIP203T	Pharmaceutical Production Technology	4	1	--	5	100
PRM-MIP204T	Entrepreneurship Management	4	1	--	5	100
PCE-MIP205P	Industrial Pharmacy Practical II	--	--	12	6	150
PCE-MIP206S	Seminar*	--	--	2	1	100
	Total	**16**	**4**	**14**	**27**	**650**
* No end-semester examination. Only continuous mode.						

Table 4. Course work of MPharm – Pharmaceutical Chemistry (MPC) specialization						
Course Code	**Course Title**	**Credit hours/week**			**Credit Points**	**Marks**
		Lecture (L)	**Tutorial (T)**	**Practical (P)**		
Semester I						
PQA-MPC101T	Modern Pharmaceutical Analytical Techniques	4	--	--	4	100
PCH-MPC102T	Advanced Organic Chemistry I	4	1	--	5	100
PCH-MPC103T	Advanced Medicinal Chemistry	4	1	--	5	100
PCH-MPC104T	Chemistry of Natural Products	4	1	--	5	100
PCH-MPC105P	Pharmaceutical Chemistry Practical I	--	--	12	6	150
PCH-MPC106S	Seminar*	--	--	2	1	100
	Total	**16**	**3**	**14**	**26**	**650**
Semester II						
PCH-MPC201T	Advanced Spectral Analysis	4	1	--	5	100
PCH-MPC202T	Advanced Organic Chemistry II	4	1	--	5	100
PCH-MPC203T	Computer Aided Drug Design	4	1	--	5	100
PCH-MPC204T	Pharmaceutical Process Chemistry	4	1	--	5	100
PCH-MPC205P	Pharmaceutical Chemistry Practical II	--	--	12	6	150
PCH-MPC206S	Seminar*	--	--	2	1	100
	Total	**16**	**4**	**14**	**27**	**650**
* No end-semester examination. Only continuous mode.						

Table 5. Course work of MPharm – Pharmaceutical Analysis (MPA) specialization						
Course Code	**Course Title**	**Credit hours/week**			**Credit Points**	**Marks**
		Lecture (L)	**Tutorial (T)**	**Practical (P)**		
Semester I						
PQA-MPA101T	Modern Pharmaceutical Analytical Techniques	4	--	--	4	100
PCH-MPA102T	Advanced Pharmaceutical Analysis	4	1	--	5	100
PCH-MPA103T	Pharmaceutical Validation	4	1	--	5	100
PCH-MPA104T	Food Analysis	4	1	--	5	100
PCH-MPA105P	Pharmaceutical Analysis Practical I	--	--	12	6	150
PCH-MPA106S	Seminar*	--	--	2	1	100
	Total	**16**	**3**	**14**	**26**	**650**
Semester II						
PCH-MPA201T	Advanced Instrumental Analysis	4	1	--	5	100
PCH-MPA202T	Modern Bioanalytical Techniques	4	1	--	5	100
PCH-MPA203T	Quality Control and Quality Assurance	4	1	--	5	100
PCH-MPA204T	Herbal and Cosmetic Analysis	4	1	--	5	100
PCH-MPA205P	Pharmaceutical Analysis Practical II	--	--	12	6	150
PCH-MPA206S	Seminar*	--	--	2	1	100
	Total	**16**	**4**	**14**	**27**	**650**
* No end-semester examination. Only continuous mode.						

Table 6. Course work of MPharm – Pharmaceutical Quality Assurance (MQA) specialization						
Course Code	**Course Title**	**Credit hours/week**			**Credit Points**	**Marks**
		Lecture (L)	**Tutorial (T)**	**Practical (P)**		
Semester I						
PQA-MQA101T	Modern Pharmaceutical Analytical Techniques	4	--	--	4	100
PQA-MQA102T	Quality Management Systems	4	1	--	5	100
PQA-MQA103T	Quality Control and Quality Assurance	4	1	--	5	100
PQA-MQA104T	Product Development and Technology Transfer	4	1	--	5	100
PQA-MQA105P	Pharmaceutical Quality Assurance Practical I	--	--	12	6	150
PQA-MQA106S	Seminar*	--	--	2	1	100
	Total	**16**	**3**	**14**	**26**	**650**
Semester II						
PQA-MQA201T	Hazards and Safety Management	4	1	--	5	100
PQA-MQA202T	Pharmaceutical Validation	4	1	--	5	100
PQA-MQA203T	Audits and Regulatory Compliance	4	1	--	5	100
PQA-MQA204T	Pharmaceutical Manufacturing Technology	4	1	--	5	100
PQA-MQA205P	Pharmaceutical Quality Assurance Practical II	--	--	12	6	150
PQA-MQA206S	Seminar*	--	--	2	1	100
	Total	**16**	**4**	**14**	**27**	**650**
* No end-semester examination. Only continuous mode.						

Table 7. Course work of MPharm – Pharmaceutical Regulatory Affairs (MRA) specialization						
Course Code	**Course Title**	**Credit hours/week**			**Credit Points**	**Marks**
		Lecture (L)	**Tutorial (T)**	**Practical (P)**		
Semester I						
PRM-MRA101T	Good Regulatory Practices	4	--	--	4	100
PRM-MRA102T	Documentation and Regulatory Writing	4	1	--	5	100
PRM-MRA103T	Clinical Research Regulations	4	1	--	5	100
PRM-MRA104T	Regulations and Legislation for Drugs & Cosmetics, Medical Devices, Biologicals & Herbals and Food & Nutraceuticals in India and Intellectual Property Rights	4	1	--	5	100
PRM-MRA105P	Regulatory Affairs Practical I	--	--	12	6	150
PRM-MRA106S	Seminar*	--	--	2	1	100
	Total	**16**	**3**	**14**	**26**	**650**
Semester II						
PRM-MRA201T	Regulatory Aspects of Drugs and Cosmetics	4	1	--	5	100
PRM-MRA202T	Regulatory Aspects of Herbal and Biologicals	4	1	--	5	100
PRM-MRA203T	Regulatory Aspects of Medical Devices	4	1	--	5	100
PRM-MRA204T	Regulatory Aspects of Food and Nutraceuticals	4	1	--	5	100
PRM-MRA205P	Regulatory Affairs Practical II	--	--	12	6	150
PRM-MRA206S	Seminar*	--	--	2	1	100
	Total	**16**	**4**	**14**	**27**	**650**
* No end-semester examination. Only continuous mode.						

Table 8. Course work of MPharm – Pharmaceutical Biotechnology (MPB) specialization						
Course Code	**Course Title**	**Credit hours/week**			**Credit Points**	**Marks**
		Lecture (L)	**Tutorial (T)**	**Practical (P)**		
Semester I						
PQA-MPB101T	Modern Pharmaceutical Analytical Techniques	4	--	--	4	100
PBT-MPB102T	Microbial and Cellular Biology	4	1	--	5	100
PBT-MPB103T	Bioprocess Engineering and Technology	4	1	--	5	100
PBT-MPB104T	Advanced Pharmaceutical Biotechnology	4	1	--	5	100
PBT-MPB105P	Pharmaceutical Biotechnology Practical I	--	--	12	6	150
PBT-MPB106S	Seminar*	--	--	2	1	100
	Total	**16**	**3**	**14**	**26**	**650**
Semester II						
PBT-MPB201T	Proteins and Protein Formulations	4	1	--	5	100
PBT-MPB202T	Immunotechnology	4	1	--	5	100
PBT-MPB203T	Bioinformatics and Computational Biotechnology	4	1	--	5	100
PBT-MPB204T	Biological Evaluation of Drug Therapy	4	1	--	5	100
PBT-MPB205P	Pharmaceutical Biotechnology Practical II	--	--	12	6	150
PBT-MPB206S	Seminar*	--	--	2	1	100
	Total	**16**	**4**	**14**	**27**	**650**
* No end-semester examination. Only continuous mode.						

Table 9. Course work of MPharm – Pharmacy Practice (MPP) specialization						
Course Code	**Course Title**	**Credit hours/week**			**Credit Points**	**Marks**
		Lecture (L)	**Tutorial (T)**	**Practical (P)**		
Semester I						
PPR-MPP101T	Clinical Pharmacy Practice	4	--	--	4	100
PPR-MPP102T	Pharmacotherapeutics I	4	1	--	5	100
PPR-MPP103T	Hospital and Community Pharmacy	4	1	--	5	100
PPR-MPP104T	Clinical Research	4	1	--	5	100
PPR-MPP105P	Pharmacy Practice Practical I	--	--	12	6	150
PPR-MPP106S	Seminar*	--	--	2	1	100
	Total	**16**	**3**	**14**	**26**	**650**
Semester II						
PPR-MPP201T	Principles of Quality Use of Medicines	4	1	--	5	100
PPR-MPP202T	Pharmacotherapeutics II	4	1	--	5	100
PPR-MPP203T	Clinical Pharmacokinetics and Therapeutic Drug Monitoring	4	1	--	5	100
PPR-MPP204T	Pharmacoepidemiology and Pharmacoeconomics	4	1	--	5	100
PPR-MPP205P	Pharmacy Practice Practical II	--	--	12	6	150
PPR-MPP206S	Seminar*	--	--	2	1	100
	Total	**16**	**4**	**14**	**27**	**650**
* No end-semester examination. Only continuous mode.						

Table 10. Course work of MPharm – Pharmacology (MPL) specialization						
Course Code	**Course Title**	**Credit hours/week**			**Credit Points**	**Marks**
		Lecture (L)	**Tutorial (T)**	**Practical (P)**		
Semester I						
PQA-MPL101T	Modern Pharmaceutical Analytical Techniques	4	--	--	4	100
PHA-MPL102T	Advanced Pharmacology I	4	1	--	5	100
PHA-MPL103T	Pharmacological and Toxicological Screening Methods I	4	1	--	5	100
PHA-MPL104T	Cellular and Molecular Pharmacology	4	1	--	5	100
PHA-MPL105P	Pharmacology Practical I	--	--	12	6	150
PHA-MPL106S	Seminar*	--	--	2	1	100
	Total	**16**	**3**	**14**	**26**	**650**
Semester II						
PHA-MPL201T	Advanced Pharmacology II	4	1	--	5	100
PHA-MPL202T	Pharmacological and Toxicological Screening Methods II	4	1	--	5	100
PHA-MPL203T	Principles of Drug Discovery	4	1	--	5	100
PHA-MPL204T	Clinical Research and Pharmacovigilance	4	1	--	5	100
PHA-MPL205P	Pharmacology Practical II	--	--	12	6	150
PHA-MPL206S	Seminar*	--	--	2	1	100
	Total	**16**	**4**	**14**	**27**	**650**
* No end-semester examination. Only continuous mode.						

Table 11. Course work of MPharm – Pharmacognosy (MPG) specialization						
Course Code	**Course Title**	**Credit hours/week**			**Credit Points**	**Marks**
		Lecture (L)	**Tutorial (T)**	**Practical (P)**		
Semester I						
PQA-MPG101T	Modern Pharmaceutical Analytical Techniques	4	--	--	4	100
PCO-MPG102T	Advanced Pharmacognosy I	4	1	--	5	100
PCO-MPG103T	Phytochemistry	4	1	--	5	100
PCO-MPG104T	Industrial Pharmacognostical Technology	4	1	--	5	100
PCO-MPG105P	Pharmacognosy Practical I	--	--	12	6	150
PCO-MPG106S	Seminar*	--	--	2	1	100
	Total	**16**	**3**	**14**	**26**	**650**
Semester II						
PCO-MPG201T	Medicinal Plant Biotechnology	4	1	--	5	100
PCO-MPG202T	Advanced Pharmacognosy II	4	1	--	5	100
PCO-MPG203T	Indian Systems of Medicine	4	1	--	5	100
PCO-MPG204T	Herbal Cosmetics	4	1	--	5	100
PCO-MPG205P	Pharmacognosy Practical II	--	--	12	6	150
PCO-MPG206S	Seminar*	--	--	2	1	100
	Total	**16**	**4**	**14**	**27**	**650**
* No end-semester examination. Only continuous mode.						

Table 13. Course work for MPharm III and IV semesters (Common for all specializations)						
Course Code	**Course Title**	**Credit hours/week**			**Credit Points**	**Marks**
		Lecture (L)	**Tutorial (T)**	**Practical (P)**		
PHA-MRM301T	Research Methodology and Biostatistics*	**4**	**--**	**--**	**4**	**100**
MJC302P	Journal Club*	**--**	**--**	**2**	**1**	**100**
MRW401P	Research Work	**--**	**--**	**70**	**35**	**600**
	Total	**4**	**--**	**72**	**40**	**800**
***** No end-semester examination. Only continuous mode						

Table 14. Semester wise course work credits distribution	
Semester	**Credit Points**
I	26
II	27
III and IV	40
Total course work credits	93
Co-curricular activities (Attending conference, scientific presentations, other scholarly activities and choice based inter/multidisciplinary courses)	Minimum=02* Maximum=07*
Total credit points	**Minimum=95 Maximum=100**

*Credit points for co-curricular activities (Table 15A) and choice based inter/multidisciplinary courses (Table 15B).

Table 15A. 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 principal of the college and the same shall be submitted to the university. The criteria to acquire this credit point shall be defined by the college from time to time.	

