



**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

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**Program Title: MPharm (Master of Pharmacy)**

**CBCS (Choice Based Credit System)**

**Specialization: Pharmaceutical Chemistry**

**Manipal College of Pharmaceutical Sciences**

**Manipal Academy of Higher Education**

**Manipal-576 104, Karnataka, India**



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.

*P. K. K. K.*

REGISTRAR



## Table of Contents

S. No.	Content	Page No.
	<b>Chapter I: Regulations</b>	<b>01-25</b>
<b>1</b>	Short title and commencement	01
<b>2</b>	Minimum qualification for admission	01
<b>3</b>	Duration of the program	01
<b>4</b>	Medium of instruction and examinations	01
<b>5</b>	Working days in each semester	01
<b>6</b>	Attendance and progress	02
<b>7</b>	Program/Course credit structure	02
<b>8</b>	Academic work	03
<b>9</b>	Course work of study	03
<b>10</b>	Program committee	17
<b>11</b>	Examinations/Assessments	17
<b>12</b>	Pass and award of performance grades	20
<b>13</b>	Make-up/Supplementary examination	23
<b>14</b>	Improvement of internal assessment	23
<b>15</b>	Promotion to the next higher class	24
<b>16</b>	Declaration of class	24
<b>17</b>	Research project work	24
<b>18</b>	Award of degree	25
<b>19</b>	Duration for completion of the program	25
<b>20</b>	Revaluation of answer papers	25
<b>21</b>	Re-admission after break of study	25
	<b>Chapter II :</b>	<b>26-33</b>
<b>22</b>	OBE Framework	29
<b>23</b>	Vision	30
<b>24</b>	Mission	30
<b>25</b>	Quality Policy	30
<b>26</b>	Program Education Objective	31
<b>27</b>	Program Outcome	33
	<b>Chapter III: Syllabus</b>	<b>35-95</b>
<b>28</b>	Sem 1-1 PQA-MPC101T	39
<b>29</b>	Sem 1-2 PCH-MPC102T	42
<b>30</b>	Sem 1-3 PCH-MPC103T	45
<b>31</b>	Sem 1-4 PCH-MPC104T	48
<b>32</b>	Sem 1-5 PCH-MPC105P	52
<b>33</b>	Sem 1-6 PCH-MPC106S	54
<b>34</b>	Sem 2-1 PCH-MPC201T	55
<b>35</b>	Sem 2-2 PCH-MPC202T	58
<b>36</b>	Sem 2-3 PCH-MPC203T	61
<b>37</b>	Sem 2-4 PCH-MPC204T	64
<b>38</b>	Sem 2-5 PCH-MPC205P	68
<b>37</b>	Sem 2-6 PCH-MPC206S	70
<b>38</b>	Sem 3-1 PHA-MRM301T	72
<b>39</b>	Sem 3-2 MJC-302P	73
<b>40</b>	Sem 4 Choice Based Electives	74



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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—

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## **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 ( $\frac{1}{2}$ ) for practical (laboratory) hours. Thus, for example, a theory course, having four lectures per week throughout the semester carries a credit of 4. Similarly, a practical having four laboratory hours per week throughout 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  $\frac{1}{2}$ .

### **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.

<b>S. No.</b>	<b>Specialization</b>	<b>Code</b>
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.

<b>Table 2. Course work of MPharm – Pharmaceutics (MPH) specialization</b>						
<b>Course Code</b>	<b>Course Title</b>	<b>Credit hours/week</b>			<b>Credit Points</b>	<b>Marks</b>
		<b>Lecture (L)</b>	<b>Tutorial (T)</b>	<b>Practical (P)</b>		
<b>Semester I</b>						
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
<b>Total</b>		<b>16</b>	<b>3</b>	<b>14</b>	<b>26</b>	<b>650</b>
<b>Semester II</b>						
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
<b>Total</b>		<b>16</b>	<b>4</b>	<b>14</b>	<b>27</b>	<b>650</b>
* No end-semester examination. Only continuous mode						



<b>Table 3. Course work of MPharm –Industrial Pharmacy (MIP) specialization</b>						
<b>Course Code</b>	<b>Course Title</b>	<b>Credit hours/week</b>			<b>Credit Points</b>	<b>Marks</b>
		<b>Lecture (L)</b>	<b>Tutorial (T)</b>	<b>Practical (P)</b>		
<b>Semester I</b>						
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
<b>Total</b>		<b>16</b>	<b>3</b>	<b>14</b>	<b>26</b>	<b>650</b>
<b>Semester II</b>						
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
<b>Total</b>		<b>16</b>	<b>4</b>	<b>14</b>	<b>27</b>	<b>650</b>
* No end-semester examination. Only continuous mode.						

<b>Table 4. Course work of MPharm – Pharmaceutical Chemistry (MPC) specialization</b>						
Course Code	Course Title	Credit hours/week			Credit Points	Marks
		Lecture (L)	Tutorial (T)	Practical (P)		
<b>Semester I</b>						
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
<b>Total</b>		<b>16</b>	<b>3</b>	<b>14</b>	<b>26</b>	<b>650</b>
<b>Semester II</b>						
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
<b>Total</b>		<b>16</b>	<b>4</b>	<b>14</b>	<b>27</b>	<b>650</b>
* No end-semester examination. Only continuous mode.						

<b>Table 5. Course work of MPharm – Pharmaceutical Analysis (MPA) specialization</b>						
<b>Course Code</b>	<b>Course Title</b>	<b>Credit hours/week</b>			<b>Credit Points</b>	<b>Marks</b>
		<b>Lecture (L)</b>	<b>Tutorial (T)</b>	<b>Practical (P)</b>		
<b>Semester I</b>						
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
<b>Total</b>		<b>16</b>	<b>3</b>	<b>14</b>	<b>26</b>	<b>650</b>
<b>Semester II</b>						
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
<b>Total</b>		<b>16</b>	<b>4</b>	<b>14</b>	<b>27</b>	<b>650</b>
* 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)		
<b>Semester I</b>						
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
<b>Total</b>		<b>16</b>	<b>3</b>	<b>14</b>	<b>26</b>	<b>650</b>
<b>Semester II</b>						
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
<b>Total</b>		<b>16</b>	<b>4</b>	<b>14</b>	<b>27</b>	<b>650</b>
* No end-semester examination. Only continuous mode.						

<b>Table 7. Course work of MPharm – Pharmaceutical Regulatory Affairs (MRA) specialization</b>						
<b>Course Code</b>	<b>Course Title</b>	<b>Credit hours/week</b>			<b>Credit Points</b>	<b>Marks</b>
		<b>Lecture (L)</b>	<b>Tutorial (T)</b>	<b>Practical (P)</b>		
<b>Semester I</b>						
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
<b>Total</b>		<b>16</b>	<b>3</b>	<b>14</b>	<b>26</b>	<b>650</b>
<b>Semester II</b>						
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
<b>Total</b>		<b>16</b>	<b>4</b>	<b>14</b>	<b>27</b>	<b>650</b>
* No end-semester examination. Only continuous mode.						

<b>Table 8. Course work of MPharm – Pharmaceutical Biotechnology (MPB) specialization</b>						
Course Code	Course Title	Credit hours/week			Credit Points	Marks
		Lecture (L)	Tutorial (T)	Practical (P)		
<b>Semester I</b>						
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
<b>Total</b>		<b>16</b>	<b>3</b>	<b>14</b>	<b>26</b>	<b>650</b>
<b>Semester II</b>						
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
<b>Total</b>		<b>16</b>	<b>4</b>	<b>14</b>	<b>27</b>	<b>650</b>
* No end-semester examination. Only continuous mode.						

<b>Table 9. Course work of MPharm – Pharmacy Practice (MPP) specialization</b>						
<b>Course Code</b>	<b>Course Title</b>	<b>Credit hours/week</b>			<b>Credit Points</b>	<b>Marks</b>
		<b>Lecture (L)</b>	<b>Tutorial (T)</b>	<b>Practical (P)</b>		
<b>Semester I</b>						
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
<b>Total</b>		<b>16</b>	<b>3</b>	<b>14</b>	<b>26</b>	<b>650</b>
<b>Semester II</b>						
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
<b>Total</b>		<b>16</b>	<b>4</b>	<b>14</b>	<b>27</b>	<b>650</b>
* No end-semester examination. Only continuous mode.						

<b>Table 10. Course work of MPharm – Pharmacology (MPL) specialization</b>						
<b>Course Code</b>	<b>Course Title</b>	<b>Credit hours/week</b>			<b>Credit Points</b>	<b>Marks</b>
		<b>Lecture (L)</b>	<b>Tutorial (T)</b>	<b>Practical (P)</b>		
<b>Semester I</b>						
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
<b>Total</b>		<b>16</b>	<b>3</b>	<b>14</b>	<b>26</b>	<b>650</b>
<b>Semester II</b>						
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
<b>Total</b>		<b>16</b>	<b>4</b>	<b>14</b>	<b>27</b>	<b>650</b>
* No end-semester examination. Only continuous mode.						



<b>Table 11. Course work of MPharm – Pharmacognosy (MPG) specialization</b>						
<b>Course Code</b>	<b>Course Title</b>	<b>Credit hours/week</b>			<b>Credit Points</b>	<b>Marks</b>
		<b>Lecture (L)</b>	<b>Tutorial (T)</b>	<b>Practical (P)</b>		
<b>Semester I</b>						
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
<b>Total</b>		<b>16</b>	<b>3</b>	<b>14</b>	<b>26</b>	<b>650</b>
<b>Semester II</b>						
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
<b>Total</b>		<b>16</b>	<b>4</b>	<b>14</b>	<b>27</b>	<b>650</b>
* No end-semester examination. Only continuous mode.						

