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: Pharmacology

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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Table of Contents

रजिस्ट्री सं० डी० एल०-33004/99 REGD. NO. D. L.-33004/99

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PHARMACY COUNCIL OF INDIA
NOTIFICATION

New Delhi, the 10th December, 2014

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

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

CHAPTER I: REGULATIONS

1. Short title and commencement

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

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

2. Minimum qualification for admission

A pass in the following examinations

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

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

3. Duration of the program

The program of study for MPharm shall extend over a period of four semesters (two academic years). The curricula and syllabi for the program shall be prescribed from time to time by Manipal Academy of Higher Education based on the inputs from Pharmacy Council of India, New Delhi.

4. Medium of instruction and examination

Medium of instruction and examination shall be in English.

5. Working days in each semester

Each semester shall consist of not less than 100 working days. The odd semesters shall be conducted from the month of July/August to November/December and the even semesters shall be conducted for the month of December/January to May/June in an academic year.

6. Attendance and progress

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

7. Program/Course credit structure

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

7.1. Credit assignment

7.1.1. Theory and laboratory courses

Courses are broadly classified as Theory and Practical. Theory courses consist of Lecture (L) and tutorial (T). Practical (P) courses consist of hours spent in the laboratory. Credits (C) for a course are dependent on the number of hours of instruction per week in that course, and is obtained by using a multiplier of one (1) for lecture/tutorial and a multiplier of half (½) for practical (laboratory) hours. Thus, for example, a theory course, having four lectures per week throughout the semester carries a credit of 4. Similarly, a practical having four laboratory hours per week throughout the semester carries a credit of 2. The contact hours of seminars, and research work and journal club shall be treated as that of practical courses for the purpose of calculating credits, i.e., the contact hours shall be multiplied by ½.

7.2. Minimum credit requirements

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

8. Academic work

A regular record of attendance both in theory, practical, seminar, assignment, journal club, discussion with the supervisor, research work presentation and dissertation shall be maintained by the department/teaching staff of the respective courses.

9. Course work of study

The specializations in MPharm program are given in Table 1.

Table 1. List of MPharm specializations and their codes

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Table 15A. Guidelines for awarding credit points for co-curricular activities	
Name of the Activity	**Maximum Credit Points Eligible/ Activity**
Participation in National level seminar/Conference/Workshop/Symposium/Training programs (related to the specialization of the student)	01
Participation in International level seminar/Conference/Workshop/Symposium/Training programs (related to the specialization of the student)	02
Academic award/ Research award from State level/National agencies	01
Academic award/Research award from International agencies	02
Research/ Review publication in National journals (Indexed in Scopus/Web of Science)	01
Research/ Review publication in International journals (Indexed in Scopus/Web of Science)	02
Note: International conference: Held outside India International journal: The editorial board outside India *The credit points assigned for extracurricular and or co-curricular activities shall be given by the principal of the college and the same shall be submitted to the university. The criteria to acquire this credit point shall be defined by the college from time to time.	

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

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

10. Program committee

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

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

3. Duties of the program committee:

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

11. Examinations/Assessments

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

Table 16. Schemes for internal assessments and end semester examinations

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

11.1. Internal assessment: Continuous mode

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

11.1.1. Sessional exams

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

Question paper pattern – MPharm Theory sessional examinations
Manipal College of Pharmaceutical Sciences **Manipal Academy of Higher Education, Manipal** **MPharm Theory Sessional Examinations, Month and Year** **Course Code. Course Title** Date: dd-mm-yyyy Duration: 2 hrs Max. Marks: 45 **Instructions: Answer ALL questions** Long Essays (2x 10 marks) = 20 marks 1. Question 2. Question Short Essays (4 x 5 marks) = 20 marks 3. Question 4. Question 5. Question 6. Question 7. Short answers (1 mark × 5 = 5 marks) 7A. 7B. 7C. 7D. 7E.

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)

Pharm 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 (10 marks × 5 = 50 marks)
1. Question
2. Question
3. Question
4. Question
5. Question

Answer the following with specific answers (5 marks × 5 = 25 marks)
6A.
6B.
6C.
6D.
6E.

Question paper pattern – MPharm practical end-semester examinations

MPharm Practical End-Semester Examinations, Month and Year

Manipal Academy of Higher Education, Manipal

Course Code. Course Title

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

Instructions: Answer ALL questions.

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

12. Pass and award of performance grades

12.1: Minimum for a pass in a course

A student should obtain a minimum of 35% marks in the end-semester exam of each course. A student shall be declared PASS if, the candidate secures E-grade separately in each course, in a 10-

Point-Relative-Letter Grading-Scheme. Accordingly, no candidate shall be declared to have passed in any course unless he/she obtains a grade not less than E-grade.

12.2 Award of performance grades

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

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

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

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

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

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

Note the following:

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

12.4 The Semester Grade Point Average (SGPA)

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

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

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

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

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

12.5. Cumulative Grade Point Average (CGPA)

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

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

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

12.6. Conversion of GPA/CGPA into a percentage

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

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

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

Percentage secured by the candidate = GPA or CGPA × 10

13. Make-up/Supplementary examination

In case, a student fails to secure an E-grade in any theory or practical courses, he/she shall reappear for the end-semester examination of that course. However, his/her marks of the internal assessment shall be carried over, and he/she is entitled for a maximum grade of 'C' only, irrespective of the students' top order performances.

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

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

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

14. Improvement of internal assessment

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

15. Promotion to the next higher class

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

16. Declaration of class

The class shall be awarded on the basis of CGPA as follows:

First Class with Distinction = CGPA of 7.50 and above
First Class = CGPA of 6.00 to 7.49
Second Class = CGPA of 5.00 to 5.99

17. Research project work

17.1 Dissertation submission

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

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

17.2 Dissertation evaluation

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

Table 19. MPharm dissertation evaluation scheme

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

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

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

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

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

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

18. Award of degree

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

19. Duration for completion of the program

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

20. Revaluation of answer papers

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

21. Re-admission after break of study

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

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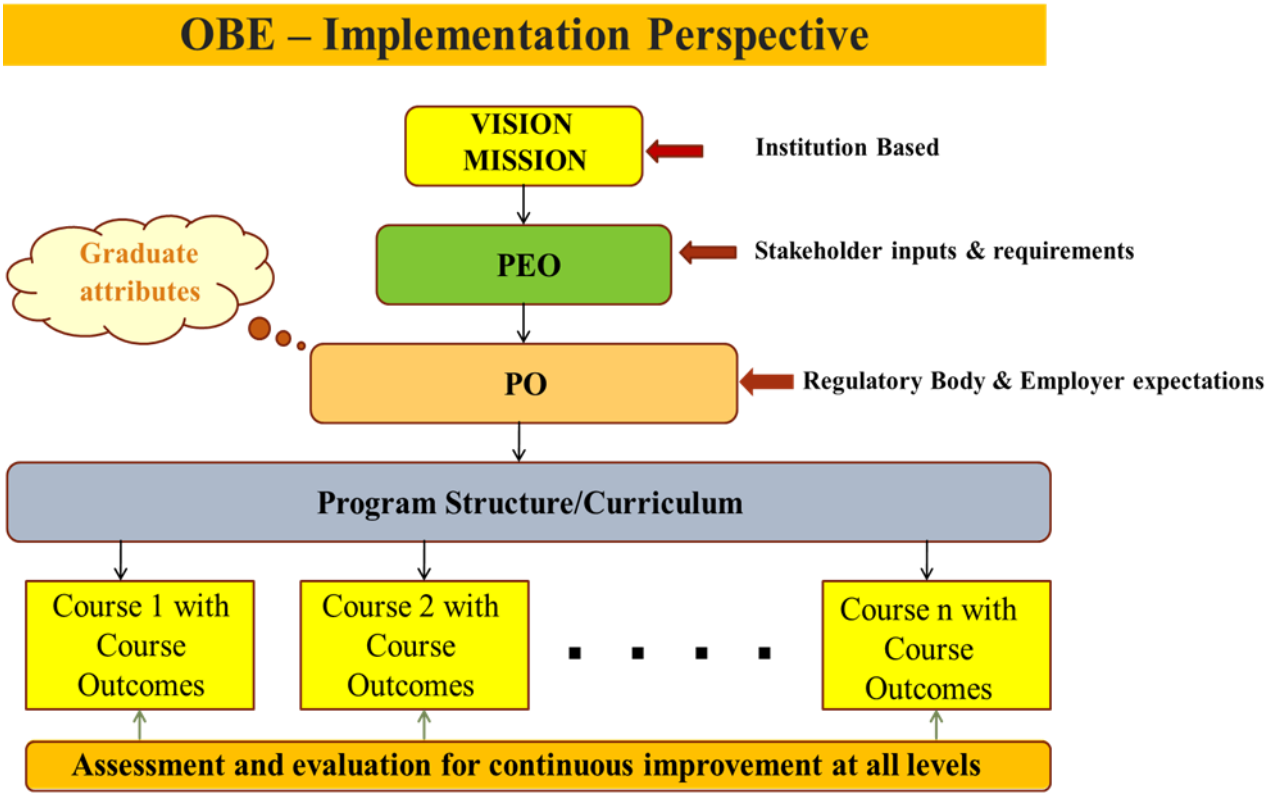
OUTCOME BASED EDUCATION (OBE)