Table 15B. List of choice based inter/multidisciplinary courses			
Course Code	**Course Title**	**Credits**	**Department/Institution offering the Course**
Interdisciplinary courses			
PCE-001E	Generic Drug Development	1	Pharmaceutics, MCOPS
PCE-002E	Pharmaceutical Dissolution Technology	1	Pharmaceutics, MCOPS
PCE-003E	Particulate Drug Delivery Systems	1	Pharmaceutics, MCOPS
PCE-004E	3D Printing in Pharmaceutical Manufacturing	1	Pharmaceutics, MCOPS
PCH-001E	Preparative Separation Techniques	1	Pharmaceutical Chemistry, MCOPS
PCH-002E	Molecular Modeling and Drug Design	1	Pharmaceutical Chemistry, MCOPS
PCH-003E	Hyphenated Techniques	1	Pharmaceutical Chemistry, MCOPS
PCH-004E	Chemicals - Environment, Health and Safety	1	Pharmaceutical Chemistry, MCOPS
PQA-001E	Theory and Practice of Analytical and Bioanalytical Method Development and Validation	1	Pharmaceutical Quality Assurance, MCOPS
PQA-002E	Good Documentation Practices and e-Documentation Practices in Pharmaceutical Industry	1	Pharmaceutical Quality Assurance, MCOPS
PQA-003E	Trouble Shooting in High Performance Liquid Chromatography	1	Pharmaceutical Quality Assurance, MCOPS

PQA-004E	Professional Development	1	Pharmaceutical Quality Assurance, MCOPS
PQA-005E	Stability Testing of Drugs and Biologicals	1	Pharmaceutical Quality Assurance, MCOPS
PQA-006E	USFDA Drug Regulatory Affairs	1	Pharmaceutical Quality Assurance, MCOPS
PQA-007E	Rest of the World Drug Regulations	1	Pharmaceutical Quality Assurance, MCOPS
PQA-008E	Evaluation of Medical Devices	1	Pharmaceutical Quality Assurance, MCOPS
PBT-001E	Clean Room Concepts	1	Pharmaceutical Biotechnology, MCOPS
PBT-002E	Biosimilars	1	Pharmaceutical Biotechnology, MCOPS
PBT-003E	Principles of Gene Cloning	1	Pharmaceutical Biotechnology, MCOPS
PBT-004E	Tissue Engineering	1	Pharmaceutical Biotechnology, MCOPS
PPR-001E	Retail Pharmacy Practice	1	Pharmacy Practice, MCOPS
PPR-002E	Fundamentals of Medical Writing	1	Pharmacy Practice, MCOPS
PPR-003E	Systematic Review and Meta-Analysis	1	Pharmacy Practice, MCOPS
PPR-004E	Pharmacokinetics Data Analysis (Employing WinNonlin)	1	Pharmacy Practice, MCOPS
PHA-001E	Cancer Biology	1	Pharmacology, MCOPS
PHA-002E	Screening Methods for Drug Development	1	Pharmacology, MCOPS
PHA-003E	Free Radical Biology and Medicine	1	Pharmacology, MCOPS
PHA-004E	Regulatory Toxicology in Drug Discovery and Development	1	Pharmacology, MCOPS
PCO-001E	Nutraceuticals	1	Pharmacognosy, MCOPS
PCO-002E	Extraction, Separation and Purification of Phytoconstituents	1	Pharmacognosy, MCOPS
PCO-003E	Nanophytopharmaceuticals	1	Pharmacognosy, MCOPS
PCO-004E	Herbal Monographs	1	Pharmacognosy, MCOPS
PRM-001E	Retail Business Management	1	Pharmaceutical Regulatory Affairs & Management, MCOPS
PRM-002E	Intellectual Property Management	1	Pharmaceutical Regulatory Affairs & Management, MCOPS
PRM-003E	General Management Principles	1	Pharmaceutical Regulatory Affairs & Management, MCOPS
PRM-004E	Entrepreneurship Development	1	Pharmaceutical Regulatory Affairs & Management, MCOPS
Multidisciplinary courses			
MU-001E	Certificate Course in Bioinformatics	3	School of Life Sciences, MU
MU-002E	Project Management	4	Department of Humanities and Social Science, MIT
MU-003E	Certificate Course in Bioethics	2/4	Centre for Bioethics, MU
MU-004E	Academic Research and Writing	3	Manipal Centre for Philosophy and Humanities, MU
MU-005E	Certificate Course in Biosecurity	5	Dept. of Public Health, MU
CR-001E	Any one of the Online courses	1 and above	Coursera

10. Program committee

1. The MPharm program shall have a program committee constituted by the Head of the Institution in consultation with all the Heads of the Departments.

2. The composition of the program committee shall be as follows: A teacher at the cadre of professor shall be the Chairperson; One teacher from each MPharm specialization and four student representatives (two from each academic year), nominated by the Head of the Institution.

3. Duties of the program 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 program 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 16.

Table 16. Schemes for internal assessments and end semester examinations

Course	Internal Assessment				End-Semester Exams		Total Marks
	Continuous Mode	Sessional Exams		Total	Marks	Duration	
		Marks	Duration				
Semester I and II							
Theory	10	15	1 hr each	25	75	3 hrs	100
Practical	20	30	6 hrs	50	100	6 hrs	150
Seminar	--	--	--	100	--	--	100
Semester III and IV							
PHA-MRM301T Research Methodology and Biostatistics*	20	40+40	2 hrs each	100	--	--	100
MJC302P Journal Club*	--	--	--	100	--	--	100
MRW401P Research Work	--	100+100	1 hr each	200	400	--	600
***** No end-semester examination. Only continuous mode							

11.1. Internal assessment: Continuous mode

The marks allocated for continuous mode of internal assessment of theory courses shall be awarded based on the students' performance in the assignments/surprise tests, etc., while in the lab course it is based on the practical record, regular viva-voce etc.

11.1.1. Sessional exams

Two sessional exams for each theory course and one sessional examination for a practical course shall be conducted as per the schedule fixed by the college. The schemes of question papers for theory and practical sessional examinations are given below. The average marks of two sessional examinations of theory courses shall be computed for internal assessment of 15 marks as given in Table 16.

Question paper pattern – MPharm Theory sessional examinations

Manipal College of Pharmaceutical Sciences
Manipal Academy of Higher Education, Manipal

MPharm Theory Sessional Examinations, Month and Year

Course Code. Course Title

Date: dd-mm-yyyy Duration: 2 hrs Max. Marks: 45

Instructions: Answer ALL questions

Long Essays (2x 10 marks) = 20 marks
1. Question
2. Question
Short Essays (4 x 5 marks) = 20 marks
3. Question
4. Question
5. Question
6. Question
7. Short answers (1 mark × 5 = 5 marks)
7A.
7B.
7C.
7D.
7E.

Sessional exam shall be conducted for 45 marks for theory and shall be computed for 15 marks. Similarly, sessional exam for practical shall be conducted for 60 marks and shall be computed for 30 marks.

Question paper pattern – MPharm practical sessional examinations
Manipal College of Pharmaceutical Sciences **Manipal Academy of Higher Education, Manipal** **MPharm Practical Sessional Examinations, Month and Year** **Course Code. Course Title** Date: dd-mm-yyyy Duration: 6 hrs Max. Marks: 60 **Instructions: Answer ALL questions.** 1. Synopsis (10 marks) 2. Major Experiment (25 marks) 3. Minor Experiment (15 marks) 4. Viva-Voce (10 marks)

MPharm seminar evaluation scheme						
PRESENTATION (50 Marks)					**Marks awarded for each criteria**	
Criteria					Teacher 1	Teacher 2
1	Preparedness (10 marks)					
2	Response to questions (10 marks)					
3	Audio-visual aids (10 marks)					
4	Clarity of presentation (10 marks)					
5	Breadth and depth of material presented (10 marks)					
				Marks awarded		
				Average marks awarded for presentation out of 50 (A) =		
WRITE UP (50 Marks)						
Marks awarded for each criterion						Marks awarded for write up out of 50 (B)
Content (optimum and relevant to topic) (10 marks)	Recent information or out of date (10 marks)	Organization (sequent and methodical) (10 marks)	Diagram, illustrations & references (10 marks)	Originality (10 marks)		
Remarks if any:						
Seminar marks awarded out of 100 = (A+B) =						

11.2 End-semester examination

End-semester examinations are conducted for eligible students twice at the end of the semester, namely, the main examination for regular students and the make-up/supplementary examinations for the failed students only before the commencement of the next semester (Table 17). In case a failed student could not clear the course in the make-up/supplementary examination, the student would have his next examination along with the regular students only in the main examination.

Table 17. Tentative schedule of end-semester examinations		
Semester	**Main Examination**	**Make-up/Supplementary Exams**
I and III	November/December	December/January
II and IV	May/June	July/August

Question paper pattern – MPharm theory end-semester examinations

Manipal Academy of Higher Education, Manipal

MPharm Theory End-Semester Examinations, Month and Year

Course Code. Course Title

Date: dd-mm-yyyy Duration: 3 hrs Max. Marks: 75

Instructions: Answer ALL questions.

Answer the following (5 marks × 10 = 50 marks)

1. Question
2. Question
3. Question
4. Question
5. Question

Answer the following with specific answers (5 marks × 5 = 25 marks)

6A.
6B.
6C.
6D.
6E.

Question paper pattern – MPharm practical end-semester examinations

MPharm Practical End-Semester Examinations, Month and Year

Manipal Academy of Higher Education, Manipal

Course Code. Course Title

Date: dd-mm-yyyy Duration: 6 hrs Max. Marks: 100

Instructions: Answer ALL questions.

1. Synopsis (15 marks)
2. Major Experiment (45 marks)
3. Minor Experiment (25 marks)
4. Viva-Voce (15 marks)

12. Pass and award of performance grades

12.1: Minimum for a pass in a course

A student should obtain a minimum of 35% marks in the end-semester exam of each course. A student shall be declared PASS if, the candidate secures E-grade separately in each course, in a 10-Point-Relative-Letter Grading-Scheme. Accordingly, no candidate shall be declared to have passed in any course unless he/she obtains a grade not less than E-grade.

12.2 Award of performance grades

The marks obtained in the end semester and internal assessments in a course are added together and a 10-Point-Relative-Letter Grading Scheme is used to allot an appropriate letter grade to the student's performance in that course.

12.3 The 10-Point-Relative-Letter-Grading- Scheme

The letter grades and grade points that are used to assess the students' performance in a course are given in the Table 18

Table 18. 10-Point-Relative-Letter Grading-Scheme

Letter Grade	Grade Point	Performance
A+	10	Outstanding
A	9	Excellent
B	8	Good
C	7	Fair
D	6	Average
E	5	Pass
F/I/DT/ab	0	Fail

F: Fails, I: Incomplete, DT: Detained, ab: Absent

Note the following:

1. Internal assessment marks and end-semester examination marks put together are taken into account for the 10-Point-Relative-Letter Grading-Scheme in each course separately. However, the scheme is applied to a student who scores minimum 35% marks in the end-semester examination of each course.
2. Appropriate letter grades, from E to A+, are awarded, in each theory and lab courses, to only such candidate who has passed the course in first attempt. However, grades E to C are only awarded to a student who makes multiple attempts to pass a course; except in case of I-grade.
3. A candidate who is eligible and registers for the end-semester examination but fails to appear in the end-semester examination or fails in the course gets a grade 'ab', indicating failure.
4. A student who is eligible and registers for the end-semester examination but fails to appear in the end-semester examination due to valid reasons will get a grade 'I', indicating incomplete. However, it needs prior approval of the HOI and the Registrar Evaluation, Manipal Academy of Higher Education.
5. The grade DT is given to a candidate who fails to put in the minimum required attendance for appearing the end-semester examination for a course.
6. A student who earns a grade 'E' or above in a course is declared to have successfully completed the course and earns the credits assigned to that particular course. A course successfully completed cannot be repeated for the purpose of improving the grade.
7. Final evaluation of the performance of a student in each course (theory and lab separately) will be carried out on a 10-Point-Letter Grading-Scheme corresponding to the marks obtained in that course. Eventually each letter grade of the course is converted into a specific grade point associated with the letter grade as given in the table above.

12.4 The Semester Grade Point Average (SGPA)

<u>Note</u>: For the calculation of SGPA and CGPA, the credits assigned for course work are only taken for account.

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 four 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:

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

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

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

12.5. 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 the 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:

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

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,…. .

12.6. Conversion of GPA/CGPA into a percentage

The performance of students who are pursuing pharmacy programs in the Manipal College of Pharmaceutical Sciences, Manipal Academy of Higher Education, Manipal is awarded on a 10-Point-Relative-Letter Grading-Scheme.

In this system the top band (top 10%) of students who score highest marks are placed at A+ which is equivalent to 10 grade point (maximum). Thus, 10 GPA or CGPA is equivalent to 100%. Accordingly, 1 GPA or CGPA is equivalent to 10%.

Based on this, the following formula is applied to convert GPA or CGPA to an appropriate percentage:

Percentage secured by the candidate = GPA or CGPA × 10

13. Make-up/Supplementary examination

In case, a student fails to secure an E-grade in any theory or practical courses, 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 is entitled for a maximum grade of 'C' only, irrespective of the students' top order performances.

However, the candidates with DT-grade will also be allowed to take this examination provided they meet the eligibility criteria laid for the candidates to appear in the end-semester examinations of the courses of the programs.

Important to Note: A student who once failed (F-grade) or DT (Detained) grade in any course, a maximum of C-grade will only be awarded in subsequent end-semester examinations, irrespective of the student's high performances in that particular course. However, those who miss regular examinations due to valid reasons (I-grade) will be allowed to retain whatever the grades they secure in the make-up/supplementary examinations. In case a candidate with DT-grade reregisters for the course to repeat the entire education process in the subsequent academic year, after paying the required course fee, the DT status in that particular course is removed and he/she is allowed to retain the grades that he/she secures in the end-semester examination.

After the results are declared, grade cards will be issued to each student, which will contain the list of courses for that semester and the grades obtained by the student.

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. Promotion to the next higher class

A student shall be eligible to carry forward all the courses of I and II semesters till the III/IV semester examinations. However, the results of IV semester (Research project) of the student shall be declared only when the student passes in all the courses of I and II semesters.

16. 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

17. Research project work

17.1 Dissertation submission

All the students shall undertake a research project under the supervision of a teacher in semester III and IV and submit a dissertation at the end of the IV semester. Four copies of the dissertation shall be submitted.

Note: If any candidate fails to submit the dissertation on or before the date prescribed, the end-semester examination of such candidate shall be at a later date, which shall not be earlier than 6 months from the date fixed in the first instance.

17.2 Dissertation evaluation

The performance of student in the dissertation work is assessed as per the scheme given in the Table 19.

Table 19. MPharm dissertation evaluation scheme

Internal Assessment			**University Examination**					**Grand Total**
Presentation 1 (III semester)	**Presentation 2 (IV semester)**	**Total**	**Dissertation Evaluation (300) by Examiners**		**Viva Voce Joint Evaluation by Internal and External Examiners (100)**		**Total**	
			Internal	External	Presentation	Viva-voce		
i	ii	i+ii=A	i	ii	iii	iv	i+ii+iii+iv =B	A+B
100	**100**	**200**	**150**	**150**	**50**	**50**	**400**	**600**

The internal and external examiners appointed by the university shall evaluate the dissertation of the research project separately as per the following evaluation criteria.

Evaluation of Dissertation: For 150 marks each separately by Internal and External Examiners

	Marks
Objective(s) of the study	25
Literature search	25
Methodology adopted	30
Results and discussions	30
Conclusions and outcomes	20
Bibliography	20
Total	**150**

Evaluation of Presentation and Viva-voce: For 100 marks jointly by Internal and External Examiners

	Marks
Presentation of work	30
Communication skills	20
Total	**50**
Viva-voce	**50**

18. Award of degree

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

19. Duration for completion of the program

The duration for the completion of the program shall be four academic years (double the duration of the prescribed duration). In case, a student is not able to complete the program within this period, the candidate has to reregister for the program.