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

<b>Table 14. Semester wise course work credits distribution</b>	
<b>Semester</b>	<b>Credit Points</b>
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*
<b>Total credit points</b>	<b>Minimum=95 Maximum=100</b>

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

<b>Name of the Activity</b>	<b>Maximum Credit Points Eligible/ Activity</b>
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
<p>Note: International conference: Held outside India</p> <p>International journal: The editorial board outside India</p> <p>*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.</p>	

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

<b>PQA-004E</b>	Professional Development	1	Pharmaceutical Quality Assurance, MCOPS
<b>PQA-005E</b>	Stability Testing of Drugs and Biologicals	1	Pharmaceutical Quality Assurance, MCOPS
<b>PQA-006E</b>	USFDA Drug Regulatory Affairs	1	Pharmaceutical Quality Assurance, MCOPS
<b>PQA-007E</b>	Rest of the World Drug Regulations	1	Pharmaceutical Quality Assurance, MCOPS
<b>PQA-008E</b>	Evaluation of Medical Devices	1	Pharmaceutical Quality Assurance, MCOPS
<b>PBT-001E</b>	Clean Room Concepts	1	Pharmaceutical Biotechnology, MCOPS
<b>PBT-002E</b>	Biosimilars	1	Pharmaceutical Biotechnology, MCOPS
<b>PBT-003E</b>	Principles of Gene Cloning	1	Pharmaceutical Biotechnology, MCOPS
<b>PBT-004E</b>	Tissue Engineering	1	Pharmaceutical Biotechnology, MCOPS
<b>PPR-001E</b>	Retail Pharmacy Practice	1	Pharmacy Practice, MCOPS
<b>PPR-002E</b>	Fundamentals of Medical Writing	1	Pharmacy Practice, MCOPS
<b>PPR-003E</b>	Systematic Review and Meta-Analysis	1	Pharmacy Practice, MCOPS
<b>PPR-004E</b>	Pharmacokinetics Data Analysis (Employing WinNonlin)	1	Pharmacy Practice, MCOPS
<b>PHA-001E</b>	Cancer Biology	1	Pharmacology, MCOPS
<b>PHA-002E</b>	Screening Methods for Drug Development	1	Pharmacology, MCOPS
<b>PHA-003E</b>	Free Radical Biology and Medicine	1	Pharmacology, MCOPS
<b>PHA-004E</b>	Regulatory Toxicology in Drug Discovery and Development	1	Pharmacology, MCOPS
<b>PCO-001E</b>	Nutraceuticals	1	Pharmacognosy, MCOPS
<b>PCO-002E</b>	Extraction, Separation and Purification of Phytoconstituents	1	Pharmacognosy, MCOPS
<b>PCO-003E</b>	Nanophytopharmaceuticals	1	Pharmacognosy, MCOPS
<b>PCO-004E</b>	Herbal Monographs	1	Pharmacognosy, MCOPS
<b>PRM-001E</b>	Retail Business Management	1	Pharmaceutical Regulatory Affairs & Management, MCOPS
<b>PRM-002E</b>	Intellectual Property Management	1	Pharmaceutical Regulatory Affairs & Management, MCOPS
<b>PRM -003E</b>	General Management Principles	1	Pharmaceutical Regulatory Affairs & Management, MCOPS
<b>PRM -004E</b>	Entrepreneurship Development	1	Pharmaceutical Regulatory Affairs & Management, MCOPS
<b>Multidisciplinary courses</b>			
<b>MU-001E</b>	Certificate Course in Bioinformatics	3	School of Life Sciences, MU
<b>MU-002E</b>	Project Management	4	Department of Humanities and Social Science, MIT
<b>MU-003E</b>	Certificate Course in Bioethics	2/4	Centre for Bioethics, MU
<b>MU-004E</b>	Academic Research and Writing	3	Manipal Centre for Philosophy and Humanities, MU
<b>MU-005E</b>	Certificate Course in Biosecurity	5	Dept. of Public Health, MU
<b>CR-001E</b>	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
	Continu- ous Mode	Sessional Exams		Total	Marks	Duration	
		Marks	Duration				
<b>Semester I and II</b>							
<b>Theory</b>	10	15	1 hr each	25	75	3 hrs	100
<b>Practical</b>	20	30	6 hrs	50	100	6 hrs	150
<b>Seminar</b>	--	--	--	100	--	--	100
<b>Semester III and IV</b>							
<b>PHA-MRM301T Research Methodology and Biostatistics*</b>	20	40+40	2 hrs each	100	--	--	100
<b>MJC302P Journal Club*</b>	--	--	--	100	--	--	100
<b>MRW401P Research Work</b>	--	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.

<b>Question paper pattern – MPharm Theory sessional examinations</b>		
<b>Manipal College of Pharmaceutical Sciences</b> <b>Manipal Academy of Higher Education, Manipal</b> <b><u>MPharm Theory Sessional Examinations, Month and Year</u></b>		
<b><u>Course Code. Course Title</u></b>		
Date: dd-mm-yyyy	Duration: 2 hrs	Max. Marks: 45
<b>Instructions: Answer ALL questions</b>		
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.		

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

<b>MPharm seminar evaluation scheme</b>					
<b>PRESENTATION (50 Marks)</b>				<b>Marks awarded for each criteria</b>	
Criteria				Teacher 1	Teacher 2
<b>1</b>	Preparedness (10 marks)				
<b>2</b>	Response to questions (10 marks)				
<b>3</b>	Audio-visual aids (10 marks)				
<b>4</b>	Clarity of presentation (10 marks)				
<b>5</b>	Breadth and depth of material presented (10 marks)				
Marks awarded					
Average marks awarded for presentation out of 50 (A) =					
<b>WRITE UP (50 Marks)</b>					
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:					
<b>Seminar marks awarded out of 100 = (A+B) =</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.

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

<b>Question paper pattern – MPharm theory end-semester examinations</b>		
<b>Manipal Academy of Higher Education, Manipal</b>		
<b><u>MPharm Theory End-Semester Examinations, Month and Year</u></b>		
<b><u>Course Code. Course Title</u></b>		
Date: dd-mm-yyyy	Duration: 3 hrs	Max. Marks: 75
<b>Instructions: Answer ALL questions.</b>		
Answer the following (5 marks × 10 = 50 marks)		
1. Question		
2. Question		
3. Question		
4. Question		
5. Question		
Answer the following with specific answers (5 marks × 5 = 25 marks)		
6A.		
6B.		
6C.		
6D.		
6E.		

<b>Question paper pattern – MPharm practical end-semester examinations</b>		
<b><u>MPharm Practical End-Semester Examinations, Month and Year</u></b>		
<b>Manipal Academy of Higher Education, Manipal</b>		
<b><u>Course Code. Course Title</u></b>		
Date: dd-mm-yyyy	Duration: 6 hrs	Max. Marks: 100
<b>Instructions: Answer ALL questions.</b>		
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

<b>Letter Grade</b>	<b>Grade Point</b>	<b>Performance</b>
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)

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

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

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

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

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

## 12.5. Cumulative Grade Point Average (CGPA)

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

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

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

## 12.6. Conversion of GPA/CGPA into a percentage

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

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

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

Percentage secured by the candidate = GPA or CGPA  $\times$  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.

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	Presenta- tion	Viva- voce		
i	ii	i+ii=A	i	ii	iii	iv	i+ii+i ii+iv =B	A+B
<b>100</b>	<b>100</b>	<b>200</b>	<b>150</b>	<b>150</b>	<b>50</b>	<b>50</b>	<b>400</b>	<b>600</b>

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
<b>Total</b>	<b>150</b>

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

	Marks
Presentation of work	30
Communication skills	20
<b>Total</b>	<b>50</b>

**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**

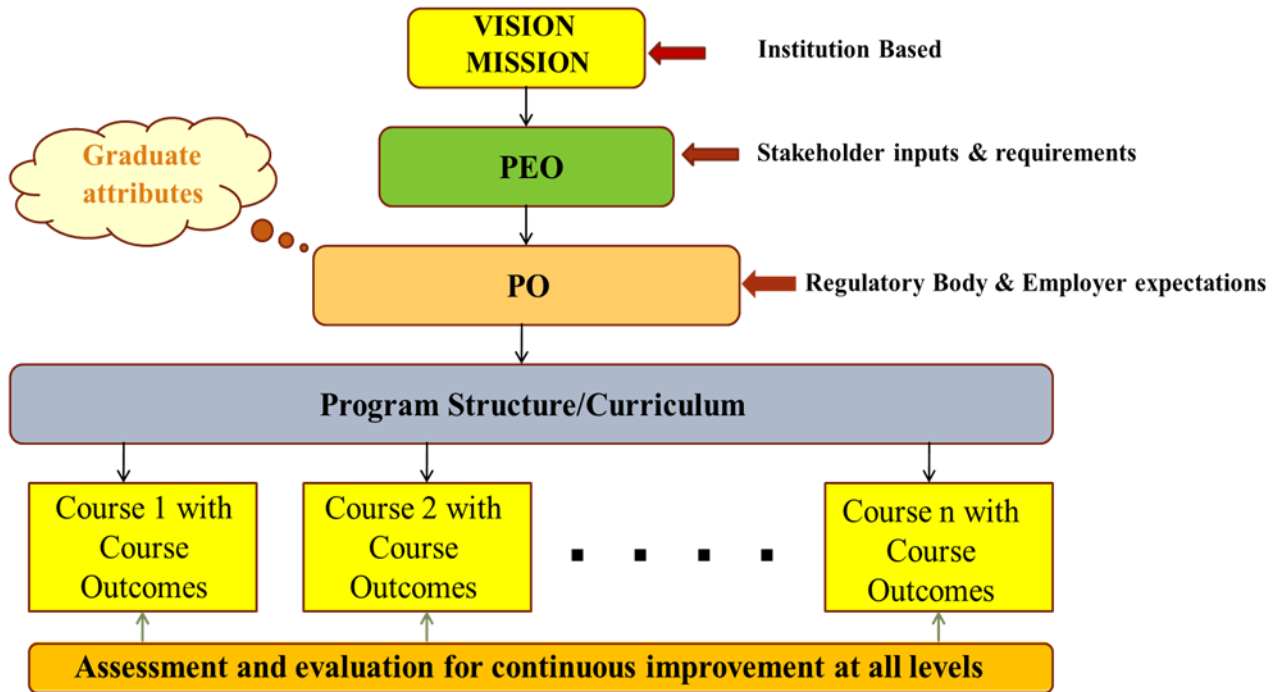




## CHAPTER II

# Outcome Based Education (OBE) Framework

### OBE – Implementation Perspective



## **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.**



# MANIPAL COLLEGE OF PHARMACEUTICAL SCIENCES

MANIPAL

(A constituent unit of MAHE, Manipal)