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 Pharmacology Program Educational Objectives

The Department of Pharmacology, Manipal College of Pharmaceutical Sciences, Manipal strives to cultivate a right avenue for self and lifelong learning that would:

PEO No	Education Objectives
PEO 1	Build education, not only to secure MPharm degree in Pharmacology, but also to develop abilities to assimilate the knowledge, skills, and research competencies for application in therapeutics and Drug Discovery and Development (DDD).
PEO 2	Hone the acumen and skills required to deliver effective services for pharmaceutical industry, academia, and health care sector.
PEO 3	Promote a proclivity for higher learning, entrepreneurial abilities and pursue a career in research.
PEO 4	Foster the best in-class psychomotor skills to perform experiments envisaging the molecular mechanisms of lead molecules using platforms such as *in-silico* tools, cell cultures and cell-based assays, animal models using state-of-the-art facilities.
PEO 5	Inspire and inculcate pharmacologists to employ ethical and good practices to serve for the benefit of society, Pharmaceutical Industry and Pharmaceutical Care.

MPharm Pharmacology Program Outcomes (POs)

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

PO No	Attribute	Competency
PO 1	**Domain knowledge**	Comprehend the fundamental knowledge of pharmacy and pharmacology in drug discovery and development process.
PO 2	**Problem analysis**	Identify, formulate, and analyze complex research problems to reach substantiated conclusions that meet the regulatory requirements in connection with pharmacokinetic, pharmacodynamic and safety issues of the drugs in use and New Chemical Entities (NCE)
PO 3	**Design/develop solutions**	Design to find solutions for complex research problems through pharmacological strategies and rational drug designs.
PO 4	**Conduct investigations of complex problems**	Conceptualize and evaluate problems to draw meaningful conclusions through hypothesis, in-silico, in-vitro, in-vivo screening methods, and translational approaches employing appropriate statistical method analysis.
PO 5	**Modern tool usage**	Handle modern analytical techniques, cell-based assays, statistical packages, and *in-silico* tools and state-of-the art animal models employed in the fields of pharmacology and toxicology.
PO 6	**Business and society**	Adopt and facilitate a multidisciplinary approach in allied fields of pharmacy and pharmacology to develop business modules in R&D, scientific consultancy, contract research, etc.
PO 7	**Environment and sustainability**	Understand the impact of the business solutions in societal and environmental contexts and to demonstrate the knowledge for sustainable development.
PO 8	**Ethics**	Inculcate and apply ethical principles in different professional activities related to pharmacy and pharmacology.
PO 9	**Individual / Teamwork**	Function effectively as an individual, and as a member or as a leader in diverse teams, and in multidisciplinary settings for team building capacities.

PO No	Attribute	Competency
PO 10	**Communication**	Build overall personality by instilling soft skills for the effective communication of ideas and to present the scientific reports in a comprehensive but focussed approach.
PO 11	**Project management and finance**	Demonstrate the knowledge of financial management to evaluate new and existing projects for effective decision making.
PO 12	**Life-long learning**	Recognize the need to engage oneself as a life-long learner.

CHAPTER – III

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

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.						

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

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

S No	Course Code	Course Name	Credits	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO1O	PO11	PO12
1	PQA-MPL101T	Modern Pharmaceutical Analytical Techniques	4	CO1 CO2 CO3	CO1 CO2 CO3	CO1 CO2 CO3	CO1	CO1 CO2 CO3	CO1	CO1 CO2 CO3	CO1 CO2 CO3	CO3	CO1 CO2 CO3	CO1 CO2 CO3	CO1 CO3
2	PHA-MPL102T	Advanced Pharmacology I	5	CO2 CO3	CO2	CO1 CO4	CO1		CO3						
3	PHA-MPL103T	Pharmacological and Toxicological Screening Methods I	5	CO2	CO3	CO3	CO4		CO1	CO1	CO1				
4	PHA-MPL104T	Cellular and Molecular Pharmacology	5	CO1 CO2 CO3 CO5	CO2	CO3 CO4		CO5							
5	PHA-MPL105P	Pharmacology Practical I	6		CO2	CO2 CO3 CO4	CO3 CO5	CO5	CO4	CO1	CO1	CO3 CO4			
6	PHA-MPL106S	Seminar*	1	CO1	CO1 CO2		CO2 CO5					CO3	CO3 CO4 CO5		CO6
7	PHA-MPL201T	Advanced Pharmacology II	5	CO1 CO3	CO1	CO2	CO2		CO3						
8	PHA-MPL202T	Pharmacological and Toxicological Screening Methods II	5	CO1 CO2 CO3	CO3 CO4	CO1 CO2 CO3	CO3 CO4	CO3 CO4	CO3	CO1	CO1	CO1 CO4		CO3	CO1 CO4
9	PHA-MPL203T	Principles of Drug Discovery	5	CO1	CO2	CO3	CO3 CO4	CO4 CO5	CO5						
10	PHA-MPL204T	Clinical Research and Pharmacovigilance	5	CO1		CO2 CO3	CO3 CO4 CO5		CO4 CO5						
11	PHA-MPL205P	Pharmacology Practical II	6	CO1	CO1 CO2	CO3	CO2 CO3	CO3							
12	PHA-MPL206S	Seminar*	1	CO1	CO1 CO2		CO2 CO5					CO3	CO3 CO4 CO5		CO6
13	PHA-MRM301T	Research Methodology and Biostatistics*	4	CO1		CO1	CO2	CO2						CO1	
14	MJC302P	Journal Club*	1	CO1	CO1		CO1					CO2 CO3	CO3		CO4
15	MRW401P	Research Work	35	CO1	CO1	CO4	CO5	CO5	CO6	CO3	CO3		CO5 CO6	CO2	

CHAPTER III: SYLLABUS
MPHARM – PHARMACOLOGY (MPL)

SEMESTER I
PQA-MPL101T: MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES

COURSE CODE	PQA-MPL 101T
COURSE TITLE	MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES (Theory)

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

Course Content and Assessment Plan

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

PQA-MPL101T: MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES

THEORY **52 hrs**

1.a. **UV-Visible Spectroscopy**: Introduction, theory, laws, instrumentation associated with UV-Visible spectroscopy, choice of solvents and solvent effect and applications of UV-Visible spectroscopy, Difference/ Derivative spectroscopy. **5 hrs**

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

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

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

2. **NMR Spectroscopy**: Quantum numbers and their role in NMR, principle, instrumentation, solvent requirement in NMR, relaxation process, NMR signals in various compounds, chemical shift, factors influencing chemical shift, Spin-Spin coupling, coupling constant, nuclear magnetic double resonance, brief outline of principles of FT-NMR and 13C NMR. Applications of NMR spectroscopy. **8 hrs**

3. **Mass Spectroscopy**: Principle, theory, instrumentation of mass spectroscopy, different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI analyzers of quadrupole and time of flight, mass fragmentation and its rules, meta stable ions, isotopic peaks and applications of mass spectroscopy. **6 hrs**

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

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

5. Other Analytical Techniques

a**. Electrophoresis**: Principle, instrumentation, working conditions, factors affecting separation and applications of the following: a) Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresis d) Zone electrophoresis e) Moving boundary electrophoresis f) Iso electric focusing. **3 hrs**

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

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

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

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

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

MPHARM – PHARMACOLOGY (MPL)

SEMESTER I

PHA-MPL102T: ADVANCED PHARMACOLOGY I

COURSE CODE	PHA- MPL 102T
COURSE TITLE	ADVANCED PHARMACOLOGY I (Theory)

SCOPE/SUMMARY	**OBJECTIVES/COURSE OUTCOMES**
The subject is designed to strengthen the basic knowledge in the field of pharmacology and to impart recent advances in the drugs used for the treatment of various diseases. Besides, this subject helps the students to understand the concepts of drug action and mechanisms involved.	Upon completion of the course, the student shall be able to: 1. Discuss the pathophysiology and pharmacotherapy of certain diseases 2. Explain the mechanism of drug actions at cellular and molecular level 3. Understand the adverse effects, contraindications and clinical uses of drugs used in treatment of diseases