20. Revaluation of answer papers

There is a provision for revaluation of the answer papers of the end-semester examination as per Manipal Academy of Higher Education policy, however, the candidates have to apply separately by paying the prescribed fee.

21. Re-admission after break of study

The candidate who seeks re-admission to the program after taking a break of the study, has to get the approval from the university.

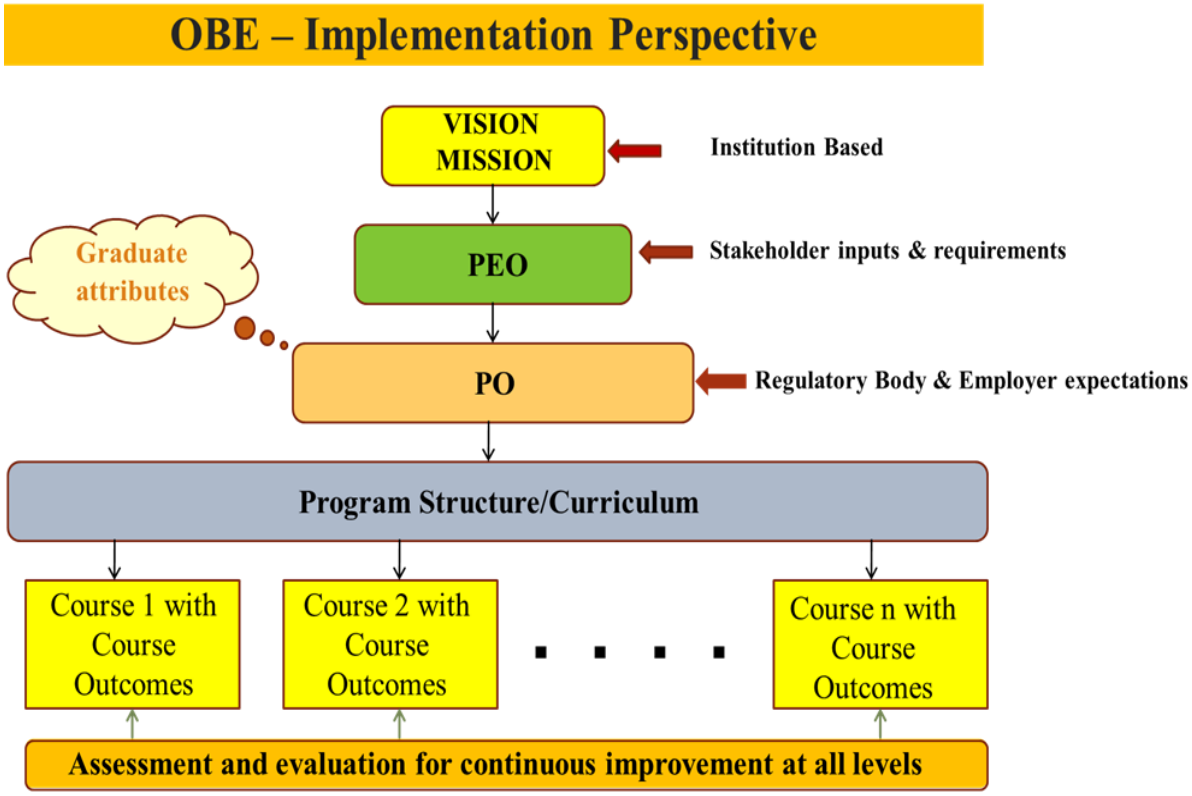
*****

OUTCOME BASED EDUCATION (OBE)

FRAMEWORK

Chapter II

Outcome Based Education (OBE) Framework



MCOPS Vision Mission

Vision:

“Excellence in Pharmaceutical Education and Research”

Mission:

“Marching with the Times”

Quality Policy

- **MCOPS is committed towards providing value-based pharmaceutical education to meet industry, hospital and community needs through continuous improvement of infrastructure and facility for learning, practice and research.**

- **MCOPS shall provide an environment conducive to the development of staff and students.**

MPharm Industrial Pharmacy Program Educational Objectives

The **Department of Pharmaceutics**, Manipal College of Pharmaceutical Sciences, Manipal, accomplishes to cultivate an attitude conducive to self-learning and lifelong learning that would:

PEO No	Education Objectives
PEO 1	Build an education leading to a Masters' degree in Industrial Pharmacy with integrated professional knowledge and technical skills in routine industrial activities and in the development and evaluation of various pharmaceutical dosage forms, with research competencies to work in the domain of pharmaceutical formulation or drug delivery science and technology
PEO 2	Equip the Masters' students with comprehensive knowledge and skills to deliver services to the pharmaceutical organizations to design, formulate, manufacture and evaluate appropriate drug products
PEO 3	Cultivate an inclination for higher education and entrepreneurship.
PEO 4	Foster the best in-class experimental hands-on training in Preformulation, formulation, optimization, scale up and manufacturing of pharmaceuticals using frontier technologies such as Nanotechnology, Hot melt extrusion, Computational tools, and evaluation using Sophisticated Instruments.
PEO 5	Empower and sensitize the Industrial Pharmacy professionals to serve the Pharmaceutical Industry, Academia, Society, Regulatory Bodies and the Profession

MPharm Industrial Pharmacy Program Outcomes (POs)

After successful completion of MPharm Industrial Pharmacy program, students will be able to:

PO No	Attribute	Competency
PO1	**Domain knowledge**	Acquire knowledge and skills in the areas of preformulation, different pharmaceutical dosage forms, industry management, optimization techniques, computational tools, Quality-by-Design, cGMP, IPR, pilot plant scale up, drug regulation, advanced manufacturing processes, biopharmaceutics and pharmacokinetics
PO 2	**Problem analysis**	Identify and analyze the problems related to design, development and manufacturing of dosage forms
PO 3	**Design/develop solutions**	Design and develop the suitable dosage forms to overcome the problems of the drugs in connection with bioavailability, drug targeting, manufacturing and stability by adapting advanced strategies
PO 4	**Conduct investigations of complex problems**	Address the complex problems related to APIs, dosage forms and processes with the help of advanced tools and techniques
PO 5	**Modern tool usage**	Apply appropriate and modern analytical methods, instrumentation, technologies, processes such as computational approaches, Quality-by-Design, nanotechnology, polymer sciences, hot melt extrusion, solubilization and lyophilization in the professional career
PO 6	**Business and society**	Develop and facilitate multidisciplinary approach for entrepreneurship and business proposition in pharmaceutical domain
PO 7	**Environment and sustainability**	Identify the impact of the organizational or business solutions in societal and environmental contexts, and to demonstrate the acquired knowledge for the sustainable development in various pharmaceutical domains
PO 8	**Ethics**	Develop a sense of fair play and sensitivity to professional ethics

PO No	Attribute	Competency
PO 9	**Individual/ team work**	Cultivate the skill and confidence to perform proficiently as an individual, as one of the team members or as a leader of the team in multidisciplinary settings for effective productivity
PO 10	**Communication**	Communicate effectively on academic, research, regulatory and IPR related activities
PO 11	**Project management and finance**	Demonstrate the knowledge of the financial management to evaluate and execute new and ongoing projects for appropriate decision making
PO 12	**Life-long learning**	Cultivate a spirit that would enable individuals to work towards self-driven performance-goals, entrepreneurial endeavors and overall leadership to tackle future challenges through lifelong learning

CHAPTER – III

- **Course Work**
- **COs POs Mapping**
- **Course Outcomes**
- **Course Content and Assessment Plan**
- **Syllabus in detail**

Course work of MPharm –Industrial Pharmacy (MIP) specialization						
Course Code	**Course Title**	**Credit hours/week**			**Credit Points**	**Marks**
		Lecture (L)	**Tutorial (T)**	**Practical (P)**		
Semester I						
PQA-MIP101T	Modern Pharmaceutical Analytical Techniques	4	--	--	4	100
PCE-MIP102T	Pharmaceutical Formulation Development	4	1	--	5	100
PCE-MIP103T	Novel Drug Delivery Systems	4	1	--	5	100
PRM-MIP104T	Intellectual Property Rights	4	1	--	5	100
PCE-MIP105P	Industrial Pharmacy Practical I	--	--	12	6	150
PCE-MIP106S	Seminar*	--	--	2	1	100
	Total	**16**	**3**	**14**	**26**	**650**
Semester II						
PCE-MIP201T	Advanced Biopharmaceutics and Pharmacokinetics	4	1	--	5	100
PCE-MIP202T	Scale-up and Technology Transfer	4	1	--	5	100
PCE-MIP203T	Pharmaceutical Production Technology	4	1	--	5	100
PRM-MIP204T	Entrepreneurship Management	4	1	--	5	100
PCE-MIP205P	Industrial Pharmacy Practical II	--	--	12	6	150
PCE-MIP206S	Seminar*	--	--	2	1	100
	Total	**16**	**4**	**14**	**27**	**650**
* No end-semester examination. Only continuous mode.						

Course work for MPharm III and IV semesters (Common for all specializations)						
Course Code	**Course Title**	**Credit hours/week**			**Credit Points**	**Marks**
		Lecture (L)	**Tutorial (T)**	**Practical (P)**		
PHA-MRM301T	Research Methodology and Biostatistics*	**4**	--	--	**4**	**100**
MJC302P	Journal Club*	--	--	**2**	**1**	**100**
MRW401P	Research Work	--	--	**70**	**35**	**600**
	Total	**4**	--	**72**	**40**	**800**
***** No end-semester examination.						

PROGRAM OUTCOMES (POs) AND COURSE OUTCOMES (COs) MAPPING

S No	Course Code	Course Name	Credits	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO1O	PO11	PO12
1	PQA-MIP101T	Modern Pharmaceutical Analytical Techniques	4	CO1 CO2 CO3	CO1 CO2 CO3	CO1 CO2 CO3	CO1	CO1 CO2 CO3	CO1	CO1 CO2 CO3	CO1 CO2 CO3	CO3	CO1 CO2 CO3	CO1 CO2 CO3	CO1 CO3
2	PCE-MIP102T	Pharmaceutical Formulation Development	5	CO1 CO2 CO3	CO1 CO2 CO3	CO1 CO2 CO3	CO1 CO2 CO3	CO1 CO2	CO1 CO2	CO1 CO3	CO1	CO2	CO2		CO1 CO3
3	PCE-MIP103T	Novel Drug Delivery Systems	5	CO1 CO2 CO3 CO4 CO5	CO1 CO2 CO3	CO1 CO2 CO3 CO4	CO1 CO2 CO3 CO4 CO5	CO1 CO2 CO3	CO1	C03	CO1	CO1 CO3			CO1 CO3 CO4
4	PRM-MIP104T	Intellectual Property Rights	5	CO1		CO1		CO1 CO2			CO2	CO1		CO1 CO2	
5	PCE-MIP105P	Industrial Pharmacy Practical I	6	CO1	CO2 CO3	CO1 CO2 CO3	CO2 CO3	CO1 CO2 CO3			CO1 CO2 CO3	CO1 CO2 CO3	CO1 CO2 CO3		CO1 CO2 CO3
6	PCE-MIP106S	Seminar*	1	CO1	CO1 CO2		CO2 CO5					CO3	CO3 CO4 CO5		CO6
7	PCE-MIP201T	Advanced Biopharmaceutics and Pharmacokinetics	5	CO1 CO2 CO3 CO4 CO5	CO2 CO5	CO2 CO3 CO4	CO4	CO3 CO4 CO5			CO1 CO2 CO3 CO4 CO5	CO2 CO4	CO4 CO5		
8	PCE-MIP202T	Scale-up and Technology Transfer	5	CO1 CO2 CO3	CO1 CO2	CO1	CO1	CO1	CO2	CO2	CO2	CO1 CO2	CO2	CO1 CO2	CO1 CO2 CO3
9	PCE-MIP203T	Pharmaceutical Production Technology	5	CO1 CO2	CO1 CO2	CO1	CO1	CO1 CO2		CO1 CO2	CO1	CO1 CO2	CO1 CO2		CO1 CO2
10	PRM-MIP204T	Entrepreneurship Management	5	CO1					CO1 CO2			CO1			CO1 CO2 CO3
11	PCE-MIP205P	Industrial Pharmacy Practical II	6	CO1	CO1 CO2	CO1	CO1 CO2	CO1 CO2		CO1	CO1 CO2	CO1 CO2	CO1 CO2	CO1	CO1 CO2
12	PCE-MIP206S	Seminar*	1	CO1	CO1 CO2		CO2 CO5					CO3	CO3 CO4 CO5		CO6
13	PHA-MRM301T	Research Methodology and Biostatistics*	4	CO1		CO1	CO2	CO2						CO1	
14	MJC302P	Journal Club*	1	CO1	CO1		CO1					CO2 CO3	CO3		CO4
15	MRW401P	Research Work	35	CO1	CO1	CO4	CO5	CO5	CO6	CO3	CO3		CO5 CO6	CO2	

CHAPTER III: SYLLABUS

MPHARM – INDUSTRIAL PHARMACY (MIP)

SEMESTER I

PQA-MIP101T: MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES

COURSE CODE	PQA-MIP101T
COURSE TITLE	MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES (Theory)

SCOPE / SUMMARY	**OBJECTIVES / COURSE OUTCOMES**
This course deals with various advanced analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are NMR, Mass spectrometer, IR, HPLC, GC etc.	After completion of the course, a student will be able to understand: 1. The theory, instrumentation & applications of UV visible spectroscopy, IR, Fluorimetry & AES. 2. The theory, instrumentation & applications of NMR spectroscopy. 3. The theory, instrumentation & applications of Mass spectrometry. 4. The theory, instrumentation & applications of chromatographic technique. 5. The theory, instrumentation & applications of electrophoresis, XRD, polarimetry, thermal & immunological assays.