## MPharm Pharmaceutical Chemistry Program Educational Objectives

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

<b>PEO No</b>	<b>Education Objective</b>
<b>PEO 1</b>	Build an education leading to a Masters' degree in Pharmaceutical Chemistry and also integrate professional knowledge and skills with research competencies in the field of drug design, discovery and development.
<b>PEO 2</b>	Equip the Masters' students with comprehensive knowledge and skills in the field of Pharmaceutical Chemistry and enable them to adapt according to evolving paradigms in Academia, Pharmaceutical industry and Research.
<b>PEO 3</b>	Cultivate an inclination for higher learning and entrepreneurship.
<b>PEO 4</b>	Foster the best in-class experimental hands-on training in Organic and Synthetic Chemistry, Rational drug design using computational tools, Natural products, Analytical tools and techniques
<b>PEO 5</b>	Empower and sensitize the medicinal chemist to serve the Academia, Pharmaceutical Industry and society with honesty and integrity.





# MANIPAL COLLEGE OF PHARMACEUTICAL SCIENCES

MANIPAL

(A constituent unit of MAHE, Manipal)

## MPharm Pharmaceutical Chemistry Program Outcomes (POs)

**After successful completion of M Pharm Pharmaceutical Chemistry program, students will be able to:**

PO No	Attribute	Competency
PO 1	Domain knowledge	Apply the fundamental knowledge of pharmacy and pharmaceutical chemistry in drug discovery and development process.
PO 2	Problem analysis	Identify, formulate and analyze the research problems to reach substantiated conclusions that meet the regulatory requirements in the process of drug discovery.
PO 3	Design/develop solutions	Develop solutions for problems related to synthesis, purification, pharmacokinetic, pharmacodynamic activity, toxicity of designed new chemical entities through strategies in Pharmaceutical Chemistry.
PO 4	Conduct investigations of complex problems	Conceptualize and investigate the problems related to rational drug design, organic synthesis, process chemistry and natural products chemistry using computational tools and analytical techniques.
PO 5	Modern tool usage	Select and apply appropriate databases, computational and analytical techniques in designing new chemical entities.
PO 6	Business and society	Develop and facilitate the pharmaceutical business model which will be cost effective and beneficial to the society.
PO 7	Environment and sustainability	Understand and provide solutions to reduce the environmental hazards by Pharmaceutical Industry through Green Chemistry approach and demonstrate the knowledge for sustainable development.
PO 8	Ethics	Inculcate and apply ethical principles while discharging professional responsibilities
PO 9	Individual / Teamwork	Function effectively as an individual, and as a member, demonstrate leadership qualities as a leader in diverse teams, and in multidisciplinary settings for team building capacities.

<b>PO Number</b>	<b>Attribute</b>	<b>Competency</b>
<b>PO 10</b>	<b>Communication</b>	Possess soft skills and communicate effectively ideas, present the scientific reports in a comprehensive and focused manner to the scientific community, regulatory agencies and society at large.
<b>PO 11</b>	<b>Project management and finance</b>	Demonstrate the knowledge of financial management to evaluate existing and new projects for effective decision making.
<b>PO 12</b>	<b>Life-long learning</b>	Comprehend 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 – Pharmaceutical Chemistry (MPC) specialization						
Course Code	Course Title	Credit hours/week			Credit Points	Marks
		Lecture (L)	Tutorial (T)	Practical (P)		
<b>Semester I</b>						
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
<b>Total</b>		<b>16</b>	<b>3</b>	<b>14</b>	<b>26</b>	<b>650</b>
<b>Semester II</b>						
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
<b>Total</b>		<b>16</b>	<b>4</b>	<b>14</b>	<b>27</b>	<b>650</b>
* 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
<b>Total</b>		<b>4</b>	<b>--</b>	<b>72</b>	<b>40</b>	<b>800</b>
* 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	PO10	PO11	PO12
1	PQA-MPC101T	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	PCH-MPC102T	Advanced Organic Chemistry I	5	CO1 CO2 CO3 CO4	CO1 CO2 CO3 CO4	CO1 CO2 CO3 CO4	CO1 CO2 CO3 CO4	CO1 CO2 CO3 CO4							
3	PCH-MPC103T	Advanced Medicinal Chemistry	5	CO1 CO2 CO3 CO4	CO1 CO2 CO3 CO4	CO1 CO2 CO3 CO4	CO1 CO2 CO3 CO4	CO1 CO4		CO3					
4	PCH-MPC104T	Chemistry of Natural Products	5	CO1 CO2 CO3 CO4	CO1 CO2 CO3 CO4	CO1 CO2 CO3 CO4	CO1 CO2 CO3 CO4		CO1 CO4	CO2					
5	PCH-MPC105P	Pharmaceutical Chemistry Practical I	6	CO1 CO2 CO3	CO1 CO3	CO1 CO2 CO3	CO2 CO3								
6	PCH-MPC106S	Seminar*	1	CO1	CO1 CO2		CO2 CO5					CO3	CO3 CO4 CO5		CO6
7	PCH-MPC201T	Advanced Spectral Analysis	5	CO1 CO2 CO3	CO1 CO2	CO1 CO2	CO1 CO2	CO1 CO2			CO1	CO1 CO3			
8	PCH-MPC202T	Advanced Organic Chemistry II	5	CO1 CO2 CO3 CO4	CO1 CO2 CO3 CO4	CO1 CO2 CO3 CO4		CO1 CO2 CO3		CO1					CO1
9	PCH-MPC203T	Computer Aided Drug Design	5	CO1	CO2	CO3	CO1	CO4	CO4	CO5					
10	PCH-MPC204T	Pharmaceutical Process Chemistry	5	CO1 CO2		CO1 CO2	CO1 CO2		CO1 CO2	CO1 CO2					
11	PCH-MPC205P	Pharmaceutical Chemistry Practical II	6	CO1 CO2 CO3	CO1 CO2	CO1 CO2 CO3	CO1	CO3	CO3						
12	PCH-MPC206S	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 –PHARMACEUTICAL CHEMISTRY (MPC)

#### SEMESTER I

#### PQA-MPC101T: MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES

<b>COURSE CODE</b>	PQA-MPC101T					
<b>COURSE TITLE</b>	MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES (Theory)					
<b>SCOPE/ SUMMARY</b>			<b>OBJECTIVES/COURSE OUTCOMES</b>			
This course deals with various advanced analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are NMR, Mass spectrometer, IR, HPLC, GC etc.			After completion of the course, a student will be able to understand: <ol style="list-style-type: none"> <li>1. The theory, instrumentation &amp; applications of UV visible spectroscopy, IR, Fluorimetry &amp; AES.</li> <li>2. The theory, instrumentation &amp; applications of NMR spectroscopy.</li> <li>3. The theory, instrumentation &amp; applications of Mass spectrometry.</li> <li>4. The theory, instrumentation &amp; applications of of chromatographic technique.</li> <li>5. The theory, instrumentation &amp; applications of electrophoresis, XRD, polarimetry, thermal &amp; immunological assays.</li> </ol>			
Course Content and Assessment Plan						
Sl No.	Course Content	Syllabus (Chapters or Units with hours)	Marks of assessment	Distribution of marks of assessment		
				Sessional exam (30% of marks of assessment)		End Sem exam (70% of marks of assessmen)
				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

## **POA-MPC101T: 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. **Spectrofluorimetry:** 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 <sup>13</sup>C 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 ultrahigh performance liquid chromatography f) Affinity chromatography g) Gel chromatography. **8 hrs**

## 5. Other Analytical Techniques

- a. **Electrophoresis:** Principle, instrumentation, working conditions, factors affecting separation and applications of the following: a) Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresis d) Zone electrophoresis e) Moving boundary electrophoresis f) Iso electric focusing. **3 hrs**
- b. **X-ray Crystallography:** Different X-ray diffraction methods, Bragg's law, Rotating crystal technique, X-ray powder technique, types of crystals and applications of X-ray diffraction. **2 hrs**
- c. **Potentiometry:** Principle and application of potentiometry. **2 hrs**
- d. **Thermal Techniques:** Principle and application of Differential Scanning Calorimetry, Differential Thermal Analysis and Thermo Gravimetric Analysis. **5 hrs**
- e. **Immunological Assays:** RIA (Radio immuno assay), ELISA. **3 hrs**