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	The students should be able to explain the dynamics of drug ADME, concepts of linear and non-linear compartment models, relationship between drug concentration and effect, and compare the types, structural and functional families of receptors.	Unit I (10 hrs)	22	7		15
2	The learners should be able to explain neurohumoral transmission in autonomic nervous system, central nervous system, Non-adrenergic non-cholinergic transmission etc.	Unit II (10 hrs)	23	8		15
3	The students should be able to learn the pharmacology of parasympathomimetics & lytics, sympathomimetics & lytics, general and local anesthetics, sedatives & hypnotics, anti-depressants, antipsychotics, anti-	Unit III a, b, c (22 hrs)	40		15	25

	epileptics, narcotic & non-narcotic analgesics, diuretics, antihypertensives, anti-ischemics, anti-arrhythmics, drugs for heart failure and hyperlipidemia hematinics, coagulants, anticoagulants, fibrinolytics and antiplatelet drugs.					
4	The candidates should be able to explain the physiological and pathological role of histamine, serotonin, kinins, prostaglandins, opioid autacoids, and pharmacological applications of antihistamines, 5HT antagonists.	Unit III d (10 hrs)	20		-	20
Total Marks of Assessment			105	15	15	75

PHA-MPL102T: ADVANCED PHARMACOLOGY I

THEORY **52 hrs**

1. General Pharmacology **10 hrs**

a. Pharmacokinetics: The dynamics of drug absorption, distribution, biotransformation and elimination. Concepts of linear and non-linear compartment models. Significance of Protein binding.

b. Pharmacodynamics: Mechanism of drug action and the relationship between drug concentration and effect. Receptors, structural and functional families of receptors, quantification of drug receptor interaction and elicited effects.

2. Neurotransmission **10 hrs**

a. General aspects and steps involved in neurotransmission.

b. Neurohumoral transmission in autonomic nervous system (Detailed study about neurotransmitters- adrenaline and acetyl choline.

c. Neurohumoral transmission in central nervous system (Detailed study about neurotransmitters- histamine, serotonin, dopamine, GABA, glutamate and glycine).

d. Non adrenergic non cholinergic transmission (NANC). Co-transmission

3. Systemic Pharmacology **32 hrs**

A detailed study on pathophysiology of diseases, mechanism of action, pharmacology and toxicology of existing as well as novel drugs used in the following systems

a. Autonomic Pharmacology: Parasympathomimetics and lytics, sympathomimetics and lytics, agents affecting neuromuscular junction. **6 hrs**

b. Central nervous system Pharmacology: General and local anesthetics, Sedatives and hypnotics, drugs used to treat anxiety, depression, psychosis, mania, epilepsy, neurodegenerative diseases, Narcotic and non-narcotic analgesics. **6 hrs**

c. Cardiovascular Pharmacology: Diuretics, antihypertensives, antiischemics, anti- arrhythmics, drugs for heart failure and hyperlipidemia. Hematinics, coagulants, anticoagulants, fibrinolytics and antiplatelet drugs. **10 hrs**

d. Autacoid Pharmacology: The physiological and pathological role of Histamine, Serotonin, Kinins, Prostaglandins, Opioid autocoids. Pharmacology of antihistamines, 5HT antagonists. **10 hrs**

REFEERENCES

1. The Pharmacological Basis of Therapeutics, Goodman and Gillman's (Latest edition).
2. Principles of Pharmacology. The Pathophysiologic basis of drug Therapy by David E Golan, Armen H, Tashjian Jr, Ehrin J,Armstrong, April W, Armstrong, Wolters, Kluwer-Lippincott Williams & Wilkins Publishers.
3. Basic and Clinical Pharmacology by B.G Katzung, (Latest edition).
4. Hand book of Clinical Pharmacokinetics by Gibaldi and Prescott. (Latest edition).
5. Applied biopharmaceutics and Pharmacokinetics by Leon Shargel and Andrew B.C.Yu.
6. Graham Smith. Oxford textbook of Clinical Pharmacology.
7. Avery Drug Treatment.
8. Dipiro Pharmacotherapy – A Pathophysiological approach.
9. Green Pathophysiology for Pharmacists.
10. Robbins & Cortan Pathologic Basis of Disease, 9th Ed. (Robbins Pathology)
11. A Complete Textbook of Medical Pharmacology by Dr. S.K Srivastava published by APC Avichal Publishing Company.
12. KD. Tripathi. Essentials of Medical Pharmacology.
13. Modern Pharmacology with Clinical Applications, Craig Charles R. & Stitzel Robert E., Lippincott Publishers.
14. Clinical Pharmacokinetics & Pharmacodynamics: Concepts and Applications – Malcolm Rowland and Thomas N. Tozer, Wolters Kluwer, Lippincott Williams & Wilkins Publishers.
15. Applied biopharmaceutics and Pharmacokinetics, Pharmacodynamics and Drug metabolism for industrial scientists.
16. Modern Pharmacology, Craig CR. & Stitzel RE, Little Brown & Company.

MPHARM – PHARMACOLOGY (MPL)
SEMESTER I

PHA-MPL103T: PHARMACOLOGICAL AND TOXICOLOGICAL SCREENING METHODS I

COURSE CODE	PHA-MPL 103T
COURSE TITLE	PHARMACOLOGICAL AND TOXICOLOGICAL SCREENING METHODS I (Theory)

SCOPE/SUMMARY	**OBJECTIVES/COURSE OUTCOMES**
This subject is designed to impart knowledge on preclinical evaluation of drugs and recent experimental techniques in the drug discovery and development. This subject also helps the students to understand the maintenance of laboratory animals as per the guidelines, basic knowledge of various *in-vitro* and *in-vivo* preclinical evaluation procedures.	Upon completion of this course, the student should be able to: 1. Appraise the regulations and ethical requirement for the usage of experimental animals. 2. Describe the various animal models and screening techniques used in drug discovery process. 3. Describe the various newer screening methods involved in the drug discovery process. 4. Appreciate and correlate the preclinical data to humans.

Course Content and Assessment Plan

Sl No.	**Course Contents**	**Syllabus (Chapters or Units with hours)**	**Total Marks of assessment**	**Distribution of marks of assessment**		
				Sessional exam *(**30** % of total marks of assessment)*		**End Sem exam** *(**70** % of total marks of assessment)*
				S1	**S2**	
1	The students will study the production, maintenance, application, anesthesia, euthanasia, blood withdrawal techniques of common laboratory and transgenic animals, as per regulatory guidelines (CPCSEA). Besides, they will learn the concept of Good Laboratory Practice and bioassay.	Unit I (10 hrs)	17	7		10
2	Learn general principles and pre-clinical methods to test drugs acting on CNS and ANS.	Unit II (12 hrs)	23	8		15
3	Study the preclinical methods to test drugs related to respiratory, reproductive, gastrointestinal, fever, pain and inflammatory disorders.	Unit III (10 hrs)	22		7	15
4	Learn general principles and pre-clinical methods to test drugs for cardiovascular and metabolic disorders, cancer and hepatic disorders	Unit IV (10 hrs)	23		8	15

5	Study pre-clinical screening techniques for immunomodulatory drugs. Understand and learn immunoassay technique to assess different biomarkers. Besides, study of limitations of animal experiments and extrapolation of *in vitro* data to pre-clinical and pre-clinical to humans.	Unit V (10 hrs)	20		--	20
Total Marks of Assessment			105	15	15	75

PHA-MPL103T: PHARMACOLOGICAL AND TOXICOLOGICAL SCREENING METHODS I

THEORY **52 hrs**

1. **Laboratory Animals** **10 hrs**

Common laboratory animals: Description, handling and applications of different species and strains of animals. Transgenic animals: Production, maintenance and applications. Anaesthesia and euthanasia of experimental animals. Maintenance and breeding of laboratory animals. CPCSEA guidelines to conduct experiments on animals. Good laboratory practice. Bioassay-Principle, scope and limitations and methods.

2. Preclinical screening of new substances for the pharmacological activity using *in vivo, in vitro*, and other possible animal alternative models. **12 hrs**

General principles of preclinical screening.

CNS Pharmacology: behavioral and muscle co-ordination, CNS stimulants and depressants, anxiolytics, anti-psychotics, anti-epileptics and nootropics. Drugs for neurodegenerative diseases like Parkinsonism, Alzheimer's and multiple sclerosis.

Drugs acting on Autonomic Nervous System.

3. Preclinical screening of new substances for the pharmacological activity using *in vivo, in vitro*, and other possible animal alternative models. **10 hrs**

Respiratory Pharmacology: anti-asthmatics, drugs for COPD and anti allergics.

Reproductive Pharmacology: Aphrodisiacs and antifertility agents

Analgesics, anti-inflammatory and antipyretic agents.