Course content and Assessment Plan

I.No	**Course contents**	**Syllabus (Chapters or Units with hours)**	**Marks of assessment**	**Distribution of marks of assessment**		
				Sessional exam (*30% of marks of assessment*)		**End Sem exam (*70% of marks of assessment*)**
				S1	**S2**	
1	Will know about theory, instrumentation and application of various spectroscopic techniques.	Unit I (15 hrs)	30	10		20
2	Will know about the theory, instrumentation and applications of NMR spectroscopy.	Unit II (8 hrs)	15	5		10
3	Will know about the theory, instrumentation and applications of Mass spectrometry.	Unit III (6 hrs)	13		3	10
4	Will know about the theory, instrumentation and applications of various chromatographic techniques.	Unit IV (8 hrs)	19		4	15
5	Will know about the theory, applications of electrophoresis, X-ray crystallography, Potentiometry, Thermal techniques and Immuno assays.	Unit V (15 hrs)	28		8	20
		Total marks of assessment	105	15	15	75

PQA-MIP101T: MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES

THEORY **52 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, Difference/ Derivative spectroscopy. **5 hrs**

b. **IR Spectroscopy**: Theory, modes of molecular vibrations, sample handling, instrumentation of dispersive and Fourier-Transform IR spectrometer, factors affecting vibrational frequencies and applications of IR spectroscopy. **5 hrs**

c. **Spectroflourimetry**: Theory of fluorescence, factors affecting fluorescence, quenchers, instrumentation and applications of fluorescence spectrophotometry. **2 hrs**

d. **Flame Emission Spectroscopy** and atomic absorption spectroscopy: Principle, instrumentation, interferences and applications. **3 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. **8 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. **6 hrs**

4. **Chromatography**: Principle, apparatus/instrumentation, chromatographic parameters, factors affecting resolution and applications of the following:

a) Planar chromatography-Paper, Thin layer chromatography and High performance thin layer chromatography b) Ion exchange chromatography c) Column chromatography d) Gas chromatography e) High performance liquid chromatography and ultra high performance liquid chromatography f) Affinity chromatography g) Gel chromatography. **8 hrs**

5. Other Analytical Techniques

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. **3 hrs**

b. **X-ray Crystallography**: Different X-ray diffraction methods, Bragg's law, Rotating crystal technique, X-ray powder technique, types of crystals and applications of X-ray diffraction. **2 hrs**

c. **Potentiometry**: Principle and application of potentiometry. **2 hrs**

d. **Thermal Techniques**: Principle and application of Differential Scanning Calorimetry, Differential Thermal Analysis and Thermo Gravimetric Analysis. **5 hrs**

e. **Immunological Assays**: RIA (Radio immuno assay), ELISA. **3 hrs**

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, Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi, 1997.
5. Organic Spectroscopy, William Kemp, 3rd edition, ELBS, 1991.
6. Quantitative Analysis of Drugs in Pharmaceutical Formulation, PD Sethi, 3rd edition, CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis-Modern Methods, Part B, J W Munson, Volume11, Marcel Dekker Series.
8. Introduction to Spectroscopy, Donald L Pavia. 8th edition, CENGAGE Learning, USA
9. Contemporary Practice of Chromatography, Poole, Colin F and Sheila A Schuette, Elsevier Science Publishers.
10. Remington: The Science and Practice of Pharmacy, latest edition, Pharmaceutical Press, UK.
11. Quantitative Analysis of Pharmaceutical Formulations by HPTLC, PD Sethi, CBS Publishers, New Delhi.

MPHARM – INDUSTRIAL PHARMACY (MIP)

SEMESTER I

PCE-MIP102T: PHARMACEUTICAL FORMULATION DEVELOPMENT

COURSE CODE	PCE-MIP102T
COURSE TITLE	PHARMACEUTICAL FORMULATION DEVELOPMENT (Theory)

SCOPE / SUMMARY	**OBJECTIVES / COURSE OUTCOMES**
This course is designed to impart knowledge and skills necessary to train the students on par with the routine of Industrial activities in R&D and F&D.	Upon completion of this course the student should be able to study: 1. The scheduled activities in a pharmaceutical firm. 2. The pre formulation studies of pilot batches of pharmaceutical industry. 3. The significance of formulation additives, solubility, dissolution and product stability in the formulation development.

Course Content and Assessment Plan

Sl. No.	**Course Outcomes**	**Syllabus (Chapters or Units with hours)**	**Marks of assessment**	**Distribution of marks of assessment**		
				Sessional exam (*30% of marks of assessment)*		**End Sem exam (*70% of marks of assessment)***
				S1	**S2**	
1	Students will know about preformulation studies of drug and pilot batches in industry.	Unit I (12 hrs)	24	9		15
2	Students will learn about the significance of formulation additives in dosage form.	Unit II (8 hrs)	16	6		10
3	Learners will understand the principles, factors influencing drug solubility and there by its absorption in body.	Unit III (10 hrs)	22		7	15
4	Students will learn about the dissolution theory and mechanisms of different dosage forms.	Unit IV (12 hrs)	23		8	15
5	Students will know the kinetics of drug stability, factors effecting and ICH guidelines for formulation stability study.	Unit V (10 hrs)	20		--	20
		Total Marks of Assessment	105	15	15	75

PCE-MIP102T: PHARMACEUTICAL FORMULATION DEVELOPMENT

THEORY **52 hrs**

1 Preformulation Studies: **12 hrs**

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

2 Formulation Additives: **8 hrs**

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

3 Solubility: **10 hrs**

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

4 Dissolution: **12 hrs**

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 and levels of correlations.

5 Product Stability: **10 hrs**

Degradation kinetics, mechanisms, stability testing of drugs and pharmaceuticals, factors influencing-temperature, media 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: The physicochemical properties of drug substances. Ellis Horwood Ltd., England, 1998.
5. 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 edn., CBS publications, New Delhi, 2008.
8. Carstensen JT, Rhodes CT. Drug stability principles and practices, 3rd edn., CBS Publishers & distributors, New Delhi, 2005.
9. Yoshioka S, Stella VJ. Stability of drugs and dosage forms, Springer (India) Pvt. Ltd., New Delhi, 2006.
10. Banker GS, Rhodes CT. Modern Pharmaceutics, 4th ed., Marcel Dekker Inc, New York, 2005.
11. W. Grimm - Stability testing of drug products.
12. Mazzo DJ. International stability testing. Eastern Press Pvt. Ltd., Bangalore, 1999.
13. 13. Beckett AH, Stenlake JB. Practical pharmaceutical chemistry, Part I & II, 4th ed., CBS Publishers & distributors, New Delhi, 2004.
14. Indian Pharmacopoeia. Controller of Publication. Delhi, 1996.
15. British Pharmacopoeia. British Pharmacopoeia Commission Office, London, 2008.
16. United States Pharmacopoeia. United States Pharmacopeial Convention, Inc., USA, 2003.
17. Encyclopedia of Pharm. Technology, Vol I – III.
18. Wells J. I. Pharmaceutical Preformulation: The physicochemical properties of drug substances, Ellis Horwood Ltd. England, 1988.

MPHARM – INDUSTRIAL PHARMACY (MIP)

SEMESTER I

PCE-MIP103T: NOVEL DRUG DELIVERY SYSTEMS

COURSE CODE	PCE-MIP103T
COURSE TITLE	NOVEL DRUG DELIVERY SYSTEMS(Theory)

SCOPE / SUMMARY	**OBJECTIVES / COURSE OUTCOMES**
This course is designed to impart knowledge and skills necessary in the area of development and evaluation of novel drug delivery systems.	On completion of this course student will be able to 1. Understand controlled drug delivery systems, release kinetic models; classification and characterization of polymers. 2. Understand the methods to formulate and evaluate various drug delivery systems 3. Understand formulation and evaluation of submicron cosmeceutical and transdermal drug delivery systems. 4. Understand the concept, importance of drug targeting, protein/ peptides and biotechnology based drug delivery system. 5. Understand the concept, importance and new trends in personalized medicine

Course Content and Assessment Plan

Sl. No.	**Course Content**	**Syllabus (Chapters or Units with hours)**	**Marks of assessment**	**Distribution of marks of assessment**		
				Sessional exam (*30% of marks of assessment)*		**End Sem exam (*70% of marks of assessment)***
				S1	**S2**	
1	Students will learn the concepts, models and release mechanisms of DDS and study the polymers used	Unit I (12 hrs)	23	8		15
2	Learners will know the design of specific DDS like mucoadhesive,, colon targeted, ocular, pulsatile and mucoadhesive DDS	Unit II (12 hrs)	27	7		20
3	Students will learn formulation aspects of transdermal preparations and submicron cosmeceuticals	Unit III (10 hrs)	20		5	15
4	Students will understand preparation of targeted DDS, protein peptide and biotechnology products	Unit IV (12 hrs)	26		6	20
5	Students will understand the essentials of personalized and customized DDS	Unit V (6 hrs)	9		4	5
		Total Marks of Assessment	105	15	15	75

PCE-MIP103T: NOVEL DRUG DELIVERY SYSTEMS

THEORY **52 hrs**

1 Concept & Models for NDDS: **7 hrs**

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: **5 hrs**

Polymers / co-polymers - introduction, classification, characterization, polymerization techniques, application in CDDS / NDDS, biodegradable & natural polymers

2 Study of Various DDS: **12 hrs**

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

3 Transdermal Drug Delivery Systems: **6 hrs**

Theory, design, formulation & evaluation including iontophoresis and other latest developments in skin delivery systems.

Submicron Cosmeceuticals: **4 hrs**

Biology, formulation science and evaluation of various cosmetics for skin, hair, nail, oral cavity, eye etc., and its regulatory aspects.

4 Targeted Drug Delivery Systems: **6 hrs**

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.

Protein / Peptide Drug Delivery Systems: **4 hrs**

Concepts, delivery techniques, formulation, stability testing, causes of protein destabilization, stabilization methods.

Biotechnology in Drug Delivery Systems: **2 hrs**

Brief review of major areas-recombinant DNA technology, monoclonal antibodies, gene therapy.

5 New trends for Personalized Medicine: **6 hrs**

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

REFERENCES

(Latest Editions)

1. Novel Drug Delivery System, Y.W. Chein, Marcel Dekker, NY.
2. Controlled Drug Delivery Systems, Robinson, Marcel Dekker, NY.
3. Transdermal Controlled Systemic Medications, YW Chein, Marcel Dekker, NY.
4. Bioadhesive DDS, E. Mathiowitz, Marcel Dekker, NY.
5. Nasal System Drug Delivery, K.S.E. Su, Marcel Dekker, NY.
6. Drug Delivery Devices, 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, Marcel Dekker, NY.
11. Drug Targeting, M.H. Rubinstein, John Wiley, NY.
12. Pharmaceutics-Drug Delivery and Targeting, Yvonne Perrie, Thomas Rades, Pharmaceutical Press, London.
13. Controlled Drug Delivery by SP Vyas and Roop C Khar Vallabh Prakashan, New Delhi. (ISBN 81-85731-29-2)

MPHARM – INDUSTRIAL PHARMACY (MIP)

SEMESTER I

PRM-MIP104T: INTELLECTUAL PROPERTY RIGHTS

COURSE CODE	PRM-MIP104T
COURSE TITLE	INTELLECTUAL PROPERTY RIGHTS (Theory)

SCOPE / SUMMARY	**OBJECTIVES / COURSE OUTCOMES**
This course deals with Intellectual Property Rights with an emphasis on Patents. It also includes Licensing and Technology Transfer.	After completion of this course a student should know: 1. Types of Intellectual Property Rights 2. Patent searching and drafting a patent

Course Content and Assessment Plan

Sl. No.	**Course Outcomes**	**Syllabus (Chapters or Units with hours)**	**Total Marks of assessment**	**Distribution of marks of assessment**		
				Sessional exam (*30 % of total marks of assessment)*		**End Sem exam (*70 % of total marks of assessment)***
				S1	**S2**	
1	Learn the historical development of IPR and its various components	Unit I (10 hrs)	21	7		14
2	Understand need for patenting, patent filing process and associated steps	Unit II (10 hrs)	21	8		13
3	Understand various treaties governing IPR	Unit IV (10 hrs)	21		8	13
4	Learn monetizing patents through licensing and tech transfer	Unit V (10 hrs)	21		7	14
5	Learn provisions related to patent infringement and patent revocation, PCT provision and process, importance of data protection and exclusivity; compulsory licensing	Unit III, VI, VII, VIII (12 hrs)	21			21
Total Marks of Assessment			105	15	15	75

PRM-MIP104T: INTELLECTUAL PROPERTY RIGHTS

THEORY **52 hrs**

1. Historical Development of Intellectual Property Rights. IPR's and its types. Brief introduction to Trademark protection. Legislative framework and patent offices-India, US, Europe. **10 hrs**

2. Definition, Need for patenting, Types of Patents, Conditions to be satisfied by an invention to be patentable, Parts of patents. Filling of patents. The essential elements of patent; Non-obviousness in Patent. Patent Search and Patent Processing Patent Drafting and Types of Claims. **10 hrs**

3. Patent Infringement issues and Revocation of Patents. **3 hrs**

4. Role of GATT, TRIPS, and WIPO. Treaties governing IPR, Budapest Treaty and Biotechnology specific IPR issues. **10 hrs**

5. Patent as a Business Tool. Licensing and Technology Transfer. **10 hrs**

6. Overview of Patent Cooperation Treaty (PCT). **3 hrs**

7. Data Protection and Exclusivity. **3 hrs**

8. Compulsory Licensing. **3 hrs**

REFERENCES

1. Intellectual Property Rights in India by VK Ahuja. Lexis Nexis, 2015.
2. Law relating to Intellectual Property by BL Wadehra. Universal Law Publishing, 2016.
3. Basic Concepts of Intellectual Property Rights by Manthan D Janodia. Manipal University Press, 2015.
4. Intellectual Property Rights (IPRs): TRIPS Agreement and Indian Laws by ET Lokganathan. New Century Publications, 2012.
5. Patent office websites: India, US, Australia, China, Japan and Canada.

MPHARM – INDUSTRIAL PHARMACY (MIP)
SEMESTER I
PCE-MIP 105P: INDUSTRIAL PHARMACY PRACTICAL I

COURSE CODE	PHA-MIP105 P
COURSE TITLE	INDUSTRIAL PHARMACY PRACTICAL – I (Practical)

SCOPE/SUMMARY	**OBJECTIVES/COURSE OUTCOMES**
This subject is designed to gain practical skills on formulation and evaluation of various dosage forms, drug delivery systems and cosmetic preparations. This course also provides knowledge on different analytical techniques used for estimation of pharmaceutical active ingredients and their formulations, and stability studies.	Upon completion of this course the student should be able to: 1. Gain knowledge on analytical techniques for estimation of pharmaceutical active ingredients and their formulations. 2. Understand the importance of stability studies and perform the stability studies of formulations. 3. Understand the formulation techniques for various types of tablets and novel drug delivery systems and evaluate them.

Course Content and Assessment Plan

Sl No.	**Course Contents**	**Syllabus (Chapters or Units with hours)**	**Total Marks of assessment**	**Distribution of marks of assessment**	
				Sessional exam (25 *% of total marks of assessment)* **S1**	**End Sem exam (75** *% of total marks of assessment)*
1	Analysis of pharmacopoeial compounds and their formulations by UV Vis spectrophotometer ;Effect of surfactants on the solubility of drugs; Effect of pH on the solubility of drugs; Dissolution methods of transdermal drug delivery systems.	Experiments 1 to 4 (44 hrs)	35	10	25
2	Stability testing of solution and solid dosage forms for photo degradation; Stability studies of drugs in dosage forms at 25°C, 60% RH and 40°C, 75% RH; Compatibility evaluation of drugs and excipients; Preparation and	Experiments 5 to 8 (52 hrs)	40	10	30

	evaluation of different polymeric membranes.				
3	Formulation and evaluation of sustained release oral matrix tablet; Formulation and evaluation of sustained release oral reservoir systems; Formulation and evaluation of microspheres / microcapsules; Formulation and evaluation of transdermal films; Design and evaluation of face wash, body- wash, creams, lotions, shampoo, toothpaste, lipstick.	Experiments 9 to 13 (60 hrs)	55	10	45
Total Marks of Assessment			130	30	100

PCE-MIP105P: INDUSTRIAL PHARMACY PRACTICAL – I

1. Analysis of pharmacopoeial compounds and their formulations by UV Vis spectrophotometer

2. Effect of surfactants on the solubility of drugs.

3. Effect of pH on the solubility of drugs.

4. Dissolution methods of transdermal drug delivery systems.

5. Stability testing of solution and solid dosage forms for photo degradation.

6. Stability studies of drugs in dosage forms at 25°C, 60% RH and 40°C, 75% RH.

7. Compatibility evaluation of drugs and excipients.

8. Preparation and evaluation of different polymeric membranes.

9. Formulation and evaluation of sustained release oral matrix tablet.

10. Formulation and evaluation of sustained release oral reservoir system.

11. Formulation and evaluation of microspheres / microcapsules.

12. Formulation and evaluation of transdermal films.

13. Design and evaluation of face wash, body- wash, creams, lotions, shampoo, toothpaste, lipstick.

REFERENCES

1. Indian Pharmacopoeia

2. United States pharmacopeia

3. https://www.ich.org/page/quality-guidelines

4. International Journal of Pharmaceutics

5. Journal of Controlled Release

6. Journal of Drug Delivery Science and Technology

MPHARM – INDUSTRIAL PHARMACY (MIP)

SEMESTER I

PCE-MIP106S: SEMINAR IN INDUSTRIAL PHARMACY

COURSE CODE	PCE-MIP106S
COURSE TITLE	SEMINAR IN INDUSTRIAL PHARMACY

SCOPE / SUMMARY	**OBJECTIVES / COURSE OUTCOMES**
The subject is designed to create an environment where teachers provide the students a critical eye and openness to fortify the presentation and academic writing skills of students in the field of industrial pharmacy and pharmaceutics	Upon completion of the course the student shall be able to: 1. Develop skills to gather, organize, deliver information, and defend a given topic in industrial pharmacy and pharmaceutics 2. Learn to organize complex concepts using audio-visual aids. 3. Acquire communication and presentation skills. 4. Effectively respond to the questions raised by peers and stand scientific scrutiny. 5. Develop a write-up on the subject of seminar presentation. 6. Cultivate a sense of upgradation of knowledge through self and continuous learning

Course Content and Assessment Plan

Sl. No.	**Course Content**	**Hours**	**Total Marks of assessment**	**Marks**
				End Sem exam
1	The students should be able to develop skills to gather, organize, deliver information, and defend a given topic in industrial pharmacy and pharmaceutics	2 hours/ week	100	No end-semester examination. Only continuous mode.

MPHARM – INDUSTRIAL PHARMACY (MIP)

SEMESTER II

PCE-MIP201T: ADVANCED BIOPHARMACEUTICS AND PHARMACOKINETICS

COURSE CODE	PCE-MIP201T
COURSE TITLE	ADVANCED BIOPHARMACEUTICS AND PHARMACOKINETICS (Theory)

SCOPE / SUMMARY	**OBJECTIVES / COURSE OUTCOMES**
This course is designed to impart knowledge and skills necessary for dose calculations, dose adjustments and to apply biopharmaceutics and pharmacokinetics concepts in practical problem solving. Theoretical discussions of the principles of biopharmaceutics and pharmacokinetics are provided to help the students to clarify these concepts.	Upon completion of this course the student should be able to understand: 1. The basic concepts, mechanisms and the various factors influencing drug absorption. 2. The fundamentals, methods, and significance of dissolution testing in the design and performance of drug products. 3. The use of raw data and derive the pharmacokinetic models and parameters that describe the process of drug absorption, distribution, metabolism, and excretion. 4. To critically evaluate biopharmaceutics studies and study designs involving drug product equivalency. 5. Pharmacokinetic problems and application of the concepts of pharmacokinetics.

Course Content and Assessment Plan

Sl. No.	**Course Contents**	**Syllabus (Chapters or Units with hours)**	**Marks of assessment**	**Distribution of marks of assessment**		
				Sessional exam (*30% of marks of assessment)*		**End Sem exam (*70% of marks of assessment)***
				S1	**S2**	
1	Will know the mechanisms of drug absorption and the various factors affecting drug absorption from the gastrointestinal tract	Unit I (10 hrs)	20	5		15
2	Understand the applications of concepts of dissolution studies in the development of drug products.	Unit II (12 hrs)	22	2	5	15
3	Learn the concepts of pharmacokinetics to design and evaluate dosage regimens of the drugs.	Unit III (12 hrs)	23	8		15

4	Understand the concepts of bioavailability and bioequivalence to evaluate the in vivo drug product performance.	Unit IV (10 hrs)	21		6	15
5	Apply pharmacokinetics principles to modified-release drug products and Individualization of Drug Dosage Regimens.	Unit V (08 hrs)	19		4	15
Total Marks of Assessment			105	15	15	75

PCE-MIP201T: ADVANCED BIOPHARMACEUTICS AND PHARMACOKINETICS

THEORY **52 hrs**

1. Drug Absorption from the Gastrointestinal tract: **10 hrs**

Gastrointestinal tract, Mechanisms of drug absorption, Factors affecting drug absorption: Physicochemical factors (particle size, polymorphism, dissociation constant-pH partition hypothesis, dissolution-dissolution process). Formulation and Processing factors: 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. Transport model to explain drug absorption. Solubility: Experimental methods. Permeability: In-vitro, in-situ and in-vivo methods.

2. Biopharmaceutic Considerations in Drug Product Design and In Vitro Drug Product Performance: **12 hrs**

Introduction, Rate-Limiting Steps in Drug Absorption, Dissolution and Drug Release Testing, Compendial Methods of Dissolution, Alternative Methods of Dissolution Testing, Meeting Dissolution Requirements, Problems of variable control in Dissolution Testing, Dissolution Profile Comparisons, Performance of Drug Products: In vitro–In vivo Correlation, Considerations in the Design of a Drug Product. High-throughput techniques for formulation development.

3. Pharmacokinetics: **12 hrs**

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 K_{max} and V_{max}. Drug interactions: Introduction, Effects of protein-binding and tissue-binding interactions, Cytochrome P450-based drug interactions, Drug interactions linked to transporters.

4. Drug Product Performance, In Vivo: Bioavailability and Bioequivalence: 10 hrs

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.

5. Application of Pharmacokinetics: 8 hrs

Modified-Release Drug Products. Relationship between Pharmacokinetics including Pharmacodynamics: Generation of a pharmacokinetic–pharmacodynamic (PKPD) equation, Individualization of Drug Dosage Regimens, Therapeutic Drug Monitoring, Drug product selection and Dosage regimen design.

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., Vallab Prakashan, Pitampura, Delhi.
3. Applied Biopharmaceutics and Pharmacokinetics by Shargel. Leon, Yu, 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 expande by Robert. E. Notari, Marcel Dekker Inc, New York and Basel, 1987.
10. Biopharmaceutics and Relevant Pharmacokinetics by John. G Wagner and M.Pemarowski, 1st edition, Drug Intelligence Publications, Hamilton, Illinois, 1971.
11. Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James. G.Boylan, Marcel Dekker Inc, New York, 1996.
12. Basic Pharmacokinetics,1 st edition, Sunil S 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.

MPHARM – INDUSTRIAL PHARMACY (MIP)

SEMESTER II

PCE-MIP202T: SCALEUP AND TECHNOLOGY TRANSFER (Theory**)**

COURSE CODE	PCE-MIP202T
COURSE TITLE	SCALEUP AND TECHNOLOGY TRANSFER (Theory)

SCOPE / SUMMARY	**OBJECTIVES / COURSE OUTCOMES**
This course is designed to impart knowledge and skills necessary to train the students to be on scale up, technology transfer process and industrial safety issues.	Upon completion of this course the student should be able to: 1. Manage the scale up process in pharmaceutical industry. 2. Assist in technology transfer. 3. To establish safety guidelines, which prevent industrial hazards.

Course Content and Assessment Plan

Sl. No.	**Course Content**	**Syllabus (Chapters or Units with hours)**	**Marks of assessment**	**Distribution of marks of assessment**		
				Sessional exam (*30% of marks of assessment)*		**End Sem exam (*70% of marks of assessment)***
				S1	**S2**	
1	This unit will help to understand process of converting pilot batches from research to scale up in manufacturing	Unit I (12 hrs)	23	8		15
2	This unit will emphasize on validation master plan	Unit II (10 hrs)	22	7		15
3	This unit will introduce the concepts in equipment qualification as per current industry standards	Unit III (10 hrs)	23		8	15
4	Students will understand qualification of process as per current FDA guidelines	Unit IV (10 hrs)	22		7	15
5	This unit shall impart knowledge on safety aspects and various primary protective equipment.	Unit V (10 hrs)	15			15
Total Marks of Assessment			105	15	15	75

PCE-MIP202T: SCALE-UP AND TECHNOLOGY TRANSFER

THEORY **52 hrs**

1 **12 hrs**

Pilot plant design: Basic requirements for design, facility, equipment selection, for tablets, capsules, liquid orals, parentrals 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, parentrals, NDDS products – stress on formula, equipment, product uniformity, stability, raw materials, physical layout, input, in-process and finished product specifications, problems encountered during transfer of technology. General introduction to pharmaceutical regulatory affairs.

2 **10 hrs**

Validation:

General concepts, types, procedures & protocols, documentation, Validation Management Forum (VMF), cleaning validation and vender qualification.

3 **10 hrs**

Equipment Qualification:

Importance, IQ, OQ, PQ for equipment – autoclave, DHS, membrane filter, rapid mixer granulator, cone blender, FBD, tablet compression machine, liquid filling and sealing machine. Aseptic room validation. User Requirement Specification (URS), Factory Acceptance Testing (FAT) and Site Acceptance Testing (SAT)

4 **10 hrs**

Process validation:

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

5 **10 hrs**

Industrial safety:

Hazards – fire, mechanical, electrical, chemical and pharmaceutical, Monitoring & prevention systems, industrial effluent testing & treatment. Control of environmental pollution. Material safety data sheets (MSDS) of chemicals used in manufacturing and various primary protective equipment (PPEs)

REFERENCES

1. Pharmaceutical process validation, JR Berry, Nash, III edition, Vol 129, 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, III edition, 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, 3rd edition, 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.

MPHARM – INDUSTRIAL PHARMACY (MIP)

SEMESTER II

PCE-MIP203T: PHARMACEUTICAL PRODUCTION TECHNOLOGY

COURSE CODE	PCE-MIP203T
COURSE TITLE	PHARMACEUTICAL PRODUCTION TECHNOLOGY (Theory)

SCOPE / SUMMARY	**OBJECTIVES / COURSE OUTCOMES**
This course is designed to impart knowledge and skills necessary to train the students to be on par with the routine of industrial activities in production.	At completion of this course it is expected that the students will be able to: 1. Understand the processes and equipment used for the formulation of granules, pellets, tablets, coating of tablets and for parenteral production. 2. Learn the process and equipment used for lyophilization, spray drying and the layout requirements, machineries for production and the process of capsules production. 3. Understand the process and equipment used for dispersion system and various types of packaging, equipment used for packaging and labelling of drug products. 4. Understand the of air handling systems, types of water and their production.

Course Content and Assessment Plan

Sl. No.	**Course Contents**	**Syllabus (Chapters or Units with hours)**	**Total marks of assessment**	**Distribution of marks of assessment**		
				Sessional exam (*30% of marks of assessment)*		**End Sem exam (*70% of marks of assessment)***
				S1	**S2**	
1	Processes and equipment used for the formulation of granules, pellets and tablets, process and equipment used for the coating of tablets and problems encountered.	Unit I (12 hrs)	20	5		15
2	Requirements of premises, equipment, utilities, personnel, locations, etc. for parenteral production.	Unit II (10 hrs)	20	5		15
3	Process, equipment used and applications of lyophilization and spray drying.	Unit III (8 hrs)	15	3		12
4	Layout requirements, equipment/machines required	Unit IV	10	2	3	5

	for production of capsules, manufacturing and storage related problems of capsules.	(6 hrs)				
5	Process and equipment used for dispersion systems.	Unit V (4 hrs)	10		3	7
6	Types of packaging and equipment used for packaging and labeling.	Unit VI (4 hrs)	10		3	7
7	Types of air handling systems and their working mechanisms.	Unit VII (4 hrs)	10		3	7
8	Types of water and their production.	Unit VIII (4 hrs)	10		3	7
Total Marks of Assessment			105	15	15	75

PCE-MIP203T: PHARMACEUTICAL PRODUCTION TECHNOLOGY

THEORY **52 hrs**

1

Improved Tablet Production: **8 hrs**

Tablet production process, unit operation improvements, granulation and pelletization equipment, continuous and batch mixing, rapid mixing granulators, rota granulators, speronizers and marumerisers, and other specialized granulation and drying equipments. Problems encountered.

Coating Technology: **4 hrs**

Process, equipment, particle coating, fluidized bed coating, and application techniques. Problems encountered

2

Parenteral Production: **10 hrs**

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

3

Lyophilization Technology and Spray drying Technology: 8 hrs

Principles, process, freeze-drying and spray drying equipments.

4

Capsule Production: 6 hrs

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

5

Disperse Systems Production: **4 hrs**

Production processes, applications of mixers, mills, disperse equipment including fine solids dispersion, problems encountered

6

Packaging Technology: **4 hrs**

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

7

Air Handling Systems: **4 hrs**

Study of AHUs, humidity & temperature control, air filtration systems, dust collectors.

8

Water Treatment Process: 4 hrs

Techniques and maintenance – RO, DM, ultra – filtration, WFI

REFERENCES

1. The theory & Practice of Industrial Pharmacy, L. Lachman, Varghese Publishing, 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 Industry, 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.

MPHARM – INDUSTRIAL PHARMACY (MIP)

SEMESTER II

PRM-MIP204T: ENTREPRENEURSHIP MANAGEMENT

COURSE CODE	PRM-MIP204T
COURSE TITLE	ENTREPRENEURSHIP MANAGEMENT (Theory)

SCOPE / SUMMARY	**OBJECTIVES / COURSE OUTCOMES**
This course is designed to impart knowledge and skills necessary to train the students on entrepreneurship management.	After completing this course it is expected that student will be able to understand: 1. The role of an enterprise in a national and global economy 2. Dynamics of motivation and concepts of entrepreneurship 3. Demands and challenges of Growth Strategies and Networking

Course Content and Assessment Plan

Sl. No.	**Course Content**	**Syllabus (Chapters or Units with hours)**	**Total Marks of assessment**	**Distribution of marks of assessment**		
				Sessional exam (*30 % of total marks of assessment)*		**End Sem exam (*70 % of total marks of assessment)***
				S1	**S2**	
1	Will understand the concept of entrepreneurship development and supporting policies	Unit I (10 hrs)	20	8		12
2	Will learn competencies and dynamics of entrepreneurship	Unit II (10 hrs)	20	7		13
3	Will get insights about market environment scanning and analyzing enabling factors for success of an enterprise	Unit III (12 hrs)	25		8	17
4	Will learn to asses and strategize for the growth of an enterprise	Unit IV (10 hrs)	20		7	13
5	Will learn skills and display entrepreneurship behavior through preparing a project Proposal	Unit V (10 hrs)	20			20
Total Marks of Assessment			105	15	15	75

PRM-MIP 204T: ENTREPRENEURSHIP MANAGEMENT

THEORY **52 hrs**

1. Conceptual Framework **10 hrs**

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.

2. Entrepreneur **10 hrs**

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.

3. Launching and Organising an Enterprise **12 hrs**

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

4. Growth Strategies and Networking **10 hrs**

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.

5. Preparing Project Proposal to Start On New Enterprise **10 hrs**

Project work – Feasibility report; Planning, resource mobilisation 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. et al (1982): Practice of Entrepreneurship, ILO, Geneva.

5. Patel, V.C. (1987): Women Entrepreneurship – Developing New Entrepreneurs, Ahmedabad EDII.

MPHARM – INDUSTRIAL PHARMACY (MIP)

SEMESTER II

PCE-MIP205P: INDUSTRIAL PHARMACY PRACTICAL II

COURSE CODE	PCE-MIP205P
COURSE TITLE	INDUSTRIAL PHARMACY PRACTICAL – II

SCOPE / SUMMARY	**OBJECTIVES / COURSE OUTCOMES**
This subject is designed to provide practical skills on formulation and evaluation of various dosage forms, in vitro studies, bioavailability studies, protein binding concepts, and quality control testing of pharmaceuticals as per pharmacopoeial requirements.	Upon completion of this course the student should be able to - 1. Gain knowledge on formulation skills and QC testing of various dosage forms. 2. Understand the importance of critical process parameters and in vitro studies.

Course Content and Assessment Plan

Sl. No.	**Course Content**	**Syllabus (Chapters or Experiments with hours)**	**Total Marks of assessment**	**Distribution of assessment marks**	
				Sessional exam (25 *% of total marks of assessment)*	**End Sem exam (75 *% of total marks of assessment)***
				S1	
1	Improvement of dissolution characteristics of slightly soluble drug by Solid dispersion technique, Comparison of dissolution of two different marketed products /brands, Protein binding studies of a highly protein bound drug & poorly protein bound drug and Bioavailability studies of Paracetamol.	Experiments 1 to 4 (53 hrs)	45	10	35
2	Pharmacokinetic and IVIVC data analysis by Winnoline^{R} software , *In vitro* cell studies for permeability and metabolism, Formulation and evaluation of tablets and Formulation and evaluation of capsules	Experiments 5 to 8 (50 hrs)	40	10	30

3	Formulation and evaluation of injections, formulation and evaluation of emulsion, Formulation and evaluation of suspension and Formulation and evaluation of enteric coating tablets.	Experiments 9 to 12 (53 hrs)	45	10	35
Total Marks of Assessment			130	30	100

PCE-MIP205P: INDUSTRIAL PHARMACY PRACTICAL II

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.
5. Pharmacokinetic and IVIVC data analysis by Winnoline^{R} 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.

REFERENCES

1. Indian Pharmacopoeia
2. United States pharmacopeia
3. International Journal of Pharmaceutics
4. International journal of pharmaceutical quality assurance
5. Indian journal of pharmaceutical education and research
6. Journal of Drug Delivery Science and Technology

MPHARM – INDUSTRIAL PHARMACY (MIP)

SEMESTER II

PCE-MIP206S: SEMINAR IN INDUSTRIAL PHARMACY

COURSE CODE	PCE-MIP206S
COURSE TITLE	SEMINAR IN INDUSTRIAL PHARMACY

SCOPE / SUMMARY	**OBJECTIVES / COURSE OUTCOMES**
The subject is designed to create an environment where teachers provide the students a critical eye and openness to fortify the presentation and academic writing skills of students in the field of industrial pharmacy and pharmaceutics	Upon completion of the course the student shall be able to: 1. Develop skills to gather, organize, deliver information, and defend a given topic in industrial pharmacy and pharmaceutics 2. Learn to organize complex concepts using audio-visual aids. 3. Acquire communication and presentation skills. 4. Effectively respond to the questions raised by peers and stand scientific scrutiny. 5. Develop a write-up on the subject of seminar presentation. 6. Cultivate a sense of upgradation of knowledge through self and continuous learning

Course Content and Assessment Plan

Sl. No.	**Course Content**	**Hours**	**Total Marks of assessment**	**Marks**
				End Sem exam
1	The students should be able to develop skills to gather, organize, deliver information, and defend a given topic in industrial pharmacy and pharmaceutics	2 hours/ week	100	No end-semester examination. Only continuous mode.

MPHARM – INDUSTRIAL PHARMACY (MIP)

SEMESTER III

PHA-MRM301T: RESEARCH METHODOLOGY AND BIOSTATISTICS

COURSE CODE	PHA-MRM301T
COURSE TITLE	RESEARCH METHODOLOGY AND BIOSTATISTICS (Theory)

SCOPE / SUMMARY	**OBJECTIVES / COURSE OUTCOMES**
This subject is designed to understand the advanced knowledge for research methodology, ethics in research, medical research, design, conduct and interpretation of results. This subject deals with principles of statistics and their applications in biostatistics involving parametric tests, non-parametric tests, correlation, regression, probability theory and statistical hypotheses.	Upon completion of the course, the student shall be able to 1. Know the various components of research design and methodology. 2. Appreciate advanced statistical techniques in solving the research problems.

Course Content and Assessment Plan

Sl No.	**Course Contents**	**Syllabus (Chapters or Units with hours)**	**Total Marks of assessment**	**Distribution of marks of assessment**		
				Sessional exam (*80 % of total marks of assessment)*		**End Sem exam**
				S1	**S2**	
1	Understand the general Research Methodology and study design.	Unit I (10 hrs)	20	20		-
2	Study the statistical principles and their application in biostatistics. Besides, learning various techniques of biostatistics to interpret the study outcomes.	Unit II (12 hrs)	20	20		-
3	Learn the CPCSEA guidelines, records and SOPs related to handling and care of experimental animals.	Unit III (10 hrs)	10		10	-
4	Student will learn the history, principles and concepts of medical research.	Unit IV (10 hrs)	20		20	-
5	Learn history, basic principles for all medical research and additional principles for medical research combined with medical care.	Unit V (10 hrs)	10		10	-
		Total Marks of Assessment	80	40	40	-

PHA-MRM301T: RESEARCH METHODOLOGY AND BIOSTATISTICS

THEORY **52 hrs**

UNIT – I

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

UNIT – II

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

UNIT – III

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

UNIT – IV

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

UNIT – V

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

MPHARM – INDUSTRIAL PHARMACY (MIP)

SEMESTER III

MJC 302P: JOURNAL CLUB IN INDUSTRIAL PHARMACY

COURSE CODE	MJC 302P
COURSE TITLE	JOURNAL CLUB IN INDUSTRIAL PHARMACY

SCOPE / SUMMARY	**OBJECTIVES / COURSE OUTCOMES**
The subject is designed to create an environment where students present a published research paper, and critically analyse it, that would enhance the communication, presentation and analytical skills of the students.	Upon completion of the course the student shall be able to: 1. Learn to organize complex research concepts using audio-visual aids. 2. Acquire communication and presentation skills. 3. Effectively respond to the questions raised by peers and stand scientific scrutiny. 4. Cultivate a sense of upgradation of knowledge through self and continuous learning

Course Content and Assessment Plan

Sl. No.	**Course Content**	**Hours**	**Total Marks of assessment**	**Marks**
				End Sem exam
1	The students should be able to develop skills to gather, organize, deliver information, and defend a given research topic in Industrial Pharmacy and Pharmaceutics	2 hours/week	100	No end-semester examination. Only continuous mode.

MPHARM – CHOICE BASED INTERDISCIPLINARY COURSES

PCE-001E: GENERIC DRUG DEVELOPMENT

(15 hrs)

Introduction to Generic Drug Product Development, API, Analytical Methods Development and Methods Validation for Solid Oral Dosage Forms, Experimental formulation development, Scale-Up, Process Validation, Technology Transfer, Drug stability, QC, QA. Drug product performance in vitro, ANDA Regulatory approval process, BE and drug product assessment in vivo, SUPAC, Outsourcing BA and BE studies to CROs, Legal and legislative hurdles.

REFERENCES

1. Handbook of Pharmaceutical Generic Development, (oral dosage form volume 24 of Drug development series), Locum publishing house, USA.
2. Generic Drug Product Development-Solid Oral dosage form, Leon Shargel and Isadore Kanfer, Marcel Dekker, USA, ISBN: 0-8247-5460-3.

PCE-002E: PHARMACEUTICAL DISSOLUTION TECHNOLOGY

(15 hrs)

Introduction and importance of dissolution. Different Pharmacopoeial requirements (Ph. Eu. JP) on dissolution.	**2 hrs**
Theories of dissolution. Noyes & Whitney equation and Hixson & Crowell Cube root.	**2 hrs**
Compendial methods and official dissolution test apparatus.	**2 hrs**
Principles, concepts and requirements of new dissolution method developments.	**2 hrs**
Alternative methods for drug release studies.	**1 hr**
Recommended apparatus for drug release studies of suppositories, topical, transdermal, powder dosage forms, controlled release products, etc.	**1 hr**
Computation of dissolution data with statistical approaches, model dependent approaches and model independent approaches.	**2 hrs**
Development of IVIVC models.	**1 hr**
Brief account on Biosimilar, Biowaiver, ICH Q4B and new regulatory prospective in dissolution.	**2 hrs**

REFERENCES

1. Pharmaceutical Dissolution Testing by Umesh V. Banakar; Singapore: CRC Press – Taylor & Francis Group.
2. Pharmaceutical Dissolution Testing by Jennifer Dressman and Johannes Krämer; Singapore: Taylor & Francis Group.

PCE-003E: PARTICULATE DRUG DELIVERY SYSTEMS

(15 hrs)

Microparticulate drug delivery Systems: Introduction, advantages, disadvantages, types, methods of preparation & characterization, in vitro & in vivo evaluations and applications.

6 hrs

Nanoparticulate drug delivery Systems: Introduction, advantages, disadvantages, types, methods of preparation & characterization, in vitro & in vivo evaluations and applications.

9 hrs

REFERENCES

1. Encyclopedia of controlled delivery, Editor- Edith Mathiowitz, Published by Wiley Interscience Publication, John Wiley and Sons, Inc, New York. Chichester/Weinheim
2. N.K. Jain, Controlled and Novel Drug Delivery, CBS Publishers & Distributors, New Delhi, First edition 1997 (reprint in 2001)
3. S.P.Vyas and R.K.Khar, Controlled Drug Delivery - concepts and advances, Vallabh Prakashan, New Delhi, First edition 2002
4. Nanoteachnology in Drug Delivery, Melgardt M. De Villers, Pornanong Aramwit and Glen S Kwon, Springer.
5. Nanoparticulate Drug Delivery Systems, Deepak Thassu, Michel Delees and Yashwant Pathak, Informa Healthcare, NY, USA.
6. Nanoparticulates as Drug Carriers, Vladimir P Torchilin, Imperial College Press, London.

PCE-004E: 3D PRINTING IN PHARMACEUTICAL MANUFACTURING

(15 hrs)

Introduction, 3D printing technologies, printing based inkjet systems, Nozzle based deposition systems, Laser based writing systems, 3D printing for customized drug delivery systems, Limitations and challenges.

REFERENCES

1. 3D printing in pharmaceutics: A new tool for designing customized drug delivery systems. Goole Jonathan and Amighi Karim, Int. J Pharm. 499 (2016), 376-394.
2. 3D fabricated polymer-based drug delivery systems, Simon Moulton and Gordon G Wallace, J of Cont. Rel. 193 (2014), 27-34.
3. Fabrication of printed drug delivery systems. Natalja Genina, Ruzica Kolakovic, Mirja Palo, Daniela Fors, Helka Juvonen, Petri Ihalainen, Jouko Peltonen, Niklas Sandler, NIP 29 and Digital Fabrication (2013), 236-238.

PCH-001E: PREPARATIVE SEPARATION TECHNIQUES

(15 hrs)

1. Column chromatography: Introduction, stationary phase, mobile phase selection, column selection, sample loading techniques, elution technique. **9 hrs**
2. Flash chromatography: Principle, advantages, instrumentation, mobile phase selection, column selection, sample loading techniques, elution technique. **6 hrs**

PCH-002E: MOLECULAR MODELLING AND DRUG DESIGN

(15 hrs)

1. Molecular Geometry, Molecular mechanics, Quantum mechanics, Molecular dynamics, Pharmcophore, Molecular docking, Library generation and structure-based drug design. **12 hrs**
2. Database and Software Resources **3 hrs**

PCH-003E: HYPHENATED TECHNIQUES

(15 hrs)

Principle and applications of following hyphenated techniques

1. GC-MS	4. EC-MS	7. LC-MS-MS	10. GC-AES
2. LC-MS	5. CE-MS	8. GC-MS-MS	
3. LC-NMR	6. GC-IR	9. GC-NMR	

PCH-004E: CHEMICALS-ENVIRONMENT, HEALTH AND SAFETY

(15 hrs)

Chemical safety, Chemical hazards, handling of chemicals/gases, storage of chemicals, chemical waste disposal. **8 hrs**

First aid procedures **1 hr**

Good laboratory practices: **2 hrs**

Personal protection **1 hr**

Radioactive materials: Regulatory requirements, hazards, handling, storage, disposal, emergency procedures. **2 hrs**

Fire safety **1 hr**

PQA-001E: THEORY AND PRACTICE OF ANALYTICAL AND BIOANALYTICAL METHOD DEVELOPMENT AND VALIDATION

(15 hrs)

1. Introduction to the concept of validation. **1 hr**
2. Development of analytical method using UV/PDA spectroscopy, Fluorimetry, HPLC, LC-MS/MS. **4 hrs**
3. Validation of the analytical method as per ICH-Q2(R1). **3 hrs**
4. Development of bioanalytical method using HPLC and LC-MS/MS. **2 hrs**
5. Validation of bioanalytical method as per USFDA guidance. **3 hrs**
6. Introduction to Novel upcoming technologies in bioanalysis like dry matrix spot analysis. **1 hr**
7. Introduction to Analysis of therapeutic proteins and peptides. **1 hr**

Evaluation

Formative: Development of validation protocols & problem-based learning. (30%)

Summative: Open book periodical tests & end semester exam. (70%)

PQA-002E: GOOD DOCUMENTATION PRACTICES AND E-DOCUMENTATION PRACTICES IN PHARMACEUTICAL INDUSTRY

(15 hrs)

1. Introduction to GDP and E – documentation **3 hrs**
2. Basic levels of documentation **6 hrs**
    a. Level -1, Level-2, Level-3 and Level-4 documentation
3. Case studies in each level **3 hrs**
4. Open lab and e-documentation concept **3 hrs**

PQA-003E: TROUBLE SHOOTING IN HIGH PERFORMANCE LIQUID CHROMATOGRAPHY

(15 hrs)

1. Introduction to HPLC modules and source of errors/malfunction in HPLC **5 hrs**
2. Startup preliminary checks for trouble shooting **6 hrs**
3. Trouble shooting in HPLC module wise including demonstration **4 hrs**

PQA-004E: PROFESSIONAL DEVELOPMENT

(15 hrs)

1. Introduction to Professional Career Development
2. Introduction to Career Planning: Self Assessment
3. Identifying Your Professional Talents
4. Introduction to Career Planning: Career Exploration
5. Developing Your Professional Resume
6. Enhancing Your Professional Resume
7. Preparing Your Career and Internship Cover Letters
8. Professional Communications
9. Preparing for Your Employment an Internship Interviews
10. Conducting Your Employment and Internship Interviews
11. Introduction to the Career Fair Search Process
12. Exploring Internship Options within Your Profession
13. Networking Search Strategies
14. Developing Your Professional Career Portfolio
15. Influencing Your Networking Partners
16. Essential practical skills and problem solving
17. communication of scientific information
18. IT skills.

Assessments:

- assignments
- case studies
- portfolios
- presentations

PQA-005E: STABILITY TESTING OF DRUGS AND BIOLOGICALS

(15 hrs)

1. Introduction to drug stability and its importance. **2 hrs**
2. Stability testing of drug substances and drug products as ICH Q1 series guidelines **11 hrs**
3. Stability testing of biotechnological/biological products as per ICH Q5C guidelines**. 2 hrs**

PQA-006E: USFDA DRUG REGULATORY AFFAIRS

(15 hrs)

1. Process of new drug development.
2. Contents of IND, NDA, CTD and eCTD, ANDA
3. SMF and DMF
4. Post marketing regulatory requirements.

PQA-007E: REST OF THE WORLD DRUG REGULATIONS

(15 hrs)

Legislation and regulations for import, manufacture, distribution and sale of drugs and pharmaceuticals in:

1. Brazil
2. ASEAN countries
3. CIS countries
4. GCC Countries.

PQA-008E: EVALUATION OF MEDICAL DEVICES

(15 hrs)

A. Biological evaluation of medical devices **10 hrs**

Scope, General principles applying to biological evaluation of medical devices, categorization of medical devices, testing, selection of biological evaluation tests, Assurance of test methods

B. Clinical evaluation of Medical devices **5 hrs**

Importance, scope, clinical evaluation in brief

PBT-001E: CLEAN ROOM CONCEPTS

(15 hrs)

Unit 1. Fundamental aspects of microbiology **3 hrs**

Morphology, Microscopy, Growth and Controlling Growth of Microorganisms.

Unit 2. Clean Room aspects **6 hrs**

Clean Room concepts, layout, facilities, HEPA and ULPA Filter, biosafety cabinets and various classes, biosafety levels, personnel controls.

Unit 3. Microbial monitoring, detection and enumeration of microorganisms **6 hrs**

Monitoring techniques, air samples, microbiological assessment of liquids, solids and semisolids, disposal of cultures.

REFERENCES

1. Cleanroom Microbiology for the Non-microbiology by David M. Carlberg, Second Edition CRC press, 2005.
2. Biopharmaceutical, Biochemistry and Biotechnology, Second Edition, Gary Walsh, Wiley Publishers, 2003.

PBT-002E: BIOSIMILARS

(15 hrs)

Unit -I Biosimilars- Introduction **7 hrs**

Definitions, Generics and Branded drugs, biosimilars, introduction to biologics, differences between biosimilars and generics, manufacturing process and technical challenges associated with production of biosimilar molecules, status of biosimilars. The role of patents in the drug industry and protein-based biopharmaceuticals.

Unit –II Guidelines on Similar Biologic: Regulatory Requirements for Registration and Marketing Authorization in India **8 hrs**

Principles for Development of Similar Biologics, Competent authorities, Selection of reference biologics, Quality consideration of similar biologics, Quality comparability study, Data requirement for preclinical study, clinical application and market authorisation, Post market data for similar biologics.

REFERENCES

1. Proposed guidelines for similar biologics in India, CDSCO.
2. Biosimilars and Interchangeable Biologics: Strategic Elements By Sarfaraz K. Niazi
3. Guidelines from Indian regulatory bodies such as CDSCO, DBT etc. issued time to time.
4. Relevant journals and periodicals.

PBT-003E: PRINCIPLES OF GENE CLONING

(15 hrs)

Unit I **3 hrs**

The aims of Gene Cloning: Techniques of gene manipulation, Outline of gene cloning.

Unit II **6 hrs**

Gene Cloning: Gene cloning procedure, tools required for gene cloning, cloning strategy, techniques for selection of clones, preservation of clones.

Unit III **6 hrs**

Applications of Gene Cloning: In production of therapeutic proteins, diagnostic proteins, transgenic animals and plants.

REFERENCES

1. Molecular biotechnology, Bernard R. Glick, Jack J. Pasternak, Cheryl L. Patten, 2010, ASM Press.
2. Biotechnology: The Biological Principles, M.D. Trevan, S. Boffey, K.H. Goulding and P. Stanbury. 1998, Tata McGraw Hill Edition.

PBT-004E: TISSUE ENGINEERING

(15 hrs)

Unit I **5 hrs**

Introduction to Tissue Engineering: Animal cell culture fundamentals, concept and need of tissue engineering, historical prospective, current status, industry challenges

Unit II **5 hrs**

Biomaterials for Tissue Engineering: Overview, features of scaffold and biomaterials, types of biomaterials, nanofiberous material as biomaterial.

Unit III **5 hrs**

Applications of Tissue Engineering: in Bone tissue regeneration, vascular tissue engineering, skin regeneration, cardiac tissue engineering and neural tissue engineering.

REFERENCES

1. Principles of Tissue Engineering, 4th Edition, Robert Vanza, Robert Langer, Joseph Vacanti. 2014, Academic Press.
2. Exploring Nanotechnology in Healthcare, Edited by N. Udupa,, 2013, Manipal University Press.

PPR-001E: RETAIL PHARMACY PRACTICE

(15 hrs)

1. Retail Pharmacy Management: Site selection, acquisition of premises for a retail pharmacy, layout of drug store, Legal aspects of retail pharmacy (includes Schedule N requirement), role of retail pharmacist and Code of ethics for practicing pharmacists. **4 hrs**
2. Purchase and inventory control, stocking, sale promotion, maintenance of records, economics and management **5 hrs**
3. Communication skills **2 hrs**
4. Medication therapy management **2 hrs**
5. Patient counselling **2 hrs**

REFERENCES

1. Philip P. Gerbino. Remington: The Science and Practice of Pharmacy. Philadelphia, PA. Lippincott Williams & Wilkins. (latest edition)
2. Revikumar KG,Miglani BD. A Text Book of Pharmacy Practice. Career Publications (latest edition)
3. G Parthasarathi, Karin Nyfort Hansen, Milep C Nahata. A Textbook of Clinical Pharmacy Practice Essential Concept and Skill. Oriental Longman Private Limited (latest edition)
4. Ashley WE, Justin J. Community and clinical pharmacy services: A step-by-step approach. The McGraw-Hill Companies, Inc, USA

PPR-002E: FUNDAMENTALS OF MEDICAL WRITING

(15 hrs)

I. Introduction **2 hrs**

- Brief overview of scientific writing
- Scope and importance
- Different types and areas of writing
- Career and opportunities

2. Basic Need To Be A Good **4 hrs**

- Language and Style in Medical Writing
- Literature search

  -Data bases (Medline, PubMed, Cochrane)

- Searching principles (using MeSH, Pub Med)
- Developing searching strategy by PICO

- Cortical Analysis Scientific Paper
- Ethics in Publication (Plagiarism, Copy Rights etc)
- Reference Writing

- Different bibliographic styles
-Citation databases
-Software used in reference writing

3. Different Types of Medical Writing **7 hrs**

- Structured abstract writing
- Report writing and sub-types
- Medication leaflets/pills
- Clinical research form
- Informed consent
- Protocol writing
- Case record form
- PSUR
- News letter

4. MANUSCRIPT WRTING AND PUBLICATION **2 hrs**

- ICMJE guidelines
- How to prepare structured manuscript (IMRA)
- Presentation of data (tables , figures and algorithms)
- Conflict of interest
- Acknowledgement
- Publication issues

Assignments: Preparation of power point, poster, abstract writing, review article with hand on training in publication issues

REFERENCES

1.Janice R Mathews, Jobin M Bowen and Robert W Mathews .Successful scientific writing- A step by step guide for the biological and medical sciences; 1996

2. Piyush Gupta, Navjeevan Singh. How to write thesis and thesis protocol-A primer for medical, dental & nursing courses; 2014
3. John Kirkman. Good style –Writing for science & Technology; 1994
4. Jennifer peat, Elizabeth Elliot, Louise Bour. Scientific writing-Easy when you know how; 1994.

PPR-003E: SYSTEMATIC REVIEW AND META-ANALYSIS

(15 hrs)

1. Study designs: Introduction to Case-control studies, Cohort studies, Randomized controlled trials **1 hr**
2. Applied statistics: Descriptive statistics, Hypothesis, Null-hypothesis, type-1 & type-2 errors, power, p-value, Confidence intervals, Odds ratio, Relative risk (risk ratio), Fixed effects & Random effects, Concept of homogeneity & heterogeneity and tests for heterogeneity, Various types bias and methods to detect bias, Funnel plot, Effect size & effect size indices, Forest plot **3 hrs**
3. Evidence based clinical practice: Definition, importance, levels of evidence. **1 hr**
4. Systematic review and meta-analysis: Definition, types, importance, applications, Meta-analysis groups (Campbell Collaboration, Cochrane Collaboration) **1 hr**
5. Steps involved in conducting Systematic review and Meta-analysis: **5 hrs**
   a. Framing the question
   b. Literature search
   c. Assessing the quality of studies
   d. Selection of studies
   e. Data synthesis & Analysis
   f.Summarizing the evidence
   g. Interpretation of the findings
6. Introduction to softwares used in meta-analysis: MedCalc, Comprehensive Meta-analysis software, RevMan, Open meta-analysis **1 hr**
7. Writing a meta-analysis protocol, Literature search, Data synthesis &analysis (Assignments) **3 hrs**

REFERENCES:

1. Higgins JPT, Green S, editors. Cochrane Handbook for Systematic Reviews of Interventions 4.2.6 [updated September 2006]. In: The Cochrane Library, Issue 4, 2006. Chichester, UK: John Wiley & Sons, Ltd.

2. Borenstein, M, Hedges LV, Higgins JPT, Rothstein HR. Introduction to Meta-Analysis. John Wiley & Sons, Ltd., 2009.

Pre-requisites: Knowledge of Biostatistics & Research Methodology, Web-based literature search

Evaluation: Based on Assignments

PPR-004E: PHARMACOKINETICS DATA ANALYSIS

(Employing WinNonlin)

(15 hrs)

1. Introduction to pharmacokinetic parameters: Elimination rate constant (ke), Elimination half-life, Bioavailability & AUC, Volume of distribution, Clearance, Bioequivalence 2 hrs
2. Bioavailability studies: In animal & human **2 hrs**
3. PK parameters for Oral & IV administration: Calculation of PK parameters for oral & IV administration by plotting concentration vs time graph (using semi-log graph paper) **2 hrs**
4. Introduction Phoenix WinNonlin: Data entry and data tools, graphs **2 hrs**
5. Non-compartmental analysis using (NCA) Phoenix WinNonlin: For Oral, IV, IV infusion, Sparse sampling and urinary excretion data **3 hrs**
6. Pharmacokinetic modeling: Compartment modelling, choosing the right compartment model, Simulating using PK model **2 hrs**
7. Bioequivalence data analysis: Parallel, Cross-over study data analysis **2 hrs**

REFERENCES

1. Gibaldi M, Perrier D. Pharmacokinetics. 2nd edition. Informa Healthcare; 2007.
2. Rowland M, Tozer TN. Clinical Pharmacokinetics: Concepts & Applications. 4th edition. Lippincott Williams& Wilkins;2011.
3. Phoenix WinNonlin examples guide. Pharsight. A Certara Company; 2012
4. Phoenix WinNonlin Users guide. Pharsight. A Certara Company; 2012.
5. Guidance for Industry: Bioavailability and Bioequivalence Studies Submitted in NDAs or INDs- General Considerations. US FDA. 2014.

Pre-requisites: Knowledge of basic pharmacokinetics.

Evaluation: Based on Assignments.

PHA-001E: CANCER BIOLOGY

(15 hrs)

Objectives/Course Outcomes

This course aims to provide students an extensive understanding about cancer and its effects on the human body. This course will also discuss the historical aspect of cancer research, basic chemotherapeutics and future scope in cancer research. All the topics will be presented in a simplified scientific manner with an emphasis on gaining a broad understanding of the disease.

1. Advanced Cell Biology- Structural and functional basis of cell, structure of chromosome and DNA, Cell cycle and its regulation. **3 hrs**
2. Molecular and genetic basis of cancer- Growth signaling, dysfunction of cell cycle leading to cancer, Oncogene, tumor suppressor gene, Apoptosis **6 hrs**
3. Cellular aspect of cancer- History of cancer, six hallmarks of cancer, Types of cancer, Metastasis, Cancer Prevention and Treatment. **3 hrs**
4. Current trends in Cancer research- Targets for development of cancer chemotherapeutics, its identification and relevance, Recent advancements in cancer therapy. **3 hrs**

PHA-002E: SCREENING METHODS FOR DRUG DEVELOPMENT

(15 hrs)

The course aims at providing the conceptual learning of a few basic pharmacological approaches to elucidate the pharmacological activity of a new chemical entity. The knowledge of screening methods facilitates the understanding of animal models, which closely mimics the human pathology, to screen the promising molecules for developing a new drug.

1. Introduction: General Screening techniques
2. Screening methods for local anesthetics
3. Screening methods for anti-hypertensive drugs
4. Screening methods for anti-arrhythmic drugs
5. Screening methods for anti-inflammatory drugs
6. Screening methods for analgesic drugs
7. Screening methods for antipyretic drugs
8. Screening methods for anticancer drugs
9. Screening methods for antidiabetic drugs

10. Screening methods for anti-dyslipidemia drugs
11. Screening methods for antiepileptic drugs
12. Screening methods for antidepressant drugs
13. Screening methods for antianxiety drugs
14. Screening methods for antiparkinsonian drugs
15. Screening methods for Alzheimer's disease related dementia

PHA-003E: FREE RADICAL BIOLOGY AND MEDICINE

(15 hrs)

Objectives

To provide fundamentals which are essential for researchers who wish to pursue problems of human health that involve free radicals, related oxidants, antioxidants, and antioxidant enzymes. Students will be able to understand, interpret, and critically think on issues associated with major causes of health problems.

1. Basics of free radicals in biology and medicine
2. Concept of oxidative stress in biology and diseases
3. Oxidative stress markers
4. Radical scavengers: The concept of antioxidants
5. Redox signaling and NRF2-ARE signaling mechanisms
6. Free radicals in inflammation and immune disorders
7. Free radicals in diabetes, obesity and metabolic disorders
8. Free radicals in cancer
9. Free radicals in cardiovascular diseases
10. Free radicals in neurodegenerative disorders
11. Free radicals and ageing
12. Free radicals in infectious diseases and antimicrobial-resistance
13. Free radicals in hepato-biliary diseases
14. Antioxidants screening methods: *In vitro* and *in vivo*
15. Recent advances in antioxidant discovery and development

Study material: Recent journal articles from reputed and Open Access Journals

PHA-004E: REGULATORY TOXICOLOGY IN DRUG DISCOVERY AND DEVELOPMENT

(15 hrs)

Objectives

This subject is to project the importance of safety testing in pre-clinical research and harmonized standards that they have to adopt for safety testing procedures.

Introduction: General Principles of Toxicology, Agencies and their guidelines regarding Toxicology studies, Concept of Good Laboratory practices. **3hrs**

Guidelines for safety testing

Pharmacological studies: Safety Pharmacology Studies for Human Pharmaceuticals, QT interval prolongation study in animals. **3 hrs**

Toxicity testing: Toxicokinetics: The Assessment of Systemic Exposure in Toxicity Studies, Pharmacokinetics: Guidance for Repeated Dose Tissue Distribution Studies, Acute, subacute and Chronic toxicity in animals **4 hrs**

Special toxicity studies: Non-clinical Carcinogenicity studies, Genotoxicity studies, Reproductive toxicology, Immunotoxicity, Safety evaluation of Biotechnology- derived products. **5 hrs**

PCO-001E: NUTRACEUTICALS

(15 hrs)

Scope

Nutraceuticals:The food or part of food with additional health benefits are emerging as major health supplements for prevention, management and some-times cure of various diseases. In the current fast lifestyle, nutraceuticals are encroaching pharma markets not only in the developed but also in the developing countries. Therefore, an additional knowledge in nutraceuticals or health supplements add an edge to the student.

Objectives

The course proposes to offer a comprehensive knowledge on the nutraceuticals and their importance to prepare the student for a pursuit in the health food sector.

1. Introduction to nutraceuticals: Overview, classification, benefits of nutraceuticals, functional foods **3 hrs**
2. In organic supplements and vitamins **1 hr**
3. Probiotics, prebiotics and digestive enzymes **1 hr**
4. Dietary supplements and fibres **1 hr**
5. Antioxidants and PUFAs **2 hrs**

6. Herbs as health foods: Poly phenols and flavonoids (*Ginkgo biloba*, Tea, Citrus fruits, Grape, Soy); Carotene and fatty acids: (Curcuma, Tomato, Flax seed, Olive oil) **5 hrs**
7. Current market scenario of nutraceuticals **1 hr**
6. Regulatory requirements for nutraceuticals **1 hr**

REFERENCES

1. Biren Shah and A.K. Seth. Text Book of Pharmacognosy and Phytochemistry, Ed1, Elsevier Health Sciences, Gurgaon, Haryana, 2010. Pp 471-83
2. S.S. Agrawal and M. Paridhavi. Herbal Drug Technology, Ed2, Universities Press, Hyderabad, Telangana, 2012. Pp 710-21
3. Alberta N.A. Aryee and Joyce Irene Boye, Current and Emerging Trends in the Formulation and Manufacture of Nutraceuticals and Functional Food products, In, Nutraceutical and Functional Food Processing Technology Edt. Joyce Irene Boye, Ed.1. Wiley Blackwell, West Sussex UK, 2015. Pp 01-52
4. Rorimi E. Aluko, Functional Foods and Nutraceuticals Springer, New York, USA, 2012.
5. C.K Kokate, A.P. Purohot and S.B. Gokhale, Pharmacognosy, Vol 1 and 2, Ed. 46, Nirali Prakashan, Pune, 2010. Pp 6.01-6.16

PCO-002E: EXTRACTION, SEPARATION AND PURIFICATION OF PHYTOCONSTITUENTS

(15 hrs)

Scope

Herbal drugs are emerging as major source of biomedicines worldwide. Secondary metabolites or phytoconstituents are responsible for medicinal attributes of a plant. Extraction, separation, and purification of these secondary metabolite is an area of interest for researchers. Therefore, this subject will provide an insight on the topic so as to enable the students to carry their research on natural products effectively**.**

Objectives

To impart stronger scientific base in the area of extraction, isolation and purification principles and methodologies of crude drugs.

1.	Introduction to plant metabolites.	**1 hr**
2.	Extraction techniques: Principle, merits & demerits, applications of maceration, decoction, infusion, percolation, soxhlet extraction, supercritical fluid extraction, microwave-assisted extraction, ultrasound extraction (sonication), advanced phytonics method of extraction, expression and enfleurage method.	**5 hrs**
3.	Phytochemical screening of natural products	**2 hrs**
4.	Separation and purification of phytoconstituents: Fractional distillation, fractional liberation, sublimation, fractional crystallization, gel filtration, counter current extraction and chromatographic techniques like Paper Chromatography, TLC, HPLC, HPTLC, column chromatography, gas-liquid chromatography, droplet counter current chromatographyand electro-chromatography (Electrophoresis).	**7 hrs**

REFERENCES

1. Evans W. C., Trease G. E., Trease and Evan's Pharmacognosy. W.B. Saunders, 2002. 16th Ed.
2. Jean Bruneton, Caroline K. Hatton, Pharmacognosy, Phytochemistry, Medicinal Plants. Lavoisier, 1999
3. Kokate C.K., Gokhale S.B. and Purohit A.P., Textbook of Pharmacognosy, Nirali Prakashan, Pune, 2008
4. Mukherjee Pulok K., Quality Control of Herbal Drugs: An Approach to Evaluation of Botanicals. Business Horizons, 2002.

PCO-003E: NANOPHYTOPHARMACEUTICALS

(15 hrs)

Scope

Nanotechnology is a cutting-edge technology that provides optimal effectiveness in low doses. The course addresses and provides an overview of phytopharmaceuticals in nano size for better therapeutic benefits along with toxicity. Students will be able to understand the benefits of nano-phytopharmaceuticals.

Objectives

To study the effectiveness in low doses and enhancement of bioavailability of phytopharmaceuticals for better therapeutic values

1. Definition and history of nanotechnology **1 hr**
2. Properties – optical, electrical and magnetic properties of nanomaterials **2 hrs**
3. Preparation techniques – Polymeric nanoparticles, liposomes, micelles and herbal nanoparticles **6 hrs**
4. Toxicity studies **2 hrs**
5. Applications of phytopharmaceuticals, nanophytopharmaceuticals in the treatment of certain diseases **4 hrs**

REFERENCES

1. Nano: The Essentials: Understanding Nanoscience and Nanotecnology, T. Pradeep, Tata McGraw-Hill Publishing Company Limited, New Delhi, 2008.
2. Nanocrystals: Synthesis, Properties and Applications, C. N. R. Rao, P. J. Thomas and G. U. Kulkarni, Springer (2007)
3. Nanostructures & Nanomaterials: Synthesis, Properties & Applications, Guozhong Cao, Imperial College Press (2004).
4. Nanoparticles as Drug carriers, Vladimir P Torchilin, Imperial College Press, USA, 2006
5. Multifunctional Pharmaceutical Nanocarriers, Vladimir Torchilin, Springer Publishing, New York, NY, 2008.

PCO-004E: HERBAL MONOGRAPHS

(15 hrs)

Scope

A monographs is written document intended to promote information exchange and international harmonised standards for the quality control and use of herbal medicines. It contains scientific information on selected medicinal plants that serves as a summary for quality assurance, clinical applications and dosage forms. The proposed course is designed to study and understand herbal monographs

Objectives

To impart knowledge on systematic study of herbal drugs with reference its identity, quality and purity

1. Introduction to monographs, purpose and content of the monographs, use of the monographs **3 hrs**
2. Systematic study of the following important plants for their monographs; **12 hrs**

   Leaf: Vasaka (*Adhatoda zeylanica)*

   Root: Shatavari (*Asparagus racemosus)*

   Rhizome:Rasna *(Alpinia galanga)*

   Bark: Cinchona (*Cinchona officinalis)*

   Fruit: Pepper (*Piper nigrum)*

   Entire herb: Kalmegh *(Andrographis paniculata).*

REFERENCES

1. WHO monographs on selected medicinal plants. – Geneva: WHO. – Vol. 1. 1999, – Vol. 2. 2002, – Vol. 3: 2004, – Vol. 4. 2005.
2. Quality Standards of Indian Medicinal Plants – Indian Council of Medical Research, New Delhi.
3. Indian Herbal Pharmacopoeia – A Joint Publication of RRL, Jammu and IDMA, Mumbai.

PRM-001E: RETAIL BUSINESS MANAGEMENT

(15 hrs)

Scope

This course is formulated to impart knowledge on retail management. It also provides an overview about the nitty-gritties of managing a pharmacy store and an overview of Online Pharmacies.

1. Introduction to Retail Management **3 hrs**
2. Strategies in Retailing **3 hrs**
3. Retail Marketing in rural areas **3 hrs**
4. Pharmacy Store Management **4 hrs**
5. Online Pharmacy Retailing **2 hrs**

REFERENCES

1. Retail Management by Barry Berman. Person Education 11th Edition.
2. Retail Management by Chetan Bajaj. Oxford 2nd Edition.
3. Retail Management: Text and Cases by UC Mathur. IK International Publishing House Pvt. Ltd.

PRM-002E: INTELLECTUAL PROPERTY MANAGEMENT

(15 hrs)

Scope

This course deals with Intellectual Property Rights with special emphasis on Patents.

1. Basic Concepts of Intellectual Property Rights	**3 hrs**
2. Patent Administration in India and Patent Filing	**3 hrs**
3. Revocation of Patents and Patent Infringement Cases	**3 hrs**
4. Data Protection and Exclusivity	**3 hrs**
5. Patent as a business tool	**3 hrs**

REFERENCES

1. Basic Concepts of Intellectual Property Rights by Manthan D Janodia. Manipal University Press, 2015.

2. Intellectual Property Rights by SRS Rosedar. Lexis Nexis 2016.

3. Intellectual Property Rights in India by VK Ahuja. Lexis Nexis, 2015.

4. Law relating to Intellectual Property by BL Wadehra. Universal Law Publishing, 2016.

PRM-003E: GENERAL MANAGEMENT PRINCIPLES

(15 hrs)

Scope

This course is designed to facilitate students to inculcate managerial skills. It includes major concepts of management.

1. Introduction to management concepts	**3 hrs**
2. Decision Making	**3 hrs**
3. Leadership and Motivation	**4 hrs**
4. Conflict Management	**3 hrs**
5. Ethical Issues related to Management	**2 hrs**

REFERENCES

1. Organisational Behaviour by Stephen P. Robbins, Prentice – Hall, India

2. Management, A global Perspective by Heinz, Weihrich and Harold Koontz. Mc Graw Hill publishing company.

3. Management, tasks, responsibilities and practices by Drucker. Peter. F., Alfied Publisher Pvt. Ltd.

4. Principles and Practice of Management by L M Prasad, Sultan Chand & Sons.

PRM-004E: ENTREPRENEURSHIP DEVELOPMENT

(15 hrs)

Scope

This course is designed to impart knowledge and skills on entrepreneurship development.

1. Entrepreneur and Entrepreneurship	**3 hrs**
2. Entrepreneurial Development	**3 hrs**
3. Launching and Organizing an enterprise	**3 hrs**
4. Cost and Pricing	**3 hrs**
5. Project proposal development for start-up	**3 hrs**

REFERENCES

1. Hisrich, R.D. and Peters, M.P. (1995): Entrepreneurship – Starting, Developing and Managing a New Enterprise, Richard D., Inwin, INC, USA.

2. Meredith, G.G. etal (1982): Practice of Entrepreneurship, ILO, Geneva.

3. Entrepreneurship Management by Vasant Desai. Himalaya Publishing House, 2011.

MPHARM – CHOICE BASED MULTIDISCIPLINARY COURSE

- **MU-001E: Certificate Course in Bioinformatics**
- **MU-002E: Project Management**
- **MU-003E: Certificate Course in Bioethics**
- **MU-004E: Academic Research and Writing**
- **MU-005E: Certificate Course in Biosecurity**

(As prescribed from time to time)