## REFERENCES

1. Spectrometric Identification of Organic Compounds, Robert M Silverstein, 6<sup>th</sup> edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis, Douglas A Skoog, F. James Holler, Timothy A. Nieman, 5<sup>th</sup> edition, Eastern Press, Bangalore, 1998.
3. Instrumental Methods of Analysis, Willards, 7<sup>th</sup> edition, CBS Publishers.
4. Practical Pharmaceutical Chemistry, Beckett and Stenlake, Vol II, 4<sup>th</sup> edition, CBS Publishers, New Delhi, 1997.
5. Organic Spectroscopy, William Kemp, 3<sup>rd</sup> edition, ELBS, 1991.
6. Quantitative Analysis of Drugs in Pharmaceutical Formulation, PD Sethi, 3<sup>rd</sup> 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. 8<sup>th</sup> 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 –PHARMACEUTICAL CHEMISTRY (MPC)**

**SEMESTER I**

**PCH-MPC102T: ADVANCED ORGANIC CHEMISTRY I**

<b>COURSE CODE</b>	PCH-MPC102T					
<b>COURSE TITLE</b>	ADVANCED ORGANIC CHEMISTRY-I (Theory)					
<b>SCOPE/ SUMMARY</b>			<b>OBJECTIVES/COURSE OUTCOMES</b>			
This course is designed to impart the fundamental knowledge about advances in organic chemistry, different techniques of organic synthesis and their application to process chemistry as well as drug discovery.			Upon completion of the course, the student shall be able to know 1. The reaction intermediates and the types of reaction mechanism. 2. The named reactions of synthetic importance with their mechanism. 3. Synthetic reagents and their applications. 4. The chemistry of heterocyclic compounds. 5. The principle and application of retrosynthesis.			
<b>Course Content and Assessment Plan</b>						
Sl No.	Course Content	Syllabus (Chapters or Units with hours)	Marks of assessment	Distribution of marks of assessment		End Sem exam (70% of marks of assessment)
				Sessional exam (30% of marks of assessment)		
				S1	S2	
1	The students will be acquainted with the basic aspects of organic chemistry	Unit I (6 hrs)	10	5		5
2	The students will be acquainted with the mechanism and applications of named reactions	Unit II (12 hrs)	20	5		15
3	Will learn about various synthetic reagents and their applications. Also the students learn about the role of protection in organic synthesis	Unit III (10 hrs)	20	5		15
4	The students learn the various aspects of heterocyclic chemistry	Unit IV (14 hrs)	30		10	20
5	Will understand about retrosynthesis and its application. They also learn about disconnection approach in organic synthesis	Unit V (10 hrs)	20		5	15

Total Marks of Assessment	105	15	15	75
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## PCH-MPC102T: ADVANCED ORGANIC CHEMISTRY I

### THEORY

**52 hrs**

#### **1. Basic Aspects of Organic Chemistry**

**6 hrs**

- a. Organic intermediates: Carbocations, carbanions, free radicals, carbenes and nitrenes. Their method of formation, stability and synthetic applications.
- b. Types of reaction mechanisms and methods of determining them,
- c. Detailed knowledge regarding the reactions, mechanisms and their relative reactivity and orientations. Chemistry of enolates.

#### **2. Study of mechanism synthetic applications of following named Reactions 12 hrs**

Suzuki-Miyaura cross coupling reaction, Heck reaction, Wittig & Horner-Emmons reaction, Mitsunobu reaction, Birch reduction, Michael addition, Cope rearrangement, Dakin Reaction, Darzens epoxidation, Dess-martin oxidation, Dimroth Rearrangement, Edman Degradation, Hofmann Rearrangement, Horner-Wadsworth-Emmons Olefination, Jones Oxidation, Meerwein-verley-ponndorf reduction, Michael Addition, Swern Oxidation, Ugi Reaction, Vilsmeier Formylation, Wittig Rearrangement, Wolff-Kishner Reduction.

#### **3. Synthetic Reagents & Applications**

**10 hrs**

Reagents in organic synthesis: Applications, properties, safety, disposal. Boron tribromide, n-butyl lithium, NBS, quaternary ammonium salts, Dess martin periodinane, DABCO, DBU, DCC, DMAP, HOBT, DIPEA, Hinge's base, Lithium HMDS, LDA, Morpho-DAST, oxalyl chloride, sodium hydride, potassium tertiary butoxide, pyridinium tribromide, sodium borohydride, tributyl phosphine, lithium aluminium hydride, BF<sub>3</sub> etherate, TBAB, TBTU, HBTU, HATU, Lawesson's reagent, metal catalysts.

#### **Protecting groups**

- a. Role of protection in organic synthesis
- b. Protection for the hydroxyl group, including 1,2-and1,3-diols: ethers, esters, carbonates, cyclic acetals & ketals
- c. Protection for the Carbonyl Group: Acetals and Ketals
- d. Protection for the Carboxyl Group: amides and hydrazides, esters
- e. Protection for the Amino Group and Amino acids: carbamates and amides

#### 4. Heterocyclic Chemistry

14 hrs

Chemistry of heterocyclic compounds: Nomenclature of heterocycles. Structure of heterocycles. Tautomerism in heterocyclic Systems. Electrophilic addition at Nitrogen. Electrophilic substitution at Carbon. Nucleophilic substitution at carbon. Radical substitution at carbon. Deprotonation of *N* – Hydrogen, oxidation and reduction of heterocyclic Rings: Structure, properties, synthesis and reactions of heterocyclic compounds: Pyridines, Quinolines, Isoquinolines, Pyrylium Benzopyrylium Ions, Pyrones, Benzopyrones, Benzo [*b*] thiophenes, Benzo [*b*] furans, Isoindoles, Benzo[*c*]thiophenes, Isobenzofurans, 1*H*-benzimidazole, Benzoxazole, Benzothiazole, Indazole, Indolizines, Aza – Indolizines, Imidazo[1,2 - *a*]pyridines, Imidazo[1,5 - *a*]pyridines, Pyrazolo[1,5-*a*] pyridines, Triazolo - and Tetrazolo – Pyridines, Thiazines, Pyrido-pyrimidines, Purines.

#### 5. Synthron approach and retrosynthesis applications

10 hrs

Basic principles, terminologies and advantages of retrosynthesis; guidelines for dissection of molecules. Functional group interconversion and addition Disconnection approach in organic synthesis: Types of strategies, group disconnections, examples.

#### REFERENCES

1. “Advanced Organic chemistry, Reaction, mechanisms and structure”, J March, John Wiley and sons, New York.
2. “Mechanism and structure in organic chemistry”, ES Gould, Hold Rinchart and Winston, New York.
3. “Organic Chemistry” Clayden, Greeves, Warren and Wothers, Oxford University Press 2001.
4. “Organic Chemistry” Vol I and II. I.L. Finar. ELBS, Sixth ed., 1995.
5. A guide to mechanisms in Organic Chemistry – Peter Skyes (Orient Longman, New Delhi).
6. Reactive intermediates in organic chemistry – Tandom and Gowel.
7. Combinational Chemistry – Synthesis and applications – Stephen R Wilson & Anthony W Czarnik.
8. Carey, Organic Chemistry, 5<sup>th</sup> Edition (Viva Books Pvt. Ltd.)
9. Organic Synthesis - The Disconnection Approach, S. Warren, Wily India
10. Principles of Organic Synthesis, ROC Norman and JM Coxan, Nelson Thorns.
11. Organic Synthesis - Special Techniques. VK Ahluwalia and R Agarwal, Narosa Publishers.
12. Organic Reaction Mechanisms IV Edn., VK Ahluwalia and RK Parashar, Narosa Publishers.



**MPHARM –PHARMACEUTICAL CHEMISTRY (MPC)**

**SEMESTER I**

**PCH-MPC103T: ADVANCED MEDICINAL CHEMISTRY**

<b>COURSE CODE</b>	PCH-MPC103T					
<b>COURSE TITLE</b>	ADVANCED MEDICINAL CHEMISTRY					
<b>SCOPE/ SUMMARY</b>			<b>OBJECTIVES/COURSE OUTCOMES</b>			
This subject deals to impart fundamental knowledge about recent advances in the field of medicinal chemistry at the molecular level including different techniques for the rational drug design.			Upon completion of this course the student will be able to understand : 1. Different stages of drug discovery 2. Importance of Stereochemistry in Drug discovery 3. Various strategies in drug design and discovery.			
<b>Course Content and Assessment Plan</b>						
SI No.	Course Content	Syllabus (Chapters or Units with hours)	Marks of assessment	Distribution of marks of assessment		
				Sessional exam (30% of marks of assessment)		End Sem exam (70% of marks of assessment)
				S1	S2	
1	Will understand various stages of drug discovery process.	Unit I (5 hrs)	10	5		5
2	Will understand about the drug targets, receptors, types and drug receptor interactions.	Unit II (5 hrs)	10	-		10
3	Will understand about the design of enzyme inhibitors: non-covalently and covalently binding enzyme inhibitors.	Unit III (8 hrs)	15	5		10
4	Will understand the concepts, types and applications of prodrugs.	Unit IV (6 hrs)	10	2		8
5	Will understand Analog design by lead modification approaches.	Unit V (9 hrs)	25	3		22
6	Will understand the importance of understanding stereochemistry in drug discovery	Unit VI (6 hrs)	10		5	5
7	Will understand about the peptidomimetics, their therapeutic values, design by various strategies.	Unit VII (6 hrs)	10		5	5

8	Will understand the principle, methodology and applications of combinatorial chemistry and high throughput screening.	Unit VIII (7 hrs)	15		5	10
Total Marks of Assessment			105	15	15	75

**PCH-MPC103T: ADVANCED MEDICINAL CHEMISTRY**

**THEORY**

**52 hrs**

- 1. Drug Discovery** **7 hrs**  
Stages of drug discovery, lead identification, modification and optimization. FBDD: Principle and case studies. Introduction to IPR.
- 2. Drug Targets** **5 hrs**  
Receptors, types, binding and activation, theories of drug receptor interaction, drug receptor interactions
- 3. Design of Enzyme Inhibitors** **8 hrs**  
Enzyme kinetics & Principles of Enzyme inhibitors, Design of non-covalently and covalently binding enzyme inhibitors.
- 4. Prodrugs: Concepts, Types and Applications** **6 hrs**
- 5. Analog Design: Introduction and lead modification approaches** **7 hrs**
- 6. Stereochemistry in Drug Discovery Programme** **6 hrs**  
Role of chirality in selective and specific therapeutic agents. Case studies, Effect of stereochemistry in pharmacokinetics and pharmacodynamics
- 7. Peptidomimetics** **6 hrs**  
Therapeutic values of Peptidomimetics, design of peptidomimetics by manipulation of the amino acids, modification of the peptide backbone, incorporating conformational constraints locally or globally.
- 8. Combinatorial Chemistry and High Throughput Screening** **7 hrs**  
Different techniques, Solid phase synthesis, Solution phase synthesis. Protection of functional groups in the peptide synthesis using combinatorial chemistry, applications of combinatorial chemistry. High Throughput Screening: General outline, importance and application.

## REFERENCES

1. Medicinal Chemistry by Burger, Vol I –VI.
2. Wilson and Gisvold's Text book of Organic Medicinal and Pharmaceutical Chemistry, 12<sup>th</sup> Edition, Lippincott Williams & Wilkins, Wolters Kluwer (India) Pvt. Ltd, New Delhi.
3. Comprehensive Medicinal Chemistry – Corwin and Hansch.
4. Computational and structural approaches to drug discovery edited by Robert M Stroud and Janet. F Moore
5. Introduction to Quantitative Drug Design by Y.C. Martin.
6. Principles of Medicinal Chemistry by William Foye, 7<sup>th</sup> Edition, Lippincott Williams & Wilkins, Wolters Kluwer (India) Pvt. Ltd, New Delhi.
7. Drug Design Volumes by Arienes, Academic Press, Elsevier Publishers, Noida, Uttar Pradesh.
8. Principles of Drug Design by Smith.
9. The Organic Chemistry of the Drug Design and Drug action by Richard B. Silverman, II Edition, Elsevier Publishers, New Delhi.
10. An Introduction to Medicinal Chemistry, Graham L. Patrick, III Edition, Oxford University Press, USA.
11. Biopharmaceutics and pharmacokinetics, DM.Brahmankar, Sunil B. Jaiswal II Edition, 2014, Vallabh Prakashan, New Delhi.
12. Peptidomimetics in Organic and Medicinal Chemistry by Antonio Guarna and Andrea Trabocchi, First edition, Wiley publishers.

**MPHARM –PHARMACEUTICAL CHEMISTRY (MPC)**

**SEMESTER I**

**PCH-MPC104T: CHEMISTRY OF NATURAL PRODUCTS**

<b>COURSE CODE</b>	PCH-MPC104T					
<b>COURSE TITLE</b>	CHEMISTRY OF NATURAL PRODUCTS (Theory)					
<b>SCOPE/ SUMMARY</b>			<b>OBJECTIVES/COURSE OUTCOMES</b>			
The subject is designed to provide detail knowledge about chemistry of medicinal compounds from natural origin and general methods of structural elucidation of such compounds. It also emphasizes on isolation, purification and characterization of medicinal compounds from natural origin.			Upon completion of the course, the student shall be able to know 1. Different types of natural compounds and their chemistry and medicinal importance 2. The importance of natural products as lead compounds for new drug discovery 3. The concept of rDNA technology as a tool for new drug discovery 4. General methods of structural elucidation of compounds of natural origin 5. Isolation, purification and characterization of few chemical constituents from natural source			
<b>Course Content and Assessment Plan</b>						
Sl No.	Course Content	Syllabus (Chapters or Units with hours)	Marks of assessment	Distribution of marks of assessment		
				Sessional exam (30% of marks of assessment)		End Sem exam (70% of marks of assessment)
				S1	S2	
1	Will be exposed to the various structural modifications as well as the chemistry for Natural products as lead compounds.	Unit I (10 hrs)	20	5		15
2	Will be acquainted with the knowledge on the various classes of alkaloids along with their stereochemistry and biological activity.	Unit II (7 hrs)	15	5		10
3	Will learn about Introduction, classification, isolation and purification of flavonoids and study the Structural elucidation of quercetin.	Unit III (3 hrs)	5	3		2

4	The students will learn the chemistry and stereochemistry of sterols, sapogenin and cardiac glycosides.	Unit IV (6 hrs)	15	2		13
5	Will upgrade his knowledge on terpenoids with reference to their properties, classification, isolation and general methods of structural elucidation for mono, di and tri terpenoids	Unit V (7 hrs)	15		4	11
6	Will keep himself abreast with the latest knowledge on various tools and techniques used in biotechnology such as rDNA technology, protein engineering, epitope mapping, site directed mutagenesis, hybridoma technology, Gene therapy, its Introduction, clinical application and recent advances.	Unit VI (6 hrs )	10		3	7
7	Will learn all the salient chemical features of Marine products along with their application	UnitVII (3 hrs)	5		2	3
8	Will learn all the important Enzymes used in organic synthesis	Unit VIII (5 hrs)	10		3	7
9	Will update the knowledge on prostaglandins along with their applications in New drug discovery	Unit IX (5 hrs)	10		3	7
Total Marks of Assessment			105	15	15	75

## PCH-MPC104T: CHEMISTRY OF NATURAL PRODUCTS

### THEORY

52 hrs

- 1. Study of Natural products as leads for the following drugs:** **10 hrs**  
Morphine, Cocaine, Paclitaxel, Docetaxel, Etoposide, Teniposide, Lovastatin, Teprotide, Dicoumarol, Curare alkaloids, Quinine, Cephalosporins (New generation), Erythromycin and Azithromycin.
  
- 2. Alkaloids** **7 hrs**  
General introduction, classification, stereochemistry, molecular modification and biological activity of alkaloids. General methods of structural determination of alkaloids. Structural elucidation of ephedrine, morphine, atropine and reserpine
  
- 3. Flavonoids** **3 hrs**  
Introduction, classification, isolation and purification of flavonoids. General methods of structural determination of flavonoids; Structural elucidation of quercetin.
  
- 4. Steroids** **6 hrs**  
General introduction, chemistry of sterols, sapogenin and cardiac glycosides. Stereochemistry and nomenclature of steroids. Structural elucidation of testosterone, estradiol, progesterone, adrenocorticoids (cortisone) and contraceptive agents.
  
- 5. Terpenoids** **7 hrs**  
Introduction, classification, isolation and general methods of structural elucidation of mono, di and tri terpenoids.
  
- 6. Biotechnology as a tool in new drug discovery:** **6 hrs**  
rDNA technology, protein engineering, epitope mapping, site directed mutagenesis, hybridoma technology. Gene therapy: Introduction, clinical application and recent advances in gene therapy.
  
- 7. Marine products:** General introduction, classification and application. **3 hrs**
  
- 8. Enzymes in organic synthesis** **5 hrs**
  
- 9. Chemistry of prostaglandins** **5 hrs**

## REFERENCES

1. Modern methods of plant analysis – Peech and M.V.Tracey.
2. Phytochemistry Vol. I and II by Miller, Jan Nostrant Rein Hld.
3. Recent advances in Phytochemistry Vol. I to IV – Scikel Runeckles.
4. Chemistry of natural products Vol I onwards IWPAC.
5. Natural Product Chemistry Nakanishi Gggolo.
6. Natural Product Chemistry “A laboratory guide” – Rapheal Khan.
7. The Alkaloid Chemistry and Physiology by THF Manske.
8. Introduction to molecular Phytochemistry – CHJ Wells, Chapmannstall.
9. Organic Chemistry of Natural Products Vol I and II by Gurdeep and Chatwall.
10. Organic Chemistry of Natural Products Vol I and II by O.P. Agarwal. 11. Organic Chemistry Vol I and II by I.L. Finar
11. Elements of Biotechnology by P.K. Gupta.
12. Pharmaceutical Biotechnology by S.P. Vyas and V.K. Dixit.
13. Biotechnology by Purohit and Mathoor.
14. Phytochemical methods of Harborne.
15. Burger’s Medicinal Chemistry.

**MPHARM –PHARMACEUTICAL CHEMISTRY (MPC)**

**SEMESTER I**

**PCH-MPC105P: PHARMACEUTICAL CHEMISTRY PRACTICAL I**

<b>COURSE CODE</b>	PCH-MPC105P				
<b>COURSE TITLE</b>	PHARMACEUTICAL CHEMISTRY PRACTICAL – I				
<b>SCOPE/ SUMMARY</b>			<b>OBJECTIVES/COURSE OUTCOMES</b>		
The practical is designed to provide detail knowledge about reactions involving synthesis of medicinally important compounds. It also emphasizes on isolation, purification and characterization of medicinal compounds from natural and synthetic origin.			Upon completion of this course the student should be able to understand: 1. Practical skills for the estimation of active ingredients/ formulations using spectrophotometric analysis 2. Process chemistry aspects involved in synthesis of intermediates/drugs 3. Isolation, determination of physicochemical properties, characterization of few phytochemical constituents & their qualitative analysis.		
<b>Course Content and Assessment Plan</b>					
Sl No.	Course Content	Syllabus (Chapters or Units with hours)	Total Marks of assessment	Distribution of assessment marks	
				Sessional exam (25 % of total marks of assessment)	End Sem exam (75 % of total marks of assessment)
				<b>S1</b>	
1	Learn to identify and estimate pharmaceutical active ingredients/formulation as a single component and simultaneous using various instrumental techniques like UV-Visible spectrophotometer, Gas chromatography, fluorimetry, flame photometry	Set-1- Experiments 1 to 7; (54 hrs)	50	10	40
2	Learn skills to handle chemicals, calculate quantities, purify organic solvents, synthesize and characterize compounds through named reactions.	Set -2 Experiments 1 to 7 (54 hrs)	50	10	40
3	Learn to estimate elements and functional groups in organic natural compounds, isolate, characterize like melting point, mixed melting point, molecular weight determination, functional group	Experiments 08 to 10 (36 hrs)	30	10	20



	analysis, co-chromatographic technique for identification of isolated compounds and interpretation of UV and IR data and degradation reactions to be carried on selected plant constituents.			
Total Marks of Assessment		130	30	100

## **PCH-MPC105P: PHARMACEUTICAL CHEMISTRY PRACTICAL I**

### **Set-1-Experiments**

1. Analysis of Pharmacopoeial compounds and their formulations by UV Vis spectrophotometer, RNA & DNA estimation **12 hrs**
2. Simultaneous estimation of multi component containing formulations by UV spectrophotometry **6 hrs**
3. Experiments based on Column chromatography **12 hrs**
4. Experiments based on HPLC **6 hrs**
5. Experiments based on Gas Chromatography **6 hrs**
6. Estimation of riboflavin/quinine sulphate by fluorimetry **6 hrs**
7. Estimation of sodium/potassium by flame photometry **6 hrs**

### **To perform the following reactions of synthetic importance (Set-2-Experiments)**

1. Purification of organic solvents, column chromatography **12 hrs**
2. Claisen-schmidt reaction. **6 hrs**
3. Benzylic acid rearrangement. **6 hrs**
4. Beckmann rearrangement. **6 hrs**
5. Hoffmann rearrangement **6 hrs**
6. Mannich reaction **6 hrs**
7. Synthesis of medicinally important compounds involving more than one step along with purification and characterization using TLC, melting point and IR spectroscopy (4 experiments) **12 hrs**
8. Estimation of elements and functional groups in organic natural compounds. **12 hrs**
9. Isolation, characterization like melting point, mixed melting point, molecular weight determination, functional group analysis, co-chromatographic technique for identification of isolated compounds and interpretation of UV and IR data. **12 hrs**
10. Some typical degradation reactions to be carried on selected plant constituents **12 hrs**

**MPHARM – PHARMACEUTICAL CHEMISTRY (MPC)****SEMESTER I****PCH- MPC106S: SEMINAR IN PHARMACEUTICAL CHEMISTRY**

<b>COURSE CODE</b>	PCH- MPC106S			
<b>COURSE TITLE</b>	SEMINAR IN PHARMACEUTICAL CHEMISTRY			
<b>SCOPE/ SUMMARY</b>		<b>OBJECTIVES/COURSE OUTCOMES</b>		
The subject is designed to create an environment where teachers provide the students a critical eye and openness to fortify the presentation and academic writing skills of students in the field of Pharmaceutical Chemistry.		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 pharmaceutical chemistry 2. Learn to organize complex pharmaceutical chemistry 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		
<b>Course Content and Assessment Plan</b>				
<b>Sl No.</b>	<b>Course Content</b>	<b>Hours</b>	<b>Total Marks of assessment</b>	<b>Marks</b>
				<b>End Sem exam</b>
1	The students should be able to develop skills to gather, organize, deliver information, and defend a given topic in pharmaceutical chemistry.	2 hours/week	100	No end-semester examination. Only continuous mode.

**MPHARM –PHARMACEUTICAL CHEMISTRY (MPC)**

**SEMESTER II**

**PCH-MPC201T: ADVANCED SPECTRAL ANALYSIS**

COURSE CODE		<b>PCH-MPC201T</b>				
COURSE TITLE		<b>ADVANCED SPECTRAL ANALYSIS (Theory)</b>				
<b>SCOPE/ SUMMARY</b>			<b>OBJECTIVES/COURSE OUTCOMES</b>			
This subject deals to impart fundamental knowledge on various analytical instrumental techniques for identification, characterization and quantification of drugs using LC-MS, GC-MS, ATR-IR and Hyphenated techniques.			Upon completion of this course the student should be able to: <ol style="list-style-type: none"> <li>1. Understand the theoretical and Interpretation skills of IR, NMR, and Mass spectra and identification of various organic compounds.</li> <li>2. Understand the theoretical and practical skills of Chromatography techniques.</li> <li>3. Understand the theoretical and practical skills of the hyphenated techniques.</li> </ol>			
<b>Course Content and Assessment Plan</b>						
Sl No.	Course Content	Syllabus (Chapters or Units with hours)	Marks of assessment	Distribution of marks of assessment		
				Sessional exam (30% of marks of assessment)		End Sem exam (70% of marks of assessment)
				S1	S2	
1	Will learn the prediction of $\lambda_{max}$ for few classes of compound based on Woodward Fieser rule. And learn to interpret the chemical structure based on IR. Learn the Hyphenated techniques of IR.	Unit I (10 hrs)	20	5		15
2	Will understand NMR spectroscopy with respect to 1D and 2D NMR, NOESY and COSY, HETCOR, Inadequate techniques and interpretation of organic compounds	Unit II (14 hrs)	30	10		20
3	Will understand about the Mass Spectroscopy with respect to mass fragmentation and its rules, fragmentation of	Unit III (12 hrs)	25		5	20

	important functional groups , meta stable ions, Mc Lafferty rearrangement, ring rule, isotopic peaks, interpretation of organic compounds.					
4	Will understand and learn about different Chromatographic techniques in terms of method development and troubleshooting etc. Will also learn Principle, procedure and applications of various hyphenated chromatographic techniques:	Unit IV (16 hrs)	30		10	20
Total Marks of Assessment			105	15	15	75

### **PCH-MPC201T: ADVANCED SPECTRAL ANALYSIS**

#### **THEORY**

**52 hrs**

**1. UV and IR spectroscopy**

**10 hrs**

Woodward-Fieser rule for 1,3- butadienes, cyclic dienes and  $\alpha$ ,  $\beta$ -carbonyl compounds and interpretation compounds of enones. NIR, ATR-IR, IR Interpretation of organic compounds.

**2. NMR spectroscopy**

**14 hrs**

1-D and 2-D NMR, NOESY and COSY, HETCOR, INADEQUATE techniques, Interpretation of organic compounds.

**3. Mass Spectroscopy**

**12 hrs**

Mass fragmentation and its rules. Fragmentation of important functional groups like alcohols, amines, carbonyl groups and alkanes, Meta stable ions, McLafferty rearrangement, Ring rule, Isotopic peaks. Interpretation of organic compounds.

**4. Chromatography**

**16 hrs**

**HPLC:** Columns, column problems, gradient HPLC, HPLC solvents, trouble shooting, sample preparation, method development, New developments in HPLC-Role and principles of ultra, nano liquid chromatography in pharmaceutical analysis. Immobilized polysaccharide CSP's: Advancement in enantiomeric separations, revised phase Chiral

method development and HILIC approaches. HPLC in Chiral analysis of pharmaceuticals. GC Derivatisation techniques.

Principle, Instrumentation and Applications of the following:

- a) GC-MS b) GC-AAS c) LC-MS d) LC-FTIR e) LC-NMR f) CE-MS g) High Performance Thin Layer chromatography h) Super critical fluid chromatography i) Ion Chromatography j) Ion-Exclusion Chromatography k) Flash chromatography.

## REFERENCES

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Douglas A Skoog, F. James Holler, Timothy A. Nieman, 5<sup>th</sup> edition, Eastern press, Bangalore, 1998.
3. Instrumental methods of analysis – Willards, 7<sup>th</sup> edition, CBS publishers.
4. Organic Spectroscopy - William Kemp, 3<sup>rd</sup> edition, ELBS, 1991.
5. Quantitative analysis of Pharmaceutical formulations by HPTLC - P D Sethi, CBS Publishers, New Delhi.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3<sup>rd</sup> Edition, CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis- Modern methods – Part B - J W Munson, Volume 11, Marcel Dekker Series.
8. Organic Spectroscopy by Donald L. Paviya, 5th Edition.

**MPHARM –PHARMACEUTICAL CHEMISTRY (MPC)**

**SEMESTER II**

**PCH-MPC202T: ADVANCED ORGANIC CHEMISTRY II**

<b>COURSE CODE</b>	PCH-MPC202T					
<b>COURSE TITLE</b>	ADVANCED ORGANIC CHEMISTRY-II (Theory)					
<b>SCOPE/ SUMMARY</b>			<b>OBJECTIVES/COURSE OUTCOMES</b>			
This course is designed to impart in depth knowledge about advances in organic chemistry, different techniques of organic synthesis and their application to process chemistry as well as drug discovery.			Upon completion of the course, the student shall be able to know 1. The principles and application of green chemistry 2. The chemistry and synthetic strategy of therapeutic peptides. 3. The reactions carried out by light as catalyst. 4. The concept of catalysis in organic reactions. 5. The concept of stereochemistry and asymmetric synthesis			
<b>Course Content and Assessment Plan</b>						
Sl No.	Course Content	Syllabus (Chapters or Units with hours)	Marks of assessment	Distribution of marks of assessment		
				Sessional exam (30% of marks of assessment)		End Sem exam (70% of marks of assessment)
				S1	S2	
1	The students will be acquainted with the basic aspects of green chemistry	Unit I (7 hrs)	15	5		10
2	The students will be acquainted with the chemistry of peptides, coupling and side reactions in peptide synthesis.	Unit II (10 hrs)	20	5		15
3	Will learn about photochemical reactions and pericyclic reactions	Unit III (9 hrs)	20	5		15
4	The students learn the various catalysts used in organic synthesis. It includes homogenous and heterogeneous catalysis	Unit IV (8 hrs)	15		5	10
5	Will understand about stereochemistry and asymmetric synthesis	Unit V (18 hrs)	35		10	25
Total Marks of Assessment			105	15	15	75

## **PCH-MPC202T: ADVANCED ORGANIC CHEMISTRY II**

### **THEORY**

**52 hrs**

#### **1. Green Chemistry**

**07 hrs**

- a. Introduction, principles of green chemistry
- b. Microwave assisted reactions: Merit and demerits of its use, increased reaction rates, mechanism, superheating effects of microwave, effects of solvents in microwave assisted synthesis, microwave technology in process optimization, its applications in various organic reactions and heterocycles synthesis
- c. Ultrasound assisted reactions: Types of sonochemical reactions, homogenous, heterogeneous liquid-liquid and liquid-solid reactions, synthetic applications
- d. Continuous flow reactors: Working principle, advantages and synthetic applications.

#### **2. Chemistry of Peptides**

**10 hrs**

- a. Coupling reactions in peptide synthesis
- b. Principles of solid phase peptide synthesis, t-BOC and Fmoc protocols, various solid supports and linkers: Activation procedures, peptide bond formation, deprotection and cleavage from resin, low and high HF cleavage protocols, formation of free peptides and peptide amides, purification and case studies, site-specific chemical modifications of peptides
- c. Segment and sequential strategies for solution phase peptide synthesis with any two case studies
- d. Side reactions in peptide synthesis: Deletion peptides, side reactions initiated by proton abstraction, protonation, over-activation and side reactions of individual amino acids.

#### **3. Photochemical Reactions**

**09 hrs**

Basic principles of photochemical reactions. Photo-oxidation, photo-addition and photo-fragmentation

##### **Pericyclic Reactions**

Mechanism, types of pericyclic reactions such as cyclo addition, electrocyclic reaction and sigmatropic rearrangement reactions with examples

#### 4. Catalysis

08 hrs

- a. Types of catalysis, heterogeneous and homogeneous catalysis, advantages and disadvantages
- b. Heterogeneous catalysis – preparation, characterization, kinetics, supported catalysts, catalyst deactivation and regeneration, some examples of heterogeneous catalysis used in synthesis of drugs.
- c. Homogeneous catalysis, hydrogenation, hydroformylation, hydrocyanation, Wilkinson catalysts, chiral ligands and chiral induction, Ziegler Natta catalysts, some examples of homogeneous catalysis used in synthesis of drugs
- d. Transition-metal and Organo-catalysis in organic synthesis: Metal-catalyzed reactions
- e. Biocatalysis: Use of enzymes in organic synthesis, immobilized enzymes/cells in organic reaction.
- f. Phase transfer catalysis - theory and applications

#### 5. Stereochemistry & Asymmetric Synthesis

18 hrs

Asymmetric synthesis: Basic principles. Reduction of ketones, hydrogenation of alkenes, alkylation of carbonyl compounds, aldol reactions, diels-alder reaction, epoxidation, dihydroxylation reactions. Catalysts and building blocks used in asymmetric synthesis and Chiral separation.

#### REFERENCES

1. “Advanced Organic chemistry, Reaction, mechanisms and structure”, J March, John Wiley and sons, New York.
2. “Mechanism and structure in organic chemistry”, ES Gould, Hold Rinchart and Winston, New York.
3. “Organic Chemistry” Clayden, Greeves, Warren and Wothers, Oxford University Press 2001.
4. “Organic Chemistry” Vol I and II. I.L. Finar. ELBS, Sixth edn., 1995.
5. Carey, Organic chemistry, 5th edition (Viva Books Pvt. Ltd.)
6. Organic synthesis-the disconnection approach, S. Warren, Wiley India
7. Principles of organic synthesis, ROC Norman and JM Coxan, Nelson thorns
8. Organic synthesis- Special techniques VK Ahluwalia and R Aggarwal, Narosa Publishers
9. Organic reaction mechanisms IV edn., VK Ahluwalia and RK Parashar, Narosa Publishers.



**MPHARM –PHARMACEUTICAL CHEMISTRY (MPC)**

**SEMESTER II**

**PCH-MPC203T: COMPUTER AIDED DRUG DESIGN**

<b>COURSE CODE</b>	PCH-MPC203T					
<b>COURSE TITLE</b>	COMPUTER AIDED DRUG DESIGN (Theory)					
<b>SCOPE/ SUMMARY</b>			<b>OBJECTIVES/COURSE OUTCOMES</b>			
This subject deals to impart fundamental knowledge on the current state of the art techniques involved in computer assisted drug design.			Upon completion of this course the student should be able to understand: <ol style="list-style-type: none"> <li>1. Role of CADD in drug discovery.</li> <li>2. Different CADD techniques and their application.</li> <li>3. Various strategies to design and develop new drug like molecules.</li> <li>4. Working with molecular modeling softwares to design new drug molecules.</li> <li>5. The in-silico virtual screening protocol.</li> </ol>			
<b>Course Content and Assessment Plan</b>						
Sl No.	Course Content	Syllabus (Chapters or Units with hours)	Marks of assessment	Distribution of marks of assessment		
				Sessional exam (30% of marks of assessment)		End Sem exam (70% of marks of assessment)
				S1	S2	
1	Will keep abreast of the latest concepts, techniques and applications in CADD and learn all the parameters in QSAR studies	Unit I (10 hrs)	20	5		15
2	Will learn QSAR approaches such as Hansch analysis, Free Wilson analysis and relationship between them. Also gain knowledge in 2-D QSAR and 3D-QSAR approaches, contour map analysis, statistical methods involved in QSAR analysis with its importance	Unit II (12 hrs)	25	10		15
3	Will understand the principle and applications of quantum mechanics and molecular mechanics in drug design pertaining to molecular modeling and docking and also get to know energy minimization methods.	Unit III (10 hrs)	20		5	15

4	Will learn the molecular properties, De novo drug design fragment based drug design. Homology modelling and generation of 3D-structure of protein.	Unit IV (10 hrs)	20		5	15
5	Will get exposure to the pharmacophore mapping and virtual screening, identification of pharmacophore features and pharmacophore modelling, conformational search used in them. Also updates knowledge in In silico drug design and virtual screening techniques.	Unit V (10 hrs)	20		5	15
Total Marks of Assessment			105	15	15	75

### **PCH-MPC203T: COMPUTER AIDED DRUG DESIGN**

#### **THEORY**

**52 hrs**

#### **1. Introduction to Computer Aided Drug Design (CADD).**

**10 hrs**

History, different techniques and applications.

Quantitative Structure Activity Relationships: Basics

History and development of QSAR: Physicochemical parameters and methods to calculate physicochemical parameters: Hammett equation and electronic parameters ( $\sigma$ ), lipophilicity effects and parameters ( $\log P$ ,  $\pi$ -substituent constant), steric effects (Taft steric and MR parameters). Experimental and theoretical approaches for the determination of these physicochemical parameters.

#### **2. Quantitative Structure Activity Relationships: Applications**

**12 hrs**

Hansch analysis, Free Wilson analysis and relationship between them, Advantages and disadvantages; Deriving 2D-QSAR equations.

3D-QSAR approaches and contour map analysis.

Statistical methods used in QSAR analysis and importance of statistical parameters.

#### **3. Molecular Modeling and Docking**

**10 hrs**

a. Molecular and Quantum Mechanics in drug design

b. Energy Minimization Methods: comparison between global minimum conformation and bioactive conformation

- c. Molecular docking and drug receptor interactions: Rigid docking, flexible docking and extra-precision docking. Agents acting on enzymes such as DHFR, HMG-CoA reductase and HIV protease, choline esterase (AchE & BchE)

**4. Molecular Properties and Drug Design** **10 hrs**

- a. Prediction and analysis of ADMET properties of new molecules and its importance in drug design.
- b. De novo drug design: Receptor/enzyme-interaction and its analysis, Receptor/enzyme cavity size prediction, predicting the functional components of cavities. Fragment based drug design.
- c. Homology modeling and generation of 3D-structure of protein.

**5. Pharmacophore Mapping and Virtual Screening** **10 hrs**

Concept of pharmacophore, pharmacophore mapping, identification of Pharmacophore features and Pharmacophore modeling; Conformational search used in pharmacophore mapping.

In Silico Drug Design and Virtual Screening Techniques

Similarity based methods and Pharmacophore based screening, structure based in-silico virtual screening protocols.

**REFERENCES**

1. Computational and structural approaches to drug design edited by Robert M Stroud and Janet. F Moore
2. Introduction to Quantitative Drug Design by Y.C. Martin.
3. Drug Design by Ariens Volume 1 to 10, Academic Press, 1975.
4. Principles of Drug Design by Smith and Williams.
5. The Organic Chemistry of the Drug Design and Drug action by Richard B. Silverman.
6. Medicinal Chemistry by Burger.
7. An Introduction to Medicinal Chemistry – Graham L. Patrick, (III Edition.)
8. Wilson and Gisvold's Text book of Organic Medicinal and Pharmaceutical Chemistry.
9. Comprehensive Medicinal Chemistry – Corwin and Hansch.

**MPHARM –PHARMACEUTICAL CHEMISTRY (MPC)**

**SEMESTER II**

**PCH-MPC204T: PHARMACEUTICAL PROCESS CHEMISTRY**

<b>COURSE CODE</b>	PCH-MPA204T					
<b>COURSE TITLE</b>	PHARMACEUTICAL PROCESS CHEMISTRY (Theory)					
<b>SCOPE/ SUMMARY</b>			<b>OBJECTIVES/COURSE OUTCOMES</b>			
<p>Process chemistry is often described as scale up reactions, taking them from small quantities created in the research lab to the larger quantities that are needed for further testing and then to even larger quantities required for commercial production. The goal of a process chemist is to develop synthetic routes that are safe, cost-effective, environmentally friendly, and efficient. The subject is designed to impart knowledge on the development and optimization of a synthetic route/s and the pilot plant procedure for the manufacture of Active Pharmaceutical Ingredients (APIs) and new chemical entities (NCEs) for the drug development phase.</p>			<p>At completion of this course it is expected that students will be able to understand-</p> <ol style="list-style-type: none"> <li>1. The strategies of scale up process of APIs and intermediates including health and safety assessment.</li> <li>2. The various unit process and various reactions in process chemistry</li> </ol>			
<b>Course Content and Assessment Plan</b>						
Sl No.	Course Content	Syllabus (Chapters or Units with hours)	Marks of assessment	Distribution of marks of assessment		
				Sessional exam (30% of marks of assessment)		End Sem exam (70% of marks of assessment)
				S1	S2	
1	Able to understand introduction to process chemistry, stages of scale up process, in-process control, solvents and selection of solvent	Unit I (10 hrs)	20	10		10
2	Able to understand unit process like crystallization techniques and preparation of pharmaceutical salts	Unit II (12 hrs)	25		5	20
3	Able to understand unit process like Nitration halogenation and oxidation	Unit III (10 hrs)	20	5		15
4	Able to understand unit process like reduction, reagent selection, reaction progress kinetic analysis	Unit IV (10 hrs)	20		5	15
5	Able to understand various topics in industrial safety like MSDS, PPE, Fire Hazards, Occupational health and safety assessment	Unit V (10 hrs)	20		5	15
Total Marks of Assessment			105	15	15	75

## PCH-MPC204T: PHARMACEUTICAL PROCESS CHEMISTRY

### THEORY

52 hrs

#### 1. Process chemistry

10 hrs

- a. Introduction, Role/ Importance of process chemistry, Principles of green process chemistry
- b. Stages of scale up process: Bench, pilot and large scale process.
- c. In-process control of large scale process.
- d. Solvents: Solvation, Solubility, selection of solvents, impurities in solvents, types of solvents. ICH guideline on residual solvents

#### 2. Unit Processes

12 hrs

- a. Crystallisation: Crystal Properties and Polymorphism, nucleation, growth kinetics, critical issues in crystallization process. Crystallization Process Options: Mixing and Crystallization, Cooling Crystallization, Evaporative Crystallization, Antisolvent Crystallization, Reactive Crystallization
- b. Pharmaceutical salts: Salt Selection in Drug Development, basic concepts in salt formation, salt-selection strategy, pharmaceutical and biological effects of salt forms, objectives of salt selection, generation of salt forms, techniques for the characterization of salts.

#### 3. Unit Processes

10 hrs

- a. **Nitration:** Nitrating agents, Aromatic nitration, kinetics and mechanism of aromatic nitration, process equipment for technical nitration, mixed acid for nitration,
- b. **Halogenation:** Kinetics of halogenations, types of halogenations, catalytic halogenations. Case study on industrial halogenation process.
- c. **Oxidation:** Introduction, types of oxidative reactions, Liquid phase oxidation with oxidizing agents. Nonmetallic Oxidizing agents such as H<sub>2</sub>O<sub>2</sub>, sodium hypochlorite, Oxygen gas, ozonolysis.

#### 4. Unit Processes

10 hrs

- a. **Reduction:** Catalytic hydrogenation, Heterogeneous and homogeneous catalyst; Hydrogen transfer reactions, Metal hydrides. Case study on industrial reduction process.
- b. Reagents: Supported Regents, Complex formation, Selection of reagents in organic synthesis: safety, toxicity, efficacy, operational convenience, environmental issues.

#### **Reaction progress kinetic analysis**

- a. Streamlining reaction steps, route selection,
- b. Characteristics of expedient routes, characteristics of cost-effective routes, reagent selection, families of reagents useful for scale-up.

### **5. Industrial Safety**

**10 hrs**

- a. MSDS (Material Safety Data Sheet), hazard labels of chemicals and Personal Protection Equipment (PPE)
- b. Fire hazards, types of fire & fire extinguishers
- c. Occupational Health & Safety Assessment Series 1800 (OHSAS-1800) and ISO-14001(Environmental Management System), Effluents and its management

### **REFERENCES**

1. Process Chemistry in the Pharmaceutical Industry: Challenges in an Ever Changing Climate-An Overview; K. Gadamasetti
2. Pharmaceutical Manufacturing Encyclopedia, 3<sup>rd</sup> edition, Volume 2.
3. Medicinal Chemistry by Burger, 6<sup>th</sup> edition, Volume 1-8.
4. W.L. McCabe, J.C Smith, Peter Harriott. Unit operations of chemical engineering, 7th edition, McGraw Hill
5. Polymorphism in Pharmaceutical Solids .Dekker Series Volume 95 Ed: H G Brittain (1999)
6. Regina M. Murphy: Introduction to Chemical Processes: Principles, Analysis, Synthesis
7. Peter J. Harrington: Pharmaceutical Process Chemistry for Synthesis: Rethinking the Routes to Scale-Up
8. P.H. Groggins: Unit processes in organic synthesis (MGH)
9. F.A. Henglein: Chemical Technology (Pergamon)
10. M. Gopal: Dryden's Outlines of Chemical Technology
11. Clausen, Mattson: Principle of Industrial Chemistry
12. Lowenheim & M.K. Moran: Industrial Chemicals

13. S.D. Shukla & G.N. Pandey: A text book of Chemical Technology Vol. II
14. J.K. Stille: Industrial Organic Chemistry (PH)
15. Srreve: Chemical Process
16. B.K.Sharma: Industrial Chemistry
17. ICH Guidelines
18. United States Food and Drug Administration official website [www.fda.gov](http://www.fda.gov)
19. Crystallization of Organic Compounds: An Industrial Perspective Hsien-Hsin Tung, Edward L. Paul, Michael Midler, James A. McCauley
20. Hand book of Pharmaceutical salts by P. Heinrich Stahl, G. Wermuth. WILEY-VCH.

**MPHARM –PHARMACEUTICAL CHEMISTRY (MPC)**

**SEMESTER II**

**PCH-MPC205P: PHARMACEUTICAL CHEMISTRY PRACTICAL II**

<b>COURSE CODE</b>		PCH-MPC205P			
<b>COURSE TITLE</b>		PHARMACEUTICAL CHEMISTRY PRACTICAL–II			
<b>SCOPE/ SUMMARY</b>		<b>OBJECTIVES/COURSE OUTCOMES</b>			
The practical is designed to provide detail knowledge about reactions involving synthesis and interpretation of medicinally important compounds. It also emphasizes on computational methods of drug design.		Upon completion of this course the student should be able to understand: 1. The practical skills in the preparation of important drugs. 2. Interpretation of spectral characterization for few of the selected synthetic drugs. 3. The various aspects of molecular modelling both in 2D and 3D QSAR along with docking studies of few of the known drugs.			
<b>Course Content and Assessment Plan</b>					
SI No.	Course Content	Syllabus (Chapters or Units with hours)	Total Marks of assessment	Distribution of assessment marks	
				Sessional exam (25 % of total marks of assessment)	End Sem exam (75 % of total marks of assessment)
1	Learn skills to handle chemicals and calculate the quantity to be taken for synthesis of organic compounds adapting different reaction approaches, comparative study of synthesis of APIs/intermediates by different synthetic routes and preparation of few mentioned organic compounds.	Experiments 1,2; and 10 (72hrs)	65	15	50
2.	Learn to characterize and interpret the synthesized compounds spectra using spectroscopic methods like UV,IR, NMR, Mass and purity by DSC. Learn to document regulatory requirements in API.	Experiments 3 to 9 (48hrs)	43	9	34
3.	Learn skills to handle computational software's to determine log P, MR, hydrogen bond donors and acceptors of selected drugs and calculate ADMET properties of drug molecules and its analysis, Pharmacophore modeling, 2D-QSAR based experiments, 3D-QSAR based experiments, Docking study based experiment ,Virtual screening based experiment.	Experiments 17 to 23 (24 hrs)	22	6	16
<b>Total Marks of Assessment</b>			<b>130</b>	<b>30</b>	<b>100</b>



## **PCH-MPC205P: PHARMACEUTICAL CHEMISTRY PRACTICAL II**

1. Synthesis of organic compounds by adapting different approaches involving (3 experiments) **24 hrs**
  - a. Oxidation b. Reduction/hydrogenation c. Nitration
2. Comparative study of synthesis of APIs/intermediates by different synthetic routes (2 experiments) **12 hrs**
3. Assignments on regulatory requirements in API (2 experiments) **6 hrs**
4. Comparison of absorption spectra by UV and Wood ward – Fieser rule **12 hrs**
5. Interpretation of organic compounds by FT-IR **6 hrs**
6. Interpretation of organic compounds by NMR **6 hrs**
7. Interpretation of organic compounds by MS **6 hrs**
8. Determination of purity by DSC in pharmaceuticals **6 hrs**
9. Identification of organic compounds using FT-IR, NMR, CNMR and Mass spectra **6 hrs**
10. To carry out the preparation of following organic compounds **36 hrs**
11. Preparation of 4-chlorobenzhydrylpiