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: Pharmacy Practice

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-PCL.—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 ProgramRegulations - 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
o-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 MetaAnalysis	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	Pharmacy Management, MCOPS
PRM-002E	Intellectual Property Management	1	Pharmacy Management, MCOPS
PRM-003E	General Management Principles	1	Pharmacy Management, MCOPS
PRM-004E	Entrepreneurship Development	1	Pharmacy 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

Short answers (1 mark × 5 = 5 marks)
7A.
7B.
7C.
7D.
7E.

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 endsemester 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:

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

The SGPA is calculated to two decimal points. It should be noted that, the SGPA for any semester shall take into consideration the F and 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:

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

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:

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

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

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	Vivavoce		
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.

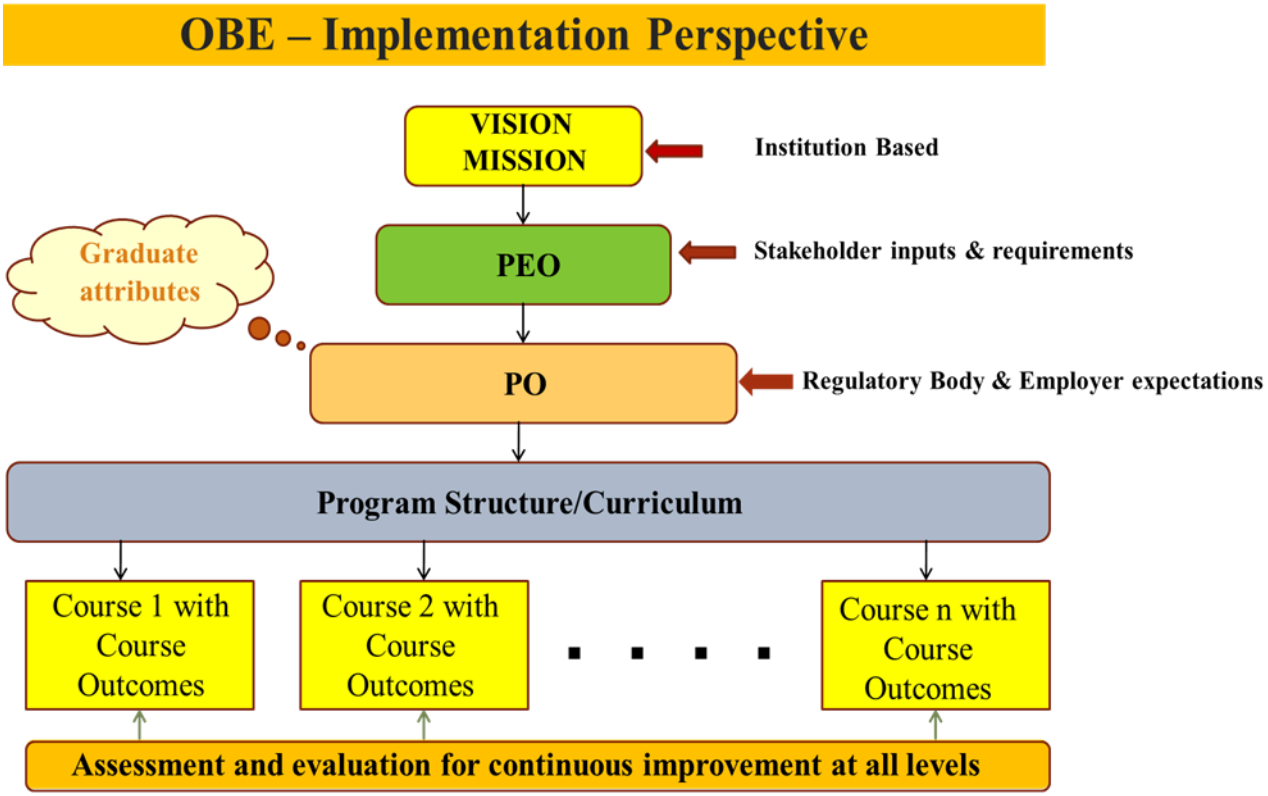
*****

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 Pharmacy Practice
Program Educational Objectives

The **Department of Pharmacy Practice**, Manipal College of Pharmaceutical Sciences, endeavors to nurture an attitude conducive to self-learning and lifelong learning that would:

PEO No	Education Objective
PEO 1	Develop the comprehensive pharmaceutical education leading to Master of pharmacy in "Pharmacy Practice" specialization with integrated professional knowledge and skills with research competencies to work in all the domains of pharmacy profession
PEO 2	Equip with comprehensive knowledge and skills to deliver pharmaceutical care in community, hospital, clinical pharmacy practice settings and pharmaceutical industries
PEO 3	Cultivate innovative thinking in clinical oriented services and nurture an ability to adapt according to evolving paradigms in health care, research, and higher studies
PEO 4	Foster the best in-class experiential hands-on training and advanced pharmacy practice services
PEO 5	Empower and sensitize to serve the society in health care and guide the next generation clinical pharmacists and academicians

MPharm Pharmacy Practice Program Outcomes (POs)

After the completion of M Pharm Pharmacy Practice program, the students will be able to:

PO No	Attribute	Competency
PO1	**Domain knowledge**	Demonstrate the ability to apply the acquired knowledge to provide preliminary solutions in specific areas such as clinical pharmacy practice and pharmaceutical care in all the practice settings.
PO 2	**Problem analysis**	Identify problems related to day to day professional needs of the healthcare system in the service domains such as clinical, hospital, community pharmacy and pharmaceutical industry.
PO 3	**Design/develop solutions**	Design and develop solutions for the problems faced in healthcare system using advances in clinical research, drug development, pharmacometrics, pharmaco-epidemiology, pharmacoeconomics and outcome research
PO 4	**Conduct investigations of complex problems**	Present their own findings based on observing, understanding, documenting compiling, analyzing, organizing data and information; eventually converting such information with judgement in areas of pharmacy practice research, specialty practice, pharmacometrics, pharmacoeconomics, clinical trials, pharmacoepidemiology, antibiotic stewardship and other emerging areas
PO 5	**Modern tool usage**	Demonstrate standards of capabilities in information technology and digital domains, by applying relevant analytical software tools in drug information, statistical analysis, data analytics, pharmacokinetic and pharmacodynamic modeling and in bioinformatics domain
PO 6	**Business and society**	Demonstrate capabilities for professional and ethical delivery of services to organizations, businesses and society at large

PO No	Attribute	Competency
PO 7	**Environment and sustainability**	Cultivate a sense of commitment to minimize the hazards in using the drugs in clinics and adhere to the norms of environmental protection and sustainability
PO 8	**Ethics**	Cultivate a sense of fair play, sensitivity to professional ethical codes of conduct, social values that includes gender-neutral attitudes and practices; respect for all races, religions, cultures, traditions, languages and nations and respect for democratic institutional values
PO 9	**Individual/ team work**	Demonstrate a capacity to work as an individual by demonstrating professionalism and integrity and at the same time engage colleagues from diverse professions
PO 10	**Communication**	Demonstrate effective communication skills with professional decorum employing conventional or digital media
PO 11	**Project management and finance**	Demonstrate the abilities to manage projects with an effective leadership and managerial skills and cultivate the effectiveness for a successful financial management
PO 12	**Life-long learning**	Cultivate a temperament that would enable individuals to set and work towards self-driven performance-goals, entrepreneurial ventures and overall leadership, with an ability to be a lifelong learner and a vision to stay ahead of times.

CHAPTER – III

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

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.						

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	PPR-MPP101T	Clinical Pharmacy Practice	4	CO1 CO2 CO3 CO4 CO5	CO2 CO3 CO4 CO5	CO1	CO2 CO4 CO5	CO2 CO5	CO1 CO2 CO3 CO5		CO1 CO2 CO3 CO4 CO5	CO1 CO2 CO5	CO1 CO2 CO3 CO4 CO5		CO2 CO4 CO5
2	PPR-MPP102T	Pharmacotherapeutics I	5	CO1 CO2 CO3 CO4 CO5	CO2 CO3 CO4 CO5	CO1	CO2 CO4 CO5	CO2 CO5	CO2 CO3 CO5		CO1 CO2 CO3 CO4 CO5	CO1 C03 C05	CO1 CO2 CO3 CO4 CO5		CO2 CO4 CO5
3	PPR-MPP103T	Hospital and Community Pharmacy	5	CO5	CO1 CO2 CO3 CO4 CO5				CO1 CO3	CO1	CO3	CO1 CO2 CO3	CO4		CO2 CO5
4	PPR-MPP104T	Clinical Research	5			CO1 CO2 CO3 CO4 CO5	CO1 CO2 CO3 CO4 CO5			CO2	CO1 CO2 CO3 CO4 CO5	CO3			CO1 CO2 CO3 CO4 CO5
5	PPR-MPP105P	Pharmacy Practice Practical I	6	CO1 CO2	CO2	CO1 CO2			CO2		CO1 CO2		CO1		CO1
6	PPR-MPP106S	Seminar*	1	CO1	CO1 CO2		CO2 CO5					CO3	CO3 CO4 CO5		CO6
7	PPR-MPP201T	Principles of Quality Use of Medicines	5	CO1 CO3 CO5	CO1 CO2 CO3 CO4 CO5	CO1 CO2 CO3 CO4 CO5	CO2 CO5		CO4	CO3 CO4 CO5					

S No	Course Code	Course Name	Credits	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO1O	PO11	PO12
8	PPR-MPP202T	Pharmacotherapeutics II	5	CO1 CO2 CO3 CO4 CO5	CO1 CO2 CO3 CO4 CO5						CO1 CO2 CO3 CO4 CO5	CO1 CO2 CO3 CO4 CO5			
9	PPR-MPP203T	Clinical Pharmacokinetics and Therapeutic Drug Monitoring	5		CO1 CO2 CO3 CO4 CO5	CO3 CO4		CO1 CO2 CO3 CO4 CO5							
10	PPR-MPP204T	Pharmacoepidemiology and Pharmacoeconomics	5	CO1 CO2 CO3 CO4 CO5	CO2 CO3 CO4 CO5	CO1 CO4 CO5	CO2 CO3 CO4 CO5		CO3 CO4 CO5					CO3 CO4 CO5	CO1 CO3
11	PPR-MPP205P	Pharmacy Practice Practical II	6	CO1	CO2	CO1 CO2		CO2			CO1		CO1		CO1
12	PPR-MPP206S	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 MPHARM – PHARMACY PRACTICE (MPP) SEMESTER I

PPR-MPP 101T: CLINICAL PHARMACY PRACTICE

COURSE CODE	PPR-MPP 101 T
COURSE TITLE	CLINICAL PHARMACY PRACTICE (Theory)

SCOPE/SUMMARY	**OBJECTIVES/COURSE OUTCOMES**
This course is designed to impart the basic knowledge and skills that are required to practice pharmacy including the provision of pharmaceutical care services to both healthcare professionals and patients in clinical settings	Upon completion of this course the student should be able to: 1. Understand the element of pharmaceutical care. 2. Learn the comprehensive patient care services. 3. Understand the importance of patient data and communications in clinical settings. 4. Interpret the laboratory data and clinical significance in various disorders. 5. Provide integrated, critically analyzed medicine and poison information to healthcare professionals, and patients/public

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	Scope of clinical pharmacy services with respect to national and International scenario.	Unit I (4 hrs)	8	2		6
2	Various clinical pharmacy services with its application and documentation.	Unit II (16 hrs)	32	10		22
3	Patient data analysis and communication skills and its applications.	Unit III (6 hrs)	12	3		9
4	Interpretation of various laboratory data for proper diagnosis.	Unit IV (16 hrs)	32		10	22
5	Drug and poison information center and services.	Unit V (10 hrs)	21		05	16
		Total Marks of Assessment	105	15	15	75

THEORY **52 hrs**

UNIT I

Introduction to Clinical Pharmacy: Definition, evolution and scope of clinical pharmacy, International and national scenario of clinical pharmacy practice, Pharmaceutical care. **04 hrs**

UNIT II

Clinical Pharmacy Services: Ward round participation, Drug therapy review (Drug therapy monitoring including medication order review, chart endorsement, clinical review and pharmacist interventions), Patient medication history interview, Basic concept of medicine and poison information services, Basic concept of pharmacovigilance, Hemovigilance, Materiovigilance and Adverse Event Following Immunization (AEFT), Patient medication counselling, Drug utilization evaluation, Documentation of clinical pharmacy services. Quality assurance of clinical pharmacy services. **16 hrs**

UNIT III

Patient Data & Practice Skills: Patient's case history - its structure and significances in drug therapy management, Common medical abbreviations and terminologies used in clinical practice, Communication skills: verbal and non-verbal communications, its applications in patient care services. **06 hrs**

UNIT IV

Lab Data Interpretation: Hematological tests, Renal function tests, Liver function tests, Tests associated with cardiac disorders, Pulmonary function tests, Thyroid function tests, Fluid and electrolyte balance, Microbiological culture sensitivity tests. **16 hrs**

UNIT V

Drug & Poison Information Services

Medicine Information Service: Definition and need for medicine information service, Medicine information resources, Systematic approach in answering medicine information queries, Preparation of verbal and written response, establishing drug information Centre. Critical evaluation of biomedical literature.

Poison Information Service: Definition, need, organization and functions of poison information centre. **10hrs**

REFERENCES

1. A Textbook of Clinical Pharmacy Practice – Essential concepts and skills.
   Parthasarathi G, Karin Nyfort-Hansen and Milap Nahata (latest edition)
2. Practice Standards and Definitions – The Society of Hospital Pharmacists of Australia (latest edition)
3. Basic skills in interpreting laboratory data – Scott LT. American Society of Health System Pharmacists Inc (latest edition)
4. Relevant review articles from recent medical and pharmaceutical literature.
5. Drug Information: A Guide for Pharmacist – Patrick M Malone, Kristen Wilkinson Mosdell, Karen L.Kier, John E. Stanovich (latest edition)

MPHARM – PHARMACY PRACTICE (MPP)
SEMESTER I
PPR-MPP102T: PHARMACOTHERAPEUTICS-1

COURSE CODE	PPR-MPP102T
COURSE TITLE	PHARMACOTHERAPEUTICS-1 (Theory)

SCOPE/SUMMARY	**OBJECTIVES/COURSE OUTCOMES**
This course aims to enable the students to understand the different treatment approaches in managing various disease conditions. Also, it imparts knowledge and skills in optimizing the drug therapy of a patient by individualizing the treatment plan through evidencebased medicines.	Upon completion of this course the student shall be able to: 1. Understand the therapeutic approaches for management for cardiovascular diseases 2. Understand the therapeutic approaches for management for respiratory and gastrointestinal diseases 3. Know the therapy for hematological diseases and rheumatologic disorders 4. Understand the pharmacotherapy of disorders related to endocrine system 5. Understand the pharmacotherapy of dermatologic disorders and ophthalmology

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	Learn the pathophysiology and pharmacotherapy of diseases related to cardiovascular system	Unit I (12 hrs)	24	07		17
2	Learn the pathophysiology and pharmacotherapy of diseases related to respiratory and gastrointestinal system	Unit II (14 hrs)	28	08		20
3	Learn the pathophysiology and pharmacotherapy hematological diseases and rheumatologic disorders	Unit III (12 hrs)	24		07	17
4	Learn the pathophysiology and pharmacotherapy of disorders related to endocrine system	Unit IV (08 hrs)	17		05	12

5	Learn the pathophysiology and pharmacotherapy of dermatol-ogic disorders and ophthalmology	Unit V (06 hrs)	12		03	09
Total Marks of Assessment			105	15	15	75

THEORY **52 hrs**

UNIT I

Cardiovascular system : Etiopathogenesis and Pharmacotherapy of Hypertension, Dyslipidemia, Ischemic heart disease, Acute coronary syndrome, Cardiac arrhythmias, Congestive heart failure. **12 hrs**

UNIT II

Respiratory system: Etiopathogenesis and Pharmacotherapy of Asthma, Chronic obstructive pulmonary disease, Drug-induced pulmonary disease.

Gastrointestinal system: Etiopathogenesis and Pharmacotherapy of Peptic ulcer disease, Gastroesophageal reflux disease, Inflammatory bowel disease, Diarrhea, Constipation, Hepatitis, Cirrhosis, Drug-induced liver disease. **14 hrs**

UNIT III

Hematological disorders: Etiopathogenesis and Pharmacotherapy of Anemias, Deep vein thrombosis, Drug induced, hematological disorders

Rheumatologic disorders: Etiopathogenesis and Pharmacotherapy of Rheumatoid arthritis, Osteoarthritis, Gout, Systemic lupus erythematosus. **12 hrs**

UNIT IV

Endocrine system: Etiopathogenesis and Pharmacotherapy of Diabetes6 Thyroid diseases, Osteoporosis, Oral contraceptives, Hormone replacement therapy, Dysmenorrhea. **8 hrs**

UNIT V

Dermatologic disorders: Etiopathogenesis and Pharmacotherapy of Psoriasis, Acne vulgaris, Eczema and scabies, Drug induced skin disorders

Ophthalmology: Etiopathogenesis and Pharmacotherapy of Conjunctivitis, Glaucoma.**6 hrs**

REFERENCES

1. Roger Walker and Cate Whittlesea. Clinical Pharmacy and Therapeutics, Churchill Livingstone publication.
2. Joseph T. Dipiro et al. Pharmacotherapy: A Pathophysiologic Approach, Appleton & Lange.
3. Robins SL. Pathologic basis of disease, W.B. Saunders publication.
4. Eric T. Herfindal. Clinical Pharmacy and Therapeutics, Williams and Wilkins Publication.
5. Lloyd Young and Koda-Kimble MA. Applied Therapeutics: The clinical Use of Drugs, Lippincott Williams and Wilkins.
6. Chisholm-Burns Wells Schwinghammer Malone and Joseph P Dipiro. Pharmacotherapy Principles and practice, McGraw Hill Publication.
7. Carol Mattson Porth. Principles of Pathophysiology, Lippincott Williams and Wilkins
8. Harrison's. Principles of Internal Medicine, McGraw Hill
9. Relevant review articles from recent medical and pharmaceutical literature.

MPHARM – PHARMACY PRACTICE (MPP)
SEMESTER I
PPR-MPP 103T: HOSPITAL AND COMMUNITY PHARMACY

COURSE CODE	PPR-MPP 103T
COURSE TITLE	HOSPITAL AND COMMUNITY PHARMACY (Theory)

SCOPE/SUMMARY	**OBJECTIVES/COURSE OUTCOMES**
This course is designed to impart basic knowledge and skills that are required to practice pharmacy in both hospital and community settings.	Upon completion of this course it is expected that students shall be able to: 1. Understand the organizational structure of hospital & hospital pharmacy, drug policy and drug committees 2. Know about procurement & drug distribution practices 3. Understand the community pharmacy management 4. Know about Skills required and value added services in hospital &community pharmacies 5. Understand the concept of health promotion and services given by the pharmacist at home level

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	Learn and understand the concepts, organization, functions of Hospital and Hospital Pharmacy and also hospital drug Policy	Unit I (12 hrs)	24	07		17
2	Learn how to manage hospital Pharmacy and importance of education and training	Unit II (12 hrs)	24	08		16
3	Understand the concept of community pharmacy practice with its management, and also regarding importance of prescription, & OTC medication	Unit III (10 hrs)	20		06	14

4	Understand and learn various skills required for medication Adherence like communication skill, patient counselling, PIL, good pharmacy practice guidelines and computer applications	Unit IV (10 hrs)	20		06	14
5	Learn to do health promotion, home medication review and research in hospital and community pharmacy	Unit V (8 hrs)	17		03	14
Total Marks of Assessment			105	15	15	75

THEORY **52 hrs**

UNIT I

Introduction to Hospital Pharmacy

Introduction to Hospitals – Definition, classification, organizational structure.

Hospital Pharmacy: Definition, pharmaceutical services/functions, Relationship of hospital pharmacy department with other departments, category of staff and work load statistics, Organizational structure, legal requirements, Infrastructural requirements, Hospital Pharmacy Budget. **6 hrs**

Hospital Drug Policy:

- Pharmacy & Therapeutics Committee,
- Infection Control committee,
- Research & Ethics Committee
- Hospital Formulary and hospital formulary System-Guidelines and development of formulary.
- Developing Therapeutic guidelines **6 hrs**

UNIT II

Hospital pharmacy management:

- Purchase and inventory control,
- Drug distribution- dispensing to inpatients, out patients, during off hours, dispensing of narcotics and controlled substances.

- Intravenous admixtures/TPN solution
- Safe use of medication
- Pharmaceutical disposal/waste management **10 hrs**

Education and training: Continuing professional development programs, Drug and therapeutics newsletter. **2 hrs**

UNIT III

Community Pharmacy Practice: Definition, roles & responsibilities of community pharmacists, relationship of community pharmacists with other health care providers (code of ethics)

Community Pharmacy management: Legal requirements to start community pharmacy, site selection, lay out & design, storage conditions and arrangements, record maintenance. **6 hrs**

Prescription – Legal requirements & interpretation, prescription related problems

OTC medication: Rational use of over the counter medications

Responding to symptoms of minor ailments **4 hrs**

UNIT IV Medication adherence

Communication skills

Patient counselling and Patient information leaflets

Good pharmacy practice guidelines for community pharmacy

Computer applications in pharmacy services **10 hrs**

UNIT V

Health Promotion: Definition and health promotion activities, family planning, Health screening services, first aid, prevention of communicable and non-communicable diseases, smoking cessation, Child & mother care. **4 hrs**

Home Medicines review program: Definition, objectives, Guidelines, method and outcomes.

Research in community pharmacy /hospital pharmacy **4 hrs**

REFERENCES

1. Hospital Pharmacy - Hassan WE. Lec and Febiger publication.
2. A text book of hospital pharmacy: S.H Merchant and Dr. J.S.Qadry's
3. Drug store and business management by Mohammed and jyoti
4. A text book of pharmacy practice by KG Revikumar and BD Miglani
5. Textbook of hospital pharmacy - Allwood MC and Blackwell.
6. Avery's Drug Treatment, 4th Edn, 1997, Adis International Limited.
7. Remington Pharmaceutical Sciences.
8. Relevant review articles from recent medical and pharmaceutical literature

MPHARM – PHARMACY PRACTICE (MPP)

SEMESTER I

PPR-MPP104T: CLINICAL RESEARCH

COURSE CODE	PPR-MPP104T
COURSE TITLE	CLINICAL RESEARCH (Theory)

SCOPE/SUMMARY	**OBJECTIVES/COURSE OUTCOMES**
This course aims to provide the students an opportunity to learn drug development process especially the phases of clinical trials and also the ethical issues involved in the conduct of clinical research. Also, it aims to imparts knowledge and develop skills on conceptualizing, designing, conducting and managing clinical trials.	Upon completion of this course it is expected that students shall be able to: 1. Know the new drug development process and Understand the regulatory and ethical requirements. 2. Learn the types and designs used in clinical research 3. Appreciate and learn the documentation in clinical trials and the clinical trials start-up activities 4. Understand the investigational Product and Clinical Trial Monitoring and Close out process 5. Learn and understand the Quality Assurance and Quality Control in Clinical Trials and data management process

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	Learn the Drug development process and Basics in Ethics in Biomedical Research	Unit I (10 hrs)	20	06		14
2	Learn different Types of study Designs used in Clinical Research and Roles and responsibilities of different key stake holders	Unit II (10 hrs)	20	06		14
3	Learn and understand the Clinical trial Documents process and different Clinical Trial Start up activities	Unit III (10 hrs)	20	03	03	14

4	Learn about importance and handling of Investigational Product and Clinical Trial Monitoring and Close out process	Unit IV (10 hrs)	20		06	14
5	Learn and understand Quality Assurance and Quality Control in Clinical Trials and data management process	Unit V (12 hrs)	25		06	19
Total Marks of Assessment			105	15	15	75

THEORY **52 hrs**

UNIT 1

Drug development process: Introduction, various approaches to drug discovery, Investigational new drug application submission.

Ethics in Biomedical Research: Ethical Issues in Biomedical Research – Principles of ethics in biomedical research, Ethical committee [institutional review board] - its constitution and functions, Challenges in implementation of ethical guidelines. **10 hrs**

UNIT II

Types and Designs used in Clinical Research: Planning and execution of clinical trials, Various Phases of clinical trials, Bioavailability and Bioequivalence studies, Randomization techniques (Simple randomization, restricted randomization, blocking method and stratification), Types of research designs based on Controlling Method (Experimental, Quasi experimental, and Observational methods) Time sequences (Prospective and retrospective) Sampling methods (Cohort study, case Control study and cross sectional study), Health outcome measures (Clinical & Physiological, Humanistic and economic) Clinical Trial Study team: Roles and responsibilities of: Investigator, Study Coordinator, Sponsor, Monitor, Contract Research Organization. **10 hrs**

UNIT III:

Clinical trial Documents: Guidelines to the preparation of following documents: Protocols, Investigator's Brochure, Informed Consent Form, Case report forms, Contracts and agreements, Dairy Cards.

Clinical Trial Start up activities: Site Feasibility Studies**,** Site/Investigator selection**,** Prestudy visit**,** Investigator meeting**,** Clinical trial agreement execution**,** Ethics committee document preparation and submission. **10 hrs**

UNIT IV:

Investigational Product: Procurement and Storage of investigation product.

Filing procedures: Essential documents for clinical trial, Trial Master File preparation and maintenance, Investigator Site File, Pharmacy File, Site initiation visit, Conduct, Report and Follow up.

Clinical Trial Monitoring and Close out:

Preparation and conduct of monitoring visit: Review of source documents, CRF, ICF, IP storage, accountability and reconciliation, Study Procedure, EC communications, Safety reporting, Monitoring visit reporting and follow-up

Close-Out visit: Study related documents collection, Archival requirement, Investigational Product reconciliation and destruction, Close-Out visit report. **10 hrs**

UNIT V:

Quality Assurance and Quality Control in Clinical Trials: Types of audits, Audit criteria, Audit process**,** Responsibilities of stakeholders in audit process**,** Audit follow-up and documentation, Audit resolution and Preparing for FDA inspections, Fraud and misconduct management.

Data Management

Infrastructure and System Requirement for Data Management: Electronic data capture systems**,** Selection and implementation of new systems**,** System validation and test procedures, Coding dictionaries**,** Data migration and archival

Clinical Trial Data Management: Standard Operating Procedures, Data management plan, CRF & Data base design considerations, Study set-up, Data entry, CRF tracking and corrections, Data cleaning, Managing laboratory and ADR data, Data transfer and database lock, Quality Control and Quality Assurance in CDM, Data mining and warehousing **12 hrs**

REFERENCES

1. Principles and practice of pharmaceutical medicine, Second edition. Authors: Lionel. D. Edward, Aadrew.J.Flether Anthony W Fos , Peter D Sloaier Publisher:Wiley;
2. Handbook of clinical research. Julia Lloyd and Ann Raven Ed. Churchill Livingstone
3. Principles of Clinical Research edited by Giovanna di Ignazio, Di Giovanna and Haynes.
4. Central Drugs Standard Control Organization. Good Clinical Practices-Guidelines for Clinical Trials on Pharmaceutical Products in India. New Delhi: Ministry of Health; 2001.
5. International Conference on Harmonization of Technical requirements for registration of Pharmaceuticals for human use. ICH Harmonized Tripartite Guideline. Guideline for Good Clinical Practice.E6; May 1996.
6. Ethical Guidelines for Biomedical Research on Human Subjects 2000. Indian Council of Medical Research, New Delhi.
7. Textbook of Clinical Trials edited by David Machin, Simon Day and Sylvan Green, March 2005, John Wiley and Sons.
8. Principles of Clinical Research edited by Giovanna di Ignazio, Di Giovanna and Haynes.
9. Clinical Data Management edited by R K Rondels, S A Varley, C F Webbs. Second Edition, Jan 2000, Wiley Publications.
10. Goodman & Gilman: JG Hardman, LE Limbard, 10th Edn. McGraw Hill Publications, 2001.
11. Relevant review articles from recent medical and pharmaceutical literature.

MPHARM – PHARMACY PRACTICE (MPP)
SEMESTER I
MPP- PPR 105P: PHARMACY PRACTICE PRACTICAL I

COURSE CODE	MPP PPR105P
COURSE TITLE	PHARMACY PRACTICE PRACTICAL I

SCOPE/SUMMARY	**OBJECTIVES/COURSE OUTCOMES**
This subject is designed to impart knowledge and skills in developing therapeutic plan and provide pharmaceutical care for different types of patients using SOAP format. The students are required to learn various skills like drug distribution, drug dispensing, manufacturing of parenteral preparations, drug information, patient counselling, and therapeutic drug monitoring for improved patient care.	On completion of the course, the student shall be able to: 1. Understand therapeutic approach for the management of cardiovascular, renal, gastrointestinal, hematological, neurological and psychiatric disorders 2. Identify the treatment goals for specific disease and able to develop the individualized therapeutic plans 3. To identify the patient-specific parameters for selection, initiation and monitoring of drug therapies 4. Provide the feedback regarding the drug related issues to the physicians 5. To understand the pharmacopoeia standards in preparation of various sterile pharmaceutical dosage formulations 6. To apply therapeutic knowledge of medication and its dispensation to improving patient health 7. Understand the regulatory and ethical requirements in clinical studies.

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 (25 *% of total marks of assessment* **S1**	**End Sem exam** (75 *% of total marks of assessment)*
1	Learn and understand comprehensive patient care services by participating in ward rounds and providing pharmaceutical care involving interpreting laboratory results to aid the clinical diagnosis of various disorders which help in providing appropriate drug and poison information enable healthcare professionals in the efficient patient management. Learn the preparation of patient Information leaflets and counselling the patient for their medication	Unit 1 (72 hrs)	60	10	50

2	Understand rational drug therapy management in various disease conditions by using SOAP format and interpreting with the help of evidence based medicine, planning drug treatment based on diagnosis in accordance which help to look at patient specific parameters relevant before the initiation of drug therapy. Learn the concept of inventory control and preparation of IV admixture solutions. Understand the regulatory and ethical requirements in conducting and managing clinical studies.	Unit II (84 hrs)	70	20	50
Total Marks of Assessment			130	30	100

MPP- PPR 105P: PHARMACY PRACTICE PRACTICAL I

Pharmacy practice practical component includes experiments covering important topics of the courses clinical pharmacy practice, Pharmacotherapeutics-I, hospital &community pharmacy and clinical research

Unit I

1. Treatment chart review (one)
2. Medication history interview (one)
3. Patient counselling (two)
4. Preparation of a patient information leaflet (two)
5. Drug information query (two)
6. Poison information query (one)
7. Laboratory data interpretation (two)

Unit II

8. Presentation of clinical cases of various disease conditions as per SOAP format (ten)
9. ABC analysis of a given list of medications (one)
10. Formulation and dispensing of IV admixtures (one)
11. Preparation of Study Protocol & Informed consent form (one)

REFERENCE:

1. A Textbook of Clinical Pharmacy Practice – Essential concepts and skills. Parthasarathi G, Karin Nyfort-Hansen and Milap Nahata (latest edition)
2. Practice Standards and Definitions - The Society of Hospital Pharmacists of Australia (latest edition)
3. Basic skills in interpreting laboratory data - Scott LT, American Society of Health System Pharmacists Inc (latest edition)
4. Drug Information: A Guide for Pharmacists – Patrick M Malone, Kristen Wilkinson Mosdell, Karen L.Kier, John E. Stanovich (latest edition)
5. Roger and Walker. Clinical Pharmacy and Therapeutics – Churchill Livingstone publication.
6. Joseph T. Dipiro et al. Pharmacotherapy: A Pathophysiologic Approach – Appleton & Lange.
7. Lloyd Young and Koda-Kimble MA. Applied Therapeutics: The clinical Use of Drugs – Lippincott Williams and Wilkins.
8. Drug store and business management by Mohammed and jyoti 9. A text book of pharmacy practice by KG Revikumar and BD Miglani
10. Remington Pharmaceutical Sciences.
11. Principles and practice of pharmaceutical medicine, Second edition. Authors: Lionel. D. Edward, Aadrew.J.Flether Anthony W Fos , Peter D Sloaier Publisher:Wiley;
12. Principles of Clinical Research edited by Giovanna di Ignazio, Di Giovanna and Haynes.
13. Central Drugs Standard Control Organization. Good Clinical Practices-Guidelines for Clinical Trials on Pharmaceutical Products in India. New Delhi: Ministry of Health; 2001.
14. International Conference on Harmonization of Technical requirements for registration of Pharmaceuticals for human use. ICH Harmonized Tripartite Guideline. Guideline for Good Clinical Practice.E6; May 1996.
15. Ethical Guidelines for Biomedical Research on Human Subjects 2000. Indian Council of Medical Research, New Delhi.

MPHARM – PHARMACY PRACTICE (MPP) SEMESTER I

PPR-MPP106S: SEMINAR IN PHARMACY PRACTICE

COURSE CODE	PPR- MPP 106S
COURSE TITLE	SEMINAR IN PHARMACY PRACTICE

SCOPE/SUMMARY	**OBJECTIVES/COURSE OUTCOMES**
The course is designed to create an environment where teachers provide the students with a critical eye and openness to fortify the presentation and academic writing skills of students in the field of Pharmacy practice.	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 pharmacy practice 2. Learn to organize complex pharmacy practice 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 pharmacy practice.	2 hours/week	100	No endsemester examination. Only continuous mode.

MPHARM – PHARMACY PRACTICE (MPP)
SEMESTER II

PPR-MPP 201T: PRINCIPLES OF QUALITY USE OF MEDICINES

COURSE CODE	PPR-MPP 201T
COURSE TITLE	PRINCIPLES OF QUALITY USE OF MEDICINES (Theory)

SCOPE/SUMMARY	**OBJECTIVES/COURSE OUTCOMES**
This course is designed to impart basic knowledge and skills that are required to practice quality use of medicines (QUM) in different healthcare settings and also to promote QUM in clinical practice through evidence-based medicine approach.	Upon completion of this course it is expected that students shall be able to: 1. Understand the principles of quality use of medicines 2. Promote rational use of medicines and practice evidence-based medicines 3. Learn the drug use in various settings and populations 4. Understand regulatory aspects of prescription and OTC medicines 5. Identify and resolve medication related problems

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	Definition and principles of quality use of medicine (QUM) and understand key partners and their responsibilities in QUM	Unit I (10 hrs)	20	06		14
2	Various concepts in QUM such as evidence based medicine, essential drug concept and rational drug use	Unit II (10 hrs)	20	06		14
3	QUM in various settings such as hospital, ambulatory care and residential care and understand QUM in special population such as pediatrics, geriatrics, pregnancy and lactation	Unit III (10 hrs)	20	03	03	14

4	Various regulatory aspects of QUM in India including OTC and complementary medicine	Unit IV (10 hrs)	20		06	14
5	Definition, categories, causes, detection, prevention and management of medication errors and understand the concept of pharmacovigilance and adverse drug reaction	Unit V (12 hrs)	25		06	19
Total Marks of Assessment			105	15	15	75

THEORY **52 hrs**

UNIT I

Introduction to Quality use of medicines (QUM):

- Definition and principles of QUM
- Key partners and responsibilities of the partners
- Building blocks in QUM
- Evaluation process in QUM
- Communication in QUM
- Cost effective prescribing **10 hrs**

UNIT II

Concepts in QUM

Evidence based medicine:

- Definition
- Concept of evidence based medicine
- Approach and practice of evidence based medicine in clinical settings

Essential drugs:

- Definition, need, concept of essential drug
- National essential drug policy and list

Rational drug use:

- Definition, concept and need for rational drug use
- Rational drug prescribing,
- Role of pharmacist in rational drug use **10 hrs**

UNIT III

QUM in various settings:

- Hospital settings
- Ambulatory care/Residential care
- Role of health care professionals in promoting the QUM
- Strategies to promote the QUM
- Impact of QUM on E-health
- Integrative medicine and multidisciplinary care **05 hrs**

QUM in special population:

- Pediatric prescribing
- Geriatric prescribing
- Prescribing in pregnancy and lactation
- Prescribing in immune compromised and organ failure patients **05 hrs**

UNIT IV

Regulatory aspects of QUM in India:

- Regulation including scheduling
- Regulation of complementary medicines
- Regulation of OTC medicines
- Professional responsibility of pharmacist
- Role of industry in QUM in medicine development **10 hrs**

UNIT V

Medication errors:

- Definition
- Categorization and causes of medication errors
- Detection and prevention of medication errors
- Role of pharmacist in monitoring and management of medication errors **6 hrs**

Pharmacovigilance:

- Definition, aims and need for pharmacovigilance
- Types, predisposing factors and mechanism of adverse drug reactions (ADRs)
- Detection, reporting and monitoring of ADRs
- Causality assessment of ADRs
- Management of ADRs
- Role of pharmacist in pharmacovigilance
- National and international regulatory norms and Regulatory inspection **6 hrs**

REFERENCES

1. A Textbook of Clinical Pharmacy Practice – Essential concepts and skills, Parthasarathi G, Karin Nyfort-Hansen and Milap Nahata (Latest edition)
2. Andrews EB, Moore N. Mann's Pharmacovigilance (Latest Edition)
3. Dipiro JT, Talbert RL, Yee GC. Pharmacotherapy: A Pathophysiologic Approach (Latest Edition)
4. Straus SE, Richardson WS, Glasziou P, Haynes RB. Evidence-Based Medicine: How to practice and teach it (Latest Edition)
5. Cohen MR. Medication Errors (Latest Edition)
6. Online:

   http://medicinesaustralia.com.au/files/2012/05/MA_QUM_External_Reduced.pdf

   http://curriculum.racgp.org.au/statements/quality-use-of-medicines/

   http://www.rug.nl/research/portal/files/14051541/Chapter_2.pdf

7. Relevant review articles from recent medical and pharmaceutical literature.

MPHARM – PHARMACY PRACTICE (MPP)
SEMESTER II

PPR-MPP202 T: PHARMACOTHERAPEUTICS II

COURSE CODE	PPR-MPP202T
COURSE TITLE	PHARMACOTHERAPEUTICS II (Theory)

SCOPE/SUMMARY	**OBJECTIVES/COURSE OUTCOMES**
This course enable students to understand the different treatment approaches in managing various disease conditions required for competent clinical practice. Also, it imparts knowledge and skills in optimizing the drug therapy of a patient by individualizing the treatment plan through evidencebased medicines.	Upon completion of this course the student shall be able to: 1. Know the pharmacotherapy of neurologic disorders. 2. Learn the therapeutic approaches for management to psychiatric disorders. 3. Know the pharmacotherapeutic management of renal disorders 4. Understand the management of various infectious diseases 5. Know about of general principles of cancer chemotherapy and management of few types of cancers

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	Learn the pathophysiology and pharmacotherapy of diseases related to neurologic disorders.	Unit I (12 hrs)	24	07		17
2	Learn the pathophysiology and pharmacotherapy of diseases related to psychiatric disorders.	Unit II (08 hrs)	16	05		11
3	Learn the pathophysiology and pharmacotherapy of renal system.	Unit III (06 hrs)	12	03		09
4	Learn the pathophysiology and pharmacotherapy of infectious diseases.	Unit IV (16 hrs)	32		10	22

5	Learn the pathophysiology and pharmacotherapy of oncology.	Unit V (10 hrs)	21		05	16
Total Marks of Assessment			105	15	15	75

THEORY **52 hrs**

UNIT I: Neurologic disorders:

Epilepsy, Parkinson's disease, Stroke, Headache disorders, Alzheimer's disease, Multiple sclerosis, Pain management. **12 hrs**

UNIT II: Psychiatric disorders:

Schizophrenia, Depression, Bipolar disorders, Anxiety disorders, Sleep disorders **8 hrs**

UNIT III: Renal system:

Acute renal failure, Chronic renal failure, Dialysis, Drug induced renal disease. **6 hrs**

UNIT IV: Infectious diseases:

General guidelines for the rational use of antibiotics and surgical prophylaxis, Urinary tract infection, Respiratory tract infections, Gastroenteritis, Tuberculosis, Malaria, Bacterial endocarditis, Septicemia, Syphilis, Gonorrhea, Meningitis, HIV and opportunistic infections, Dengue fever, Scrub typhus, H1N1, Helminthiasis, Fungal infections. **16 hrs**

UNIT V: Oncology:

General principles of cancer chemotherapy, Pharmacotherapy of Breast cancer, Lung cancer, Hematological malignancies, Management of chemotherapy induced nausea and vomiting.

10 hrs

REFERENCES

1. Roger Walker and Cate Whittlesea. Clinical Pharmacy and Therapeutics, Churchill Livingstone publication.
2. Joseph T. Dipiro et al. Pharmacotherapy: A Pathophysiologic Approach, Appleton & Lange
3. Robins SL. Pathologic basis of disease, W.B. Saunders publication
4. Eric T. Herfindal. Clinical Pharmacy and Therapeutics, Williams and Wilkins Publication
5. Lloyd Young and Koda-Kimble MA Applied Therapeutics: The clinical Use of Drugs, Lippincott Williams and Wilkins
6. Chisholm-Burns Wells Schwinghammer Malone and Joseph P Dipiro. Pharmacotherapy Principles and practice, McGraw Hill Publication
7. Carol Mattson Porth. Principles of Pathophysiology, Lippincott Williams and Wilkins
8. Harrison's. Principles of Internal Medicine, McGraw Hill
9. Relevant review articles from recent medical and pharmaceutical literature

MPHARM – PHARMACY PRACTICE (MPP)
SEMESTER II

PPR -MPP 203T: CLINICAL PHARMACOKINETICS AND THERAPEUTIC DRUG MONITORING

COURSE CODE	PPR -MPP 203T
COURSE TITLE	CLINICAL PHARMACOKINETICS AND THERAPEUTIC DRUG MONITORING (Theory)

SCOPE/SUMMARY	**OBJECTIVES/COURSE OUTCOMES**
This course is designed to enable students to understand the basics principles and applications of pharmacokinetics in designing the individualized dosage regimen, to interpret the plasma drug concentration profile in altered pharmacokinetics, drug interactions and in therapeutic drug monitoring processes to optimize the drug dosage regimen. Also, it enable students to understand the basic concepts of pharmacogenetics, pharmacometrics for modeling and simulation of pharmacokinetic data.	Upon completion of this course it is expected that students shall be able to: 1. Design the drug dosage regimen for individual patients 2. Manage drug interactions 3. Understand the concepts of population pharmacokinetics 4. Recommend dosage adjustment for paediatrics and geriatrics and TDM of cardiovascular and seizure drugs 5. Manage the TDM of Psychiatric, antibiotics and organ transplant drugs.

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	Understand the concepts of clinical pharmacokinetics, Design dosage regimen using appropriate approaches including dosing nomograms	Unit I (10 hrs)	20	06		14

2	Learn the mechanisms of pharmacokinetic drug interactions, enzyme induction and inhibition. Learn the concepts of pharmacogenomics and Bayesian approaches for dosage regimen	Unit II (10 hrs)	20	06		14
3	Learn the concepts of population pharmacokinetics and components of population pharmacokinetic modeling with NONMEM approach	Unit III (10 hrs)	20	03	03	14
4	Learn the concepts of dosage adjustment in special population like pediatrics, geriatrics and pregnant women. Learn dosage adjustment in renal and hepatic failure. Learn the concepts of therapeutic drug monitoring and TDM of Cardiovascular & Seizure disorder drugs	Unit IV (16 hrs)	32		10	22
5	Learn the concepts of therapeutic drug monitoring principles with specific classes of drugs like Psychiatry drugs, antibiotics, organ transplant drugs	Unit V (6 hrs)	13		02	11
		Total Marks of Assessment	105	15	15	75

THEORY **52 hrs**

UNIT I

Introduction to Clinical pharmacokinetics: Absorption, distribution, metabolism and elimination. Compartmental and Non-compartmental models, Renal and non-renal clearance, Organ extraction and models of hepatic clearance, Estimation and determinants of bioavailability, Multiple dosing, Calculation of loading and maintenance doses.

Designing of dosage regimens: Determination of dose and dosing intervals, Conversion from intravenous to oral dosing, Nomograms and Tabulations in designing dosage regimen. **10 hrs**

UNIT II

Pharmacokinetics of Drug Interaction: Pharmacokinetic drug interactions**,** Inhibition and Induction of Drug metabolism**,** Inhibition of Biliary Excretion.

Pharmacogenetics: Genetic polymorphism in Drug metabolism: Cytochrome P-450 Isoenzymes, Genetic Polymorphism in Drug Transport and Drug Targets, Pharmacogenetics and Pharmacokinetic / Pharmacodynamic considerations.

Introduction to Pharmacometrics: Introduction to Bayesian Theory, Adaptive method or Dosing with feedback, Analysis of Population pharmacokinetic Data. **10 hrs**

UNIT III

Non Linear Mixed Effects Modelling: The Structural or Base Model, Modeling Random Effects, Modeling Covariate Relationships, Mixture Model, Estimation Methods, Model Building Techniques, Covariate Screening Methods, Testing the model assumptions, Precision of the parameter estimates and confidence intervals, Model misspecification and violation of the model assumptions, Model Validation, Simulation of dosing regimens and dosing recommendations, Pharmacometrics software. **10 hrs**

UNIT IV

Altered Pharmacokinetics and Therapeutic Drug Monitoring: Drug dosing in the elderly, Drug dosing in the paediatrics, Drug dosing in the obese patients, Drug dosing in the pregnancy and lactation**,** Drug dosing in the renal failure and extracorporeal removal of drugs, Drug dosing in the in hepatic failure.

Introduction of TDM. Individualization of drug dosage regimen (Variability – Genetic, age, weight, disease and Interacting drugs), Indications for TDM, Protocol for TDM, Pharmacokinetic/Pharmacodynamic Correlation in drug therapy, TDM of drugs used in the following conditions: Cardiovascular disease: Digoxin, Lidocaine, Amiodarone**;** Seizure disorders: Phenytoin, Carbamazepine, Sodium Valproate. **16 hrs**

UNIT V

Therapeutic Drug monitoring: TDM of Psychiatric conditions: Lithium, Fluoxetine, Amitriptyline; Organ transplantations: Cyclosporine**;** Cytotoxic Agents: Methotrexate, 5-FU, Cisplatin; Antibiotics: Vancomycin, Gentamicin, Meropenem. **6 hrs**

REFERENCES

1. Leon Shargel, Susanna Wu-Pong, Andrew Yu. Applied Biopharmaceutics & Pharmacokinetics. 6th Edition. New York: Mc Graw Hill;2012.
2. Peter L. Bonate. Pharmacokinetic - Pharmacodynamic Modeling and Simulation. 2nd edition. USA: Springer;2011.
3. Michael E. Burton, Leslie M. Shaw, Jerome J. Schentag, William E.Evans. Applied Pharmacokinetics & Pharmacodynamics: Principles of Therapeutic Drug Monitoring.4th edition. US: Iippincott Williams & Wilkins; 2005.
4. Steven How-Yan Wong, Irving Sunshine. Handbook of Analytical Therapeutic Drug Monitoring and Toxicology. 1st edition. USA: CRC Press; 1996.
5. Soraya Dhillon, Andrzej Kostrzewski. Clinical pharmacokinetics. 1st edition. London: Pharmaceutical Press;2006.
6. Joseph T.Dipiro, William J.Spruill, William E.Wade, Robert A.Blouin and Jane M.Pruemer .Concepts in Clinical Pharmacokinetics. 4th edition. US: American Society of Health-System Pharmacists;2005.
7. Malcolm Rowland, Thomas N. Tozer .Clinical Pharmacokinetics and pharmacodynamics: concepts and applications.4th edition.US: Iippincott Williams & Wilkins; 2010.
8. Evans, Schentag, Jusko. Applied pharmacokinetics. 2nd edition.US: American Society of Health system Pharmacists;2006.
9. Michael E. Winter. Basic Clinical Pharmacokinetics. 5th edition. US: Iippincott Williams & Wilkins; 2012.

MPHARM – PHARMACY PRACTICE (MPP)
SEMESTER II

PPR-MPP204 T: PHARMACOEPIDEMIOLOGY AND PHARMACOECONOMICS

COURSE CODE	PPR-MPP204T
COURSE TITLE	PHARMACOEPIDEMIOLOGY AND PHARMACOECONOMICS (Theory)

SCOPE/SUMMARY	**OBJECTIVES/COURSE OUTCOMES**
This course enables students to understand various pharmacoepidemio-logical methods and their clinical applications. Also, it aims to impart knowledge on basic concepts, assumptions, terminology, and methods associated with pharmacoeconomics and health related outcomes, and when should be appropriate pharmaco-economic model should be applied for a health care regimen.	Upon completion of this course the student should be able to: 1. Understand the applications, outcome measurements and concept of risks 2. Comprehend epidemiological methods and their applications. 3. Understand the fundamental principles, outcomes and measurements of pharmacoeconomics. 4. Understand various pharmacoeconomics models 5. To learn the different aspects of health related quality of life (HRQL) and methods to analyze cost and outcomes and understand various software's used.

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	Definition, scope, applications, outcome measurements and concept of risk in pharmacoepidemiology	Unit I (10 hrs)	20	06		14
2	Different Pharmacoepidemiological methods	Unit II (12 hrs)	24	07		17
3	Basic of pharmaco-economics, cost categorization and outcome measurements	Unit III (10 hrs)	20	02	04	14

4	Various types of pharmacoeconomic evaluations	Unit V (10 hrs)	20		06	14
5	Different aspects of health related quality of life (HRQL) and methods to analyse cost and outcomes and understand various software's used.	Unit IV (10 hrs)	21		05	16
Total Marks of Assessment			105	15	15	75

THEORY **52 hrs**

UNIT I

Introduction to Pharmacoepidemiology: Definition, scope, need, aims & applications.

Outcome measurement: Drug use measures: monetary units, number of prescriptions, units of drug dispensed, defined daily doses, prescribed daily doses, diagnosis and therapy surveys, prevalence, incidence, medications adherence measurements.

Concept of risk: Measurement of risk, attributable risk and relative risk, time- risk relationship and odds ratio **10 hrs**

UNIT II

Pharmacoepidemiological Methods: Qualitative models: Drug utilization review; Quantitative models: case reports, case series, cross sectional studies, cohort and case control studies, calculation of odds ratio, meta-analysis models. Drug effects study in populations: spontaneous reporting, prescription event monitoring, post marketing surveillance, record linkage systems, application of phamacoepdemiology. **12 hrs**

UNIT III

Introduction to Pharmacoeconomics: Definition, history of pharmacoeconomics, applications of pharmacoeconomics, need of pharmacoeconomic studies in Indian healthcare system.

Cost categorization and resources for cost estimation: Direct costs, indirect costs, intangible costs.

Outcomes and Measurements of Pharmacoeconomics: Types of outcomes: clinical outcome, economic outcomes, humanistic outcomes; quality adjusted life years, disability

adjusted life years, incremental cost-effectiveness ratio, average cost-effectiveness ratio, person-time, willingness to pay, time trade off and discounting. **10 hrs**

UNIT IV

Pharmacoeconomic evaluations: Definition, steps involved, applications, advantages and disadvantages of the following pharmacoeconomic models: cost-minimization analysis (CMA), cost-benefit analysis (CBA), cost-effectiveness analysis (CEA), cost utility analysis (CUA), cost of illness (COI), cost consequences analysis (CCA). **10 hrs**

UNIT – V

Health related quality of life (HRQoL): Definition, need for measurement of HRQoL, common HRQOL measures, domains of health status, assessing HRQoL instruments.

Advanced topics: Definition, steps involved, and applications of the following: Decision analysis and decision tree, sensitivity analysis, Markov Modeling, software's used in pharmacoeconomic analysis and its applications. **10 hrs**

REFERENCES

1. Strom B, Kimmel S, Hennessy S. Textbook of Pharmacoepidemiology. 3rd Edn, West Sussex: John Wiley & Sons, Ltd; 2022.
2. Park K. Park's textbook of preventive and social medicine. 25th ed. Banarsidas Bhanot; 2019.
3. Rascati K. Essentials of pharmacoeconomics. 2nd ed. Philadelphia: Lippincott Williams & Wilkins; 2013.
4. Revikumar KG. Pharmacoepdemiology and pharmacoeconomics concepts and practice. PharmaMed Press/BSP Books;2019.
5. Getzen T. Health economics:Fundamentals and Flow of Funds. 2nd ed. New York, NY: John Wiley & Sons; 2003.
6. Briggs A, Claxton K, Sculpher M. Decision modelling for health economic evaluation. Oxford: Oxford University Press; 2011.
7. Drummond M, Sculpher M, Claxton K, Stoddart G, Torrance G. Methods for the economic evaluation of health care programmes. 4th ed. Oxford (United Kingdom): Oxford University Press; 2015.
8. MacKinnon G. Understanding health outcomes and pharmacoeconomics. Washington, DC: American Pharmacists Association; 2017.

9. Grauer D. Pharmacoeconomics & outcomes. 2nd ed. Kansas City, Mo.: ACCP; 2003.
10. Walley T, Haycox A, Boland A. Pharmacoeconomics. 1st ed. Edinburgh: Churchill Livingstone; 2004.
11. Relevant review articles from recent medical and pharmaceutical literature

MPHARM – PHARMACY PRACTICE (MPP)

SEMESTER II

MPP-PPR205P: PHARMACY PRACTICE PRACTICAL II

COURSE CODE	MPP-PPR205P
COURSE TITLE	PHARMACY PRACTICE PRACTICAL II

SCOPE/SUMMARY	**OBJECTIVES/COURSE OUTCOMES**
This course is designed to impart knowledge and skills necessary for practice of clinical pharmacy and the promotion of rational use of medicines through case-based learning by using SOAP format and bed-side teaching This course is designed to impart knowledge and skills in various pharmacokinetics techniques for Calculation of Pharmacokinetic parameters using Phoenix WinNonlin software	On completion of the course, the student shall be able to: 1. Understand therapeutic approach for the management of gastrointestinal disorders, hematological disorders, neurological disorders, psychiatric disorders and pain management 2. Identify the treatment goals for specific disease and able to develop the individualized therapeutic plans 3. Identify the patient-specific and drug related issues for selection, initiation and monitoring of drug therapies 4. Develop pharmacokinetics skills by using using Phoenix WinNonlin software

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 (25 *% of total marks of assessment)* **S1**	**End Sem exam** (75 *% of total marks of assessment)*
1	Learn and understand comprehensive patient care services by participating in ward rounds and providing pharmaceutical care by assessing the cases using SOAP format. Learn the reporting & causality assessment of adverse drug reactions and detection & management of medication errors	Unit 1 (117 hrs)	98	25	73
2	Learn various pharmacokinetics skills for Calculation of Pharmacokinetic parameters using Phoenix WinNonlin software	Unit II (39 hrs)	32	05	27
		Total Marks of Assessment	130	30	100

PHARMACY PRACTICE (MPP)
SEMESTER II
MPP-PPR205P: PHARMACY PRACTICE PRACTICAL II

Pharmacy Practice practical II component includes experiments covering important topics of the courses Principles of Quality Use of Medicines, Pharmacotherapeutics-II, Clinical Pharmacokinetics & Therapeutic Drug Monitoring and Pharmacoepidemiology and Pharmacoeconomics.

UNIT I

1. Ward round participation
2. Causality assessment of adverse drug reactions (three)
3. Detection and management of medication errors (three)
4. Presentation of clinical cases of various disease conditions as per SOAP format (twelve)

UNIT II

5. Calculation of Pharmacokinetic parameters after IV & Oral administration (two)
6. Non-compartmental analysis of IV & oral administration using Phoenix WinNonlin (two)
7. Calculation of bioavailability and bioequivalence from the given data using Phoenix WinNonlin (two)

REFERENCES

1. Roger Walker, Cate Whittlesea Clinical Pharmacy and Therapeutics. Fifth edition. Churchill Livingstone publication, London.
2. Joseph T. DiPiro, Robert L. Talbert, Gary C. Yee, Gary R. Matzke, Barbara G. Wells, L. Michael Posey. Pharmacotherapy: A Pathophysiologic Approach. 10th edition. McGrawHill, USA.
3. Basic Skills in Interpreting Laboratory Data: Illustrated with Case Studies; Traub, Scott L. Bethesda, Md: ASHP (Latest edition).
4. Comprehensive Pharmacy Review; Leon Shargel, Alan H, Mutnick etal. Lippincott Williams & Wilkins (Latest edition).
5. Concepts in Clinical Pharmacokinetics. Joseph.T.Dipiro eds. Fourth Edition. American Society of Health System Pharmacists. 2005
6. Applied Clinical Pharmacokinetics. Larry A. Bauer. Second Edition. McGraw Hill Medical. 2008.
7. Applied Biopharmaceutics and Pharmacokinetics by Leon Shargel and Andrew Yu. McGraw Hill. Seventh Edition. 2016
8. Pharmacokinetic-Pharmacodynamic Modeling and Simulation. Peter L Bonate. Springer. 2006

PHARMACY PRACTICE (MPP)

SEMESTER II

PPR-MPP206S: SEMINAR IN PHARMACY PRACTICE

COURSE CODE	PPR- MPP 206S
COURSE TITLE	SEMINAR IN PHARMACY PRACTICE

SCOPE/SUMMARY	**OBJECTIVES/COURSE OUTCOMES**
The course is designed to create an environment where teachers provide the students with a critical eye and openness to fortify the presentation and academic writing skills of students in the field of Pharmacy Practice.	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 pharmacy practice 2. Learn to organize complex pharmacy practice 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**	**End Sem exam**
1	The students should be able to develop skills to gather, organize, deliver information, and defend a given topic in pharmacy practice.	2 hours/week	100	No end-semester examination. Only continuous mode.

PHARMACY PRACTICE (MPP)
SEMESTER III
PHA-MRM301T: RESEARCH METHODOLOGY AND BIOSTATISTICS

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

SCOPE/SUMMARY	**OBJECTIVE/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, nonparametric 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

Sr. No.	**Course Content**	**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	-

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, nonmaleficence, 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 – PHARMACY PRACTICE (MPP)

SEMESTER III

MJC 302P: JOURNAL CLUB IN PHARMACY PRACTICE

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

SCOPE/SUMMARY	**OBJECTIVE/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**	**End Sem exam**
1	The students should be able to develop skills to gather, organize, deliver information, and defend a given research topic in pharmacy practice	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. **1hr**

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 rs)

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. 0020 **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*, **5 hrs**

Tea, Citrus fruits, Grape, Soy); Carotene and fatty acids: (Curcuma, Tomato, Flax seed, Olive oil)

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 electrochromatography (Electrophoresis).

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)