Gastrointestinal drugs: anti-ulcer, anti -emetic, antidiarrheal and laxatives.

4. Preclinical screening of new substances for the pharmacological activity using *in vivo, in vitro*, and other possible animal alternative models. **10 hrs**

Cardiovascular Pharmacology: antihypertensives, antiarrhythmics, antianginal, antiatherosclerotic agents and diuretics. Drugs for metabolic disorders like anti-diabetic, antidyslipidemic agents.

Anti-cancer agents. Hepatoprotective screening methods.

5. Preclinical screening of new substances for the pharmacological activity using *in vivo, in vitro*, and other possible animal alternative models. **10 hrs**

Immunomodulators, Immunosuppressants and immunostimulants

General principles of immunoassay: theoretical basis and optimization of immunoassay, heterogeneous and homogenous immunoassay systems. Immunoassay methods evaluation, protocol outline, objectives and preparation. Immunoassay for digoxin and insulin, Limitations of animal experimentation and alternate animal experiments. Extrapolation of *in vitro* data to preclinical and preclinical data to humans

REFERENCES

1. Biological standardization by J.H. Burn, D.J. Finney, and I.G. Goodwin.
2. Screening methods in Pharmacology by Robert Turner. A.
3. Evaluation of drugs activities by Laurence and Bachrach.
4. Methods in Pharmacology by Arnold Schwartz.
5. Fundamentals of experimental Pharmacology by M.N. Ghosh.
6. Pharmacological experiment on intact preparations by Churchill Livingstone.
7. Drug discovery and Evaluation by Vogel H.G.
8. Experimental Pharmacology by R.K. Goyal.
9. Preclinical evaluation of new drugs by S.K. Gupta
10. Handbook of Experimental Pharmacology, SK. Kulkarni.
11. Practical Pharmacology and Clinical Pharmacy, SK. Kulkarni, 3rd Edition.
12. David R. Gross. Animal Models in Cardiovascular Research, 2nd Edition, Kluwer Academic Publishers, London, UK.
13. Screening Methods in Pharmacology, Robert A. Turner.
14. Rodents for Pharmacological Experiments, Dr. Tapan Kumar Chatterjee.
15. Practical Manual of Experimental and Clinical Pharmacology by Bikash Medhi (Author), Ajay Prakash (Author).

MPHARM – PHARMACOLOGY (MPL)

SEMESTER I

PHA-MPL104T: CELLULAR AND MOLECULAR PHARMACOLOGY

COURSE CODE	PHA-MPL 104T
COURSE TITLE	CELLULAR AND MOLECULAR PHARMACOLOGY (Theory)

SCOPE /SUMMARY	**OBJECTIVES/COURSE OUTCOMES**
This subject imparts a fundamental knowledge of the structure and functions of cellular components and helps to understand the interaction of these components with drugs. This information will further help the student to apply the knowledge in drug discovery process.	Upon completion of the course, the student shall be able to: 1. Explain the receptor signal transduction processes 2. Describe the molecular pathways affected by drugs 3. Appreciate the applicability of molecular pharmacology and biomarkers in drug discovery process 4. Demonstrate molecular biology techniques as applicable for pharmacology.

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	Student will learn about the structural and functional aspects of cell and its organelles, cellular events, and applic ations of gene sequencing.	Unit I (10 hrs)	22	7		15
2	Student will understand the various types of receptors and roles of secondary messengers in relation to cellular function.	Unit II (12 hrs)	23	8		15
3	Student will comprehend the principles and applications of different genomic and proteomic tools.	Unit III (10 hrs)	17		7	10
4	Student will understand pharmacogenomics and its application.	Unit IV (10 hrs)	23		8	15

	Further, applications of genomics, proteomics, metabolomics and functionomics will be grasped.					
5	Student will learn the basics, types, procedure of cell culture and the related instruments required for sub-culturing. Principles and applications of various cell-based assays and biosimilar will be understood.	Unit V (10 hrs)	20			20
Total Marks of Assessment			105	15	15	75

PHA-MPL104T: CELLULAR AND MOLECULAR PHARMACOLOGY

THEORY **52 hrs**

1. **Cell biology** **10 hrs**

Structure and functions of the cell and its organelles, Genome organization. Gene expression and its regulation, importance of siRNA and micro RNA, gene mapping and gene sequencing, Cell cycles and its regulation. Cell death– events, regulators, intrinsic and extrinsic pathways of apoptosis. Necrosis and autophagy.

2. **Cell signaling** **12 hrs**

Intercellular and intracellular signaling pathways.

Classification of receptor family and molecular structure ligand-gated ion channels, G-protein coupled receptors, tyrosine kinase receptors and nuclear receptors.

Secondary messengers: cyclic AMP, cyclic GMP, calcium ion, inositol 1, 4, 5-trisphosphate, (IP3), NO, and diacylglycerol.

Detailed study of following intracellular signaling pathways: cyclic AMP signaling pathway, mitogen-activated protein kinase (MAPK) signaling, Janus kinase (JAK)/signal transducer and activator of transcription (STAT) signaling pathway.

3. **Principles and applications of genomic and proteomic tools** **10 hrs**

DNA electrophoresis, PCR (reverse transcription and real time), Gene sequencing, micro array technique, SDS page, ELISA and western blotting, recombinant DNA technology and gene therapy, Basic principles of recombinant DNA technology-Restriction enzymes, various types of vectors. Applications of recombinant DNA technology.

Gene therapy- Various types of gene transfer techniques, clinical applications and recent advances in gene therapy.

4. **Pharmacogenomics** **10 hrs**

Gene mapping and cloning of disease gene. Genetic variation and its role in health/ pharmacology, Polymorphisms affecting drug metabolism, Genetic variation in drug transporters, Genetic variation in G-protein coupled receptors, Applications of proteomics science: Genomics, proteomics, metabolomics, functionomics, nutrigenomics. **Immunotherapeutics,** Types of immunotherapeutics, humanised antibody therapy, immunotherapeutics in clinical practice.

5. **Cell culture techniques and Biosimilars** **10 hrs**

Basic equipment used in a cell culture lab. Cell culture media, various types of cell culture, general procedure for cell cultures; isolation of cells, subculture, cryopreservation, characterization of cells and their application. Principles and applications of cell viability assays, glucose uptake assay, Calcium influx assays. Principles and applications of flow cytometry. Biosimilars

REFERENCES

1. The Cell, A Molecular Approach. Geoffrey M Cooper.
2. Pharmacogenomics: The Search for Individualized Therapies. Edited by J. Licinio and M -L. Wong.
3. Handbook of Cell Signaling (Second Edition) Edited by Ralph A. et al.
4. Molecular Pharmacology: From DNA to Drug Discovery. John Dickenson et al.
5. Basic Cell Culture protocols by Cheril D. Helgason and Cindy L. Miller.
6. Basic Cell Culture (Practical Approach) by J. M. Davis (Editor).
7. Animal Cell Culture: A Practical Approach by John R. Masters (Editor).
8. Current protocols in molecular biology vol I to VI edited by Frederick M. Ausuvel et al.

MPHARM – PHARMACOLOGY (MPL)

SEMESTER I

PHA-MPL105P: PHARMACOLOGY PRACTICAL I

COURSE CODE	PHA-MPL 105P
COURSE TITLE	PHARMACOLOGY PRACTICAL – I (Practical)

SCOPE/SUMMARY	**OBJECTIVES/COURSE OUTCOMES**
This subject is designed to gain practical skills on various preclinical testing procedures of drugs and recent experimental techniques in the drug discovery and development. This subject also helps the students to understand the maintenance of laboratory animals as per the guidelines, basic knowledge of various *in-vitro and in-vivo* preclinical evaluation procedures.	Upon completion of this course, the student should be able to: 1. Understand the ethical consideration governing the animal experimentation and Learn the best practices for safe handling of animals. Explain the regulations and ethical requirement for the usage of experimental animals. 2. Experiment and analyze to identify, and estimate pharmaceutical active ingredients/formulation using various instrumental techniques 3. Plan, design and interpret preclinical evaluation techniques for drug discovery process. 4. Critically analyze the various animal models used in drug discovery process. 5. Correlate the preclinical data to humans

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)*	**End Sem exam (75** *% of total marks of assessment)*
				S1	
1	Experiment and analyze to identify, and estimate pharmaceutical active ingredients/formulation and biological samples using various instrumental techniques like UV-Visible spectrophotometer, simultaneous estimation using UV spectroscopy, Gas chromatography, fluorimetry, flame photometry.	Experiments 1 to 6; 27 and 29 (**48 hrs**)	39	9	30
2	Inculcate best practices and skills to handle, with-draw blood, anesthetize, euthanize small laboratory animals. Functional observation battery test; Evaluate and interpret test compounds action on various animal models of pain, inflammation,	Experiments 7 to 15 (**90 hrs**)	75	17	58

	CNS activity, diuretic, local anesthetic, ulcer, and blood sugar level.				
3	Isolation, identification and estimation of DNA, RNA, proteins by suitable methods. Demonstrate various in-vitro procedures used to understand molecular aspects of drug action like PCR, western blotting, enzyme-based assays, ELISA, Electrophoresis, fluorescent-based assays, and statistical software for Data analysis	Experiments 16 to 26 (**18 hrs**)	16	4	12
Total Marks of Assessment			130	30	100

PHA-MPL105P: PHARMACOLOGY PRACTICAL I

1. Analysis of pharmacopeial compounds and their formulations by UV-Vis spectrophotometer.
2. Simultaneous estimation of multi-component formulations by UV spectrophotometry.
3. Experiments based on HPLC.
4. Experiments based on Gas Chromatography.
5. Estimation of riboflavin/quinine sulphate by fluorimetry.
6. Estimation of sodium/potassium by flame photometry.
7. Handling of laboratory animals.
8. Various routes of drug administration.
9. Techniques of blood sampling, anesthesia and euthanasia of experimental animals.
10. Functional observation battery tests (modified Irwin test).
11. Evaluation of CNS stimulant, depressant, anxiogenics and anxiolytic, anticonvulsant activity.
12. Evaluation of analgesic, anti-inflammatory, local anesthetic, mydriatic and miotic activity.
13. Evaluation of diuretic activity.
14. Evaluation of antiulcer activity by pylorus ligation method.
15. Oral glucose tolerance test.
16. Isolation and identification of DNA from various sources (Bacteria, Cauliflower, Onion, Goat liver).
17. Isolation of RNA from yeast.
18. Estimation of proteins by Bradford/Lowry method in biological samples. Estimation of RNA/DNA by UV Spectroscopy.

19. Gene amplification by PCR.
20. Protein quantification by Western Blotting.
21. Enzyme based *in-vitro* assays (MPO, AChEs, α amylase, α glucosidase).
22. Cell viability assays (MTT/Trypan blue/SRB).
23. DNA fragmentation assay by agarose gel electrophoresis.
24. DNA damage study by Comet assay.
25. Apoptosis determination by fluorescent imaging studies.
26. Pharmacokinetic studies and data analysis of drugs given by different routes of administration using software.
27. Enzyme inhibition and induction activity.
28. Extraction of drugs from various biological samples and estimation of drug in biological fluids using different analytical techniques (UV).
29. Extraction of drugs from various biological samples and estimation of drug in biological fluids using different analytical techniques (HPLC).

REFERENCES

1. CPCSEA, OECD, ICH, USFDA, Schedule Y, EPA guidelines.
2. Fundamentals of experimental Pharmacology by M.N. Ghosh.
3. Handbook of Experimental Pharmacology by S.K. Kulkarni.
4. Drug discovery and Evaluation by Vogel H.G.
5. Spectrometric Identification of Organic compounds - Robert M Silverstein.
6. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman.
7. Vogel's Textbook of quantitative chemical analysis - Jeffery, Basset, Mendham, Denney.
8. Basic Cell Culture protocols by Cheril D. Helgason and Cindy L.Mille.
9. Basic Cell Culture (Practical Approach) by J. M. Davis (Editor).
10. Animal Cell Culture: A Practical Approach by John R. Masters (Editor).
11. Practical Manual of Experimental and Clinical Pharmacology by Bikash Medhi (Author), Ajay Prakash (Author) Jaypee Brothers' Medical Publishers Pvt. Ltd.

MPHARM – PHARMACOLOGY (MPL)

SEMESTER I

PHA-MPL106S: SEMINAR IN PHARMACOLOGY

COURSE CODE	PHA- MPL 106S
COURSE TITLE	SEMINAR IN PHARMACOLOGY

SCOPE/SUMMARY	**OBJECTIVES/COURSE OUTCOMES**
The subject 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 Pharmacology.	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 pharmacology 2. Learn to organize complex pharmacology 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 Contents**	**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 pharmacology.	2 hours/week	100	No end-semester examination. Only continuous mode.

MPHARM – PHARMACOLOGY (MPL)

SEMESTER II

PHA-MPL201T: ADVANCED PHARMACOLOGY II

COURSE CODE	PHA- MPL201T
COURSE TITLE	**ADVANCED PHARMACOLOGY II** (Theory)

SCOPE/SUMMARY	**OBJECTIVES/COURSE OUTCOMES**
The subject is designed to strengthen the basic knowledge in the field of pharmacology and to impart recent advances in the drugs used for the treatment of various diseases. Besides, this subject helps the students to understand the concepts of drug action and mechanisms involved.	Upon completion of the course, the student shall be able to: 1. Explain the mechanism of drug actions at cellular and molecular level. 2. Discuss the pathophysiology and pharmacotherapy of certain diseases. 3. Understand the adverse effects, contraindications and clinical uses of drugs used in treatment of diseases.

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 advanced cellular/ molecular mechanisms, safety and therapeutic uses of hormones and related drugs.	Unit I (10 hrs)	17	7		10
2	Study the actions, resistance, safety, and therapeutic profile of different classes of antimicrobials. Study the specific chemotherapeutic agents used against infection and cancer.	Unit II (12 hrs)	23	8		15
3	Learn the actions of mediators involved in immune & allergic reactions, and role of immunomodulatory drugs. Study about respiratory disorders and their treatment guidelines.	Unit III (10 hrs)	22		7	15
4	Study the actions and safety profile of drugs used for the treatment of gastro-intestinal disorders. Acquire the advance knowledge pertaining to effect of drugs varying due to timing of drug administration.	Unit IV (10 hrs)	23		8	15
5	Learn how the oxidative stress and free radicals involved in various pathological conditions and therapeutic role of	Unit V (10 hrs)	22		-	20

	antioxidants. Study the advancements in therapy of cancer, diabetes mellitus, Alzheimer's and Parkinson's disease.					
Total Marks of Assessment			105	15	15	75

PHA-MPL201T: ADVANCED PHARMACOLOGY II

THEORY **52 hrs**

1. **Endocrine Pharmacology** **10 hrs**

Molecular and cellular mechanism of action of hormones such as growth hormone, prolactin, thyroid, insulin and sex hormones, Anti-thyroid drugs, Oral hypoglycemic agents, Oral contraceptives, Corticosteroids. Drugs affecting calcium regulation.

2. **Chemotherapy** **12 hrs**

Cellular and molecular mechanism of actions and resistance of antimicrobial agents such as ß-lactams, aminoglycosides, quinolones, macrolide antibiotics. antifungal, antiviral, and anti-TB drugs. Drugs used in Protozoal Infections, Drugs used in the treatment of Helminthiasis, Chemotherapy of cancer.

3. **Inflammation, Respiratory and Immunopharmacology** **10 hrs**

Cellular and biochemical mediators of inflammation and immune response. Allergic or hypersensitivity reactions. Pharmacotherapy of asthma and COPD. Immunopharmacology, Immunosuppressants and Immunostimulants.

4. **GIT and Chronopharmacology** **10 hrs**

Antiulcer drugs, Prokinetics, antiemetics, anti-diarrhoeals and drugs for constipation and drugs for irritable bowel syndrome. Chronopharmacology. Biological and circadian rhythms, applications of chronotherapy in various diseases like cardiovascular disease, diabetes, asthma and peptic ulcer

5. **Free radical Pharmacology** **10 hrs**

Generation of free radicals, role of free radicals in etiopathology of various diseases such as diabetes, neurodegenerative diseases, and cancer. Protective activity of certain important antioxidants Recent advances in the treatment of Alzheimer's disease, Parkinson's disease, Cancer, Diabetes mellitus.

REFERENCES

1. The Pharmacological basis of therapeutics - Goodman and Gilman.
2. Principles of Pharmacology. The Pathophysiologic basis of drug therapy by David E. Golan et al.
3. Basic and Clinical Pharmacology by B.G. Katzung.
4. Pharmacology by H.P. Rang and M.M. Dale.
5. Handbook of Clinical Pharmacokinetics by Gibaldi and Prescott.
6. Text book of Therapeutics, drug and disease management by E T. Herfindal and Gourley.
7. Applied biopharmaceutics and Pharmacokinetics by Leon Shargel and Andrew B.C. Yu.
8. Handbook of Essential Pharmacokinetics, Pharmacodynamics and Drug Metabolism for Industrial Scientists.
9. Robbins & Cortan Pathologic Basis of Disease, 9^{th} Ed. (Robbins Pathology).
10. A Complete Textbook of Medical Pharmacology by Dr. S.K Srivastava published by APC Avichal Publishing Company.
11. KD. Tripathi. Essentials of Medical Pharmacology.
12. Principles of Pharmacology. The Pathophysiologic basis of drug Therapy by David E Golan, Armen H, Tashjian Jr, Ehrin J, Armstrong, April W, Armstrong, Wolters, Kluwer-Lippincott Williams & Wilkins Publishers.

MPHARM – PHARMACOLOGY (MPL)

SEMESTER II

PHA-MPL202T: PHARMACOLOGICAL AND TOXICOLOGICAL SCREENING METHODS II

COURSE CODE	PHA-MPL202T
COURSE TITLE	PHARMACOLOGICAL AND TOXICOLOGICAL SCREENING METHODS II (Theory)

SCOPE/SUMMARY	**OBJECTIVES/COURSE OUTCOMES**
This subject imparts knowledge on the preclinical safety and toxicological evaluation of drug & new chemical entity. This knowledge will make the student competent in regulatory toxicological evaluation.	Upon completion of the course, the student shall be able to: 1. Understand and apply the principles of GLP in safety pharmacology and toxicological studies 2. Explain the various types of toxicity studies. 3. Understand the concepts of investigational new drug and apply it's enabling studies to meet the drug development process. 4. Demonstrate the theoretical and practical skills required to conduct toxicokinetic studies and alternative methods of animal toxicity in drug development 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 (*30 % of total marks of assessment)*		**End Sem exam** (**7***0 % of total marks of assessment)*
				S1	**S2**	
1	Learn the general aspect of toxicology, regulatory guidelines, Good Laboratory Practices, and develop SOP's for the conduct of regulatory toxicity.	Unit I (10 hrs)	18	8		10
2	Understand the procedures involved in the toxicity studies, eye irritation, skin sensitization, dermal irritation, and dermal toxicity studies according to OECD guidelines.	Unit II (10 hrs)	22	7		15
3	Learn the protocols of special toxicity studies such as reproductive, teratogenicity and genotoxicity studies etc.	Unit III (10 hrs)	22		7	15

4	Learn the IND enabling studies requirements, significance, industry perspective of IND submission, safety pharmacology related to CVS, CNS, respiratory, GI, renal and other studies.	Unit IV (12 hrs)	23		8	15
5	Provide knowledge on different aspects of toxicokinetics in drug discovery and development process and alternative methods of animal toxicity.	Unit V (10 hrs)	20		--	20
Total Marks of Assessment			105	15	15	75

PHA-MPL202T: PHARMACOLOGICAL AND TOXICOLOGICAL SCREENING METHODS II

THEORY **52 hrs**

1. Basic definition and types of toxicology (general, mechanistic, regulatory and descriptive) Regulatory guidelines for conducting toxicity studies OECD, ICH, EPA and Schedule Y, OECD principles of Good laboratory practice (GLP), history, concept and its importance in drug development. **10 hrs**

2. Acute, sub-acute and chronic- oral, dermal and inhalational studies as per OECD guidelines. Acute eye irritation, skin sensitization, dermal irritation & dermal toxicity studies. Test item characterization- importance and methods in regulatory toxicology studies. **10 hrs**

3. Reproductive toxicology studies, male reproductive toxicity studies, female reproductive studies (segment I and segment III), Teratogenecity studies (segment II), genotoxicity studies (Ames Test, *in vitro* and *in vivo* Micronucleus and Chromosomal aberrations studies), *in vivo* carcinogenicity studies. **10 hrs**

4. IND enabling studies (IND studies) - Definition of IND, the importance of IND, industry perspective, list of studies needed for IND submission. Safety pharmacology studies- origin, concepts, and importance of safety pharmacology. Tier 1- CVS, CNS, and respiratory safety pharmacology, hERG assay. Tier 2- GI, renal and other studies. **12 hrs**

5. Toxicokinetics - Toxicokinetic evaluation in preclinical studies, saturation kinetics Importance and applications of toxicokinetic studies. Alternative methods to animal toxicity testing. **10 hrs**

REFERENCES

1. Handbook on GLP, Quality practices for regulated non-clinical research and development (http://www.who.int/tdr/publications/documents/glphandbook.pdf).
2. Schedule Y Guideline: drugs and cosmetics (second amendment) rules, 2005, Ministry of Health and Family Welfare (Department of Health) New Delhi.
3. Drugs from discovery to approval by Rick NG.
4. Animal Models in Toxicology, 3rd Edition, Lower and Bryan.
5. OECD test guidelines.
6. Principles of toxicology by Karen E. Stine, Thomas M. Brown.
7. Guidance for Industry M3(R2) Nonclinical Safety Studies for the Conduct of Human Clinical Trials and Marketing Authorization for Pharmaceuticals (http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm073246.pdf).

MPHARM – PHARMACOLOGY (MPL)

SEMESTER II

PHA-MPL203T: PRINCIPLES OF DRUG DISCOVERY

COURSE CODE	PHA-MPL203T
COURSE TITLE	PRINCIPLES OF DRUG DISCOVERY **(**Theory**)**

SCOPE/SUMMARY	**OBJECTIVES/COURSE OUTCOMES**
The subject imparts basic knowledge of drug discovery process. This information will make the student competent in drug discovery process.	Upon completion of the course, the student shall be able to: 1. Explain the process of drug discovery and development including cosmeceuticals. 2. Appreciate the importance of the role of genomics, proteomics, and bioinformatics in drug discovery 3. Explain drug targets in drug discovery process 4. Explain lead seeking methods and lead optimization 5. Appreciate the importance of the role of computer-aided drug design in drug discovery

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 (7***0 % of total marks of assessment)*
				S1	**S2**	
1	Understanding the fundamentals of the modern drug discovery process. Students will also understand the role of Genomics, Proteomics and Bioinformatics in drug discovery. Further, students will learn the principle involved in in microarrays, siRNAs, antisense oligonucleotides and the role of transgenic animals in drug discovery	Unit I (12 hrs)	18	8		10
2	Appreciate advanced technologies in drugs discovery such as combinatorial chemistry and high throughput screening, in-silico lead discovery, assay development and hit identification etc. for lead identification. Appreciate the protein structure, application of NMR and X-	Unit II (10 hrs)	22	7		15

	ray crystallography in the drug discovery process.					
3	Students can compare traditional and rational drug design. Students will also learn the structure-based and pharmacophore-based drug designs.	Unit III (10 hrs)	22		7	15
4	Students learn the molecular docking and appreciate structure-activity relationship (SAR), and QSAR.	Unit IV (10 hrs)	23		8	15
5	Students will learn advances in QSAR-statistical methods.	Unit V (10 hrs)	24			20
Total Marks of Assessment			105	15	15	75

PHA-MPL203T: PRINCIPLES OF DRUG DISCOVERY

THEORY **52 hrs**

1. **An overview of modern drug discovery process:** **12 hrs**

Target identification, target validation, lead identification and lead Optimization. Economics of drug discovery. Target Discovery and Validation-Role of Genomics, Proteomics and Bioinformatics. Role of Nucleic acid microarrays, Protein microarrays, Antisense technologies, siRNAs, antisense oligonucleotides, Zinc finger proteins. Role of transgenic animals in target validation.

2. **Lead Identification:** **10 hrs**

Combinatorial chemistry & high throughput screening, in-silico lead discovery techniques, Assay development for hit identification. Protein structure, Levels of protein structure, Domains, motifs, and folds in protein structure. Computational prediction of protein structure: Threading and homology modeling methods. Application of NMR and X-ray crystallography in protein structure prediction.

3. **Rational Drug Design:** **10 hrs**

Traditional vs rational drug design, Methods followed in traditional drug design, High throughput screening, Concepts of Rational Drug Design, Rational Drug Design Methods: Structure and Pharmacophore based approaches, Virtual Screening techniques: Drug likeness screening, Concept of pharmacophore mapping and pharmacophore based Screening.

4. **Molecular docking**: **10 hrs**

Rigid docking, flexible docking, manual docking; Docking based screening. de Novo drug design. Quantitative analysis of Structure Activity Relationship, History and development of QSAR, SAR versus QSAR, Physicochemical parameters, Hansch analysis, Free-Wilson analysis and relationship between them.

5. **QSAR Statistical methods** **10 hrs**

Regression analysis, partial least square analysis (PLS) and other multivariate statistical methods. 3D-QSAR approaches like COMFA and COMSIA, Prodrug design-Basic concept, Prodrugs to improve patient acceptability, Drug solubility, Drug absorption and distribution, site specific drug delivery and sustained drug action. Rationale of prodrug design and practical consideration of prodrug design. Basic concepts of cosmeceutical sciences – Herbal cosmeceuticals, Trends and future research in cosmeceuticals.

REFERENCES

1. Mouldy Sioud. Target Discovery and Validation Reviews and Protocols: Volume 2 Emerging Molecular Targetsand Treatment Options. 2007 Humana Press Inc.
2. Darryl León, Scott Markel. In Silico Technologies in Drug Target Identification and Validation. 2006 by Taylor and Francis Group, LLC.
3. Johanna K. DiStefano. Disease Gene Identification. Methods and Protocols. Springer New York Dordrecht Heidelberg London.
4. Hugo Kubiny. QSAR: Hansch Analysis and Related Approaches. Methods and Principles in Medicinal Chemistry. Publisher Wiley-VCH.
5. Klaus Gubernator, Hans-Joachim Böhm. Structure-Based Ligand Design. Methods and Principles in Medicinal Chemistry. Publisher Wiley-VCH.
6. Abby L., Parrill. M., Rami Reddy. Rational Drug Design. Novel Methodology and Practical Applications. ACS Symposium Series; American Chemical Society: Washington, DC, 1999.
7. J. Rick Turner. New drug development design, methodology and, analysis. John Wiley & Sons, Inc., New Jersey.

MPHARM – PHARMACOLOGY (MPL)

SEMESTER II

PHA-MPL204T: CLINICAL RESEARCH AND PHARMACOVIGILANCE

COURSE CODE	PHA- MPL 204T
COURSE TITLE	CLINICAL RESEARCH AND PHARMACOVIGILANCE (Theory)

SCOPE/SUMMARY	**OBJECTIVES/COURSE OUTCOMES**
This subject will provide value addition and current requirement for the students in clinical research and pharmacovigilance. It will teach the students on conceptualizing, designing, conducting, managing and reporting of clinical trials. This subject also focuses on global scenario of pharmacovigilance in different methods that can be used to generate safety data. It will teach the students in developing drug safety data in pre-clinical, clinical phases of drug development and post-marketing surveillance.	Upon completion of this course, the student should be able to: 1. Explain the regulatory requirements for conducting a clinical trial and medical devices 2. Demonstrate the types of clinical trial designs 3. Explain the responsibilities of key players involved in clinical trials 4. Execute safety monitoring, reporting and close-out activities 5. Explain the principles of pharmacovigilance 6. Detect new adverse drug reactions and their assessment 7. Perform the adverse drug reaction reporting systems and communication in pharmacovigilance

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	The students will learn the origin and principles of ICH-GCP guidelines, functioning of an institutional review board, explain the ethical guidelines for biomedical research and human participants, Schedule Y and informed consent process.	Unit I (10 hrs)	17	7		10
2	The students will understand the types and designs of clinical trials, responsibilities of clinical trial personnel and contract research organization	Unit II (10 hrs)	23	8		15

3	The students will learn the guidelines for preparation of clinical trial protocol, investigator brochure, case report forms, clinical study report, clinical trial and safety monitoring, and examine the severity and seriousness assessment of ADRs.	Unit III (10 hrs)	22		7	15
4	The students will know the aspects of pharmacovigilance program and evaluation of medication safety.	Unit IV (12 hrs)	20		8	12
5	The students will understand aspects of pharmaco-epidemiology, pharmaco-economics and safety pharmacology including medical devices.	Unit V (10 hrs)	20		-	20
Total Marks of Assessment			105	15	15	75

PHA-MPL204T: CLINICAL RESEARCH AND PHARMACOVIGILANCE

THEORY **52 hrs**

1. **Regulatory Perspectives of Clinical Trials**: **10 hrs**

Origin and Principles of International Conference on Harmonization (ICH) - Good Clinical Practice (ICH-GCP) guidelines. Ethics Committee: Institutional Review Board, Ethical Guidelines for Biomedical Research and Human Participant-Schedule Y, ICMR, Informed Consent Process: Structure and content of an Informed Consent Process. Ethical principles governing informed consent process.

2. **Clinical Trials:** **10 hrs**

Types and Design, Experimental Study- RCT and Non RCT, Observation Study: Cohort, Case-Control, Cross-sectional

Clinical Trial Study Team, Roles and responsibilities of Clinical Trial Personnel: Investigator, Study Coordinator, Sponsor, Contract Research Organization and its management.

3. **Clinical Trial Documentation** **10 hrs**

Guidelines for the preparation of documents. Preparation of protocol, Investigator Brochure, Case Report Forms, Clinical Study Report, Clinical Trial Monitoring-Safety Monitoring in CT, Adverse Drug Reactions: Definition and types. Detection and reporting methods. Severity and seriousness assessment. Predictability and preventability assessment, Management of adverse drug reactions; Terminologies of ADR.

4. **Basic aspects, terminologies and establishment of pharmacovigilance 12 hrs**

History and progress of pharmacovigilance, Significance of safety monitoring, Pharmacovigilance in India and international aspects, WHO international drug monitoring programme, WHO and Regulatory terminologies of ADR, evaluation of medication safety, Establishing pharmacovigilance centres in Hospitals, Industry and National programmes related to pharmacovigilance. Roles and responsibilities in Pharmacovigilance Methods, ADR reporting and tools used in Pharmacovigilance.

International classification of diseases, International Nonproprietary names for drugs, Passive and Active surveillance, Comparative observational studies, targeted clinical investigations and Vaccine safety surveillance. Spontaneous reporting system and Reporting to regulatory authorities, Guidelines for ADRs reporting. Argus, Aris G Pharmacovigilance, VigiFlow, Statistical methods for evaluating medication safety data. Introduction to medical devices-regulations governing development and use of medical devices, Medical devices safety and performance.

5. **Pharmacoepidemiology, Pharmacoeconomics, safety pharmacology**. **10 hrs**

REFERENCES

1. Central Drugs Standard Control Organization- Good Clinical Practices, Guidelines for Clinical Trials on Pharmaceutical Products in India. New Delhi: Ministry of Health; 2001.
2. 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.
3. Ethical Guidelines for Biomedical Research on Human Subjects 2000. Indian Council of Medical Research, New Delhi.
4. Textbook of Clinical Trials edited by David Machin, Simon Day and Sylvan Green, March 2005, John Wiley and Sons.
5. Clinical Data Management edited by RK Rondels, SA Varley, CF Webbs. Second Edition, Jan 2000, Wiley Publications.
6. Handbook of clinical Research. Julia Lloyd and Ann Raven Ed. Churchill Livingstone.
7. Principles of Clinical Research edited by Giovanna di Ignazio, Di Giovanna and Haynes.

MPHARM – PHARMACOLOGY (MPL)

SEMESTER II

PHA-MPL205P: PHARMACOLOGY PRACTICAL II

COURSE CODE	PHA-MPL 205P
COURSE TITLE	PHARMACOLOGY PRACTICAL – II

SCOPE/SUMMARY	**OBJECTIVES/COURSE OUTCOMES**
This subject is designed to gain practical skills on preclinical testing procedures of drugs and recent experimental techniques in the drug discovery and development. This subject also helps the students learn in-silico drug design, dose-response relationships of drugs, international guidelines for preclinical and clinical studies.	Upon completion of this course, the student should be able to: 1. Demonstrate, analyze, and compare dose-response relationship of drugs and quantification of responses of receptor ligands. 2. Understand and apply international guidelines to evaluate drug toxicities and its report. 3. Plan and design in-silico drug candidates for a target protein and critically analyze its druggability.

Course Content and Assessment Plan

Sl No.	**Course Content**	**Syllabus (Chapters or Experiments with hours)**	**Total Marks of assessment**	**Distribution of marks of assessment**	
				Sessional exam (25 *% of total marks of assessment)*	**End Sem exam** (75 *%g of total marks of assessment)*
				S1	
1	Experiment, demonstrate and analyse dose- response of receptor ligands using in-vitro tissue preparations and quantify their effects, and estimate the concentration of a given receptor-ligand by comparing it with the response of a standard drug solution using various bioassays.	Experiments 1 to 10 (90 hrs)	75	17	58
2	Learn and understand various international guidelines like OECD guidelines for toxicity testing in animals and apply the knowledge to design toxicity studies and design protocol for clinical studies based on GCP guidelines. Analyze and compare adverse reactions to drugs in patients and learn various ADR reporting methods.	Experiments 11 to 16 and 21 (48 hrs)	39	9	30

3	Understand and demonstrate in-silico drug design using docking tools, pharmacophore-based screening and evaluate the data using QSAR studies.	Experiments 17 to 20 (18 hrs)	16	4	12
Total Marks of Assessment			130	30	100

PHA-MPL205P: PHARMACOLOGY PRACTICAL II

1. To record the DRC of agonist using suitable isolated tissue preparation.
2. To study the effects of antagonist/potentiating agents on DRC of agonist using suitable isolated tissue preparation.
3. To determine the strength of unknown sample by matching bioassay using suitable tissue preparation.
4. To determine the strength of unknown sample by interpolation bioassay using suitable tissue preparation
5. To determine the strength of unknown sample by bracketing bioassay using suitable tissue preparation
6. To determine the strength of unknown sample by multiple point bioassay using suitable tissue preparation.
7. Estimation of PA_2 values of various antagonists using suitable isolated tissue preparations.
8. To study the effects of various drugs on isolated heart preparations
9. Recording of rat BP, heart rate.
10. Recording of rat ECG
11. Drug absorption studies by averted chick ileum preparation.
12. Acute oral toxicity studies as per OECD guidelines.
13. Acute dermal toxicity studies as per OECD guidelines.
14. Repeated dose toxicity studies- Serum biochemical, haematological, urine analysis, functional observation tests and histological studies.
15. Drug mutagenicity study using mouse bone-marrow chromosomal aberration test.
16. Protocol design for a clinical trial. (3 Nos.)
17. Design of ADR monitoring protocol.
18. In-silico docking studies. (2 Nos.)

19. In-silico pharmacophore-based screening.
20. In-silico QSAR studies.
21. ADR reporting

REFERENCES

1. Fundamentals of experimental Pharmacology by M.N. Ghosh.
2. Hand book of Experimental Pharmacology-S.K. Kulkarni.
3. Text book of in-vitro practical Pharmacology by Ian Kitchen.
4. Bioassay Techniques for Drug Development by Atta-ur-Rahman, Iqbal Choudhary and William Thomsen.
5. Applied Biopharmaceutics and Pharmacokinetics by Leon Shargel and Andrew B.C. Yu.
6. Handbook of Essential Pharmacokinetics, Pharmacodynamics and Drug Metabolism for Industrial Scientists.

MPHARM – PHARMACOLOGY (MPL)

SEMESTER II

PHA-MPL206S: SEMINAR IN PHARMACOLOGY

COURSE CODE	PHA- MPL 206S
COURSE TITLE	SEMINAR IN PHARMACOLOGY

SCOPE/SUMMARY	**OBJECTIVE/COURSE OUTCOMES**
The subject 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 Pharmacology.	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 pharmacology 2. Learn to organize complex pharmacology 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 pharmacology.	2 hours/week	100	No end-semester examination. Only continuous mode.

MPHARM – PHARMACOLOGY (MPL)

SEMESTER III

PHA-MRM301T: RESEARCH METHODOLOGY AND BIOSTATISTICS

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

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

Course Content and Assessment Plan

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

PHA-MRM301T: RESEARCH METHODOLOGY AND BIOSTATISTICS

THEORY **52 hrs**

UNIT – I

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

UNIT – II

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

UNIT – III

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

UNIT – IV

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

UNIT – V

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

MPHARM – PHARMACOLOGY (MPL)

SEMESTER III

MJC 302P: JOURNAL CLUB IN PHARMACOLOGY

COURSE CODE	MJC 302P
COURSE TITLE	JOURNAL CLUB IN PHARMACOLOGY

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

Course Content and Assessment Plan

Sl. No.	**Course Contents**	**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 pharmacology.	2 hours/week	100	No end-semester examination. Only continuous mode.

MPHARM – CHOICE BASED INTERDISCIPLINARY COURSES

PCE-001E: GENERIC DRUG DEVELOPMENT

(15 hrs)

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

REFERENCES

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

PCE-002E: PHARMACEUTICAL DISSOLUTION TECHNOLOGY

(15 hrs)

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

REFERENCES

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

PCE-003E: PARTICULATE DRUG DELIVERY SYSTEMS

(15 hrs)

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

6 hrs

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

9 hrs

REFERENCES

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

PCE-004E: 3D PRINTING IN PHARMACEUTICAL MANUFACTURING

(15 hrs)

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

REFERENCES

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

PCH-001E: PREPARATIVE SEPARATION TECHNIQUES

(15 hrs)

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

PCH-002E: MOLECULAR MODELLING AND DRUG DESIGN

(15 hrs)

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

PCH-003E: HYPHENATED TECHNIQUES

(15 hrs)

Principle and applications of following hyphenated techniques

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

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

(15 hrs)

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

First aid procedures **1 hr**

Good laboratory practices: **2 hrs**

Personal protection **1 hr**

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

Fire safety **1 hr**

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

(15 hrs)

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

Evaluation

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

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

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

(15 hrs)

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

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

(15 hrs)

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

PQA-004E: PROFESSIONAL DEVELOPMENT

(15 hrs)

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

Assessments:

- assignments
- case studies
- portfolios
- presentations

PQA-005E: STABILITY TESTING OF DRUGS AND BIOLOGICALS

(15 hrs)

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

PQA-006E: USFDA DRUG REGULATORY AFFAIRS

(15 hrs)

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

PQA-007E: REST OF THE WORLD DRUG REGULATIONS

(15 hrs)

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

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

PQA-008E: EVALUATION OF MEDICAL DEVICES

(15 hrs)

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

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

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

Importance, scope, clinical evaluation in brief

PBT-001E: CLEAN ROOM CONCEPTS

(15 hrs)

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

Morphology, Microscopy, Growth and Controlling Growth of Microorganisms.

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

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

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

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

REFERENCES

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

PBT-002E: BIOSIMILARS

(15 hrs)

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

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

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

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

REFERENCES

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

PBT-003E: PRINCIPLES OF GENE CLONING

(15 hrs)

Unit I **3 hrs**

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

Unit II **6 hrs**

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

Unit III **6 hrs**

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

REFERENCES

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

PBT-004E: TISSUE ENGINEERING

(15 hrs)

Unit I **5 hrs**

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

Unit II **5 hrs**

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

Unit III **5 hrs**

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

REFERENCES

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

PPR-001E: RETAIL PHARMACY PRACTICE

(15 hrs)

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

REFERENCES

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

PPR-002E: FUNDAMENTALS OF MEDICAL WRITING

(15 hrs)

I. Introduction **2 hrs**

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

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

- Language and Style in Medical Writing
- Literature search

  -Data bases (Medline, PubMed, Cochrane)

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

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

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

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

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

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

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

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

REFERENCES

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

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

PPR-003E: SYSTEMATIC REVIEW AND META-ANALYSIS

(15 hrs)

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

REFERENCES:

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

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

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

Evaluation: Based on Assignments

PPR-004E: PHARMACOKINETICS DATA ANALYSIS

(Employing WinNonlin)

(15 hrs)

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

REFERENCES

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

Pre-requisites: Knowledge of basic pharmacokinetics.

Evaluation: Based on Assignments.

PHA-001E: CANCER BIOLOGY

(15 hrs)

Objectives/Course Outcomes

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

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

PHA-002E: SCREENING METHODS FOR DRUG DEVELOPMENT

(15 hrs)

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

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

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

PHA-003E: FREE RADICAL BIOLOGY AND MEDICINE

(15 hrs)

Objectives

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

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

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

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

(15 hrs)

Objectives

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

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

Guidelines for safety testing

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

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

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

PCO-001E: NUTRACEUTICALS

(15 hrs)

Scope

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

Objectives

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

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

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

REFERENCES

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

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

(15 hrs)

Scope

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

Objectives

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

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

REFERENCES

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

PCO-003E: NANOPHYTOPHARMACEUTICALS

(15 hrs)

Scope

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

Objectives

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

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

REFERENCES

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

PCO-004E: HERBAL MONOGRAPHS

(15 hrs)

Scope

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

Objectives

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

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

   Leaf: Vasaka (*Adhatoda zeylanica)*

   Root: Shatavari (*Asparagus racemosus)*

   Rhizome:Rasna *(Alpinia galanga)*

   Bark: Cinchona (*Cinchona officinalis)*

   Fruit: Pepper (*Piper nigrum)*

   Entire herb: Kalmegh *(Andrographis paniculata).*

REFERENCES

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

PRM-001E: RETAIL BUSINESS MANAGEMENT

(15 hrs)

Scope

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

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

REFERENCES

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

PRM-002E: INTELLECTUAL PROPERTY MANAGEMENT

(15 hrs)

Scope

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

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

REFERENCES

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

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

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

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

PRM-003E: GENERAL MANAGEMENT PRINCIPLES

(15 hrs)

Scope

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

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

REFERENCES

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

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

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

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

PRM-004E: ENTREPRENEURSHIP DEVELOPMENT

(15 hrs)

Scope

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

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

REFERENCES

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

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

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

MPHARM – CHOICE BASED MULTIDISCIPLINARY COURSE

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

(As prescribed from time to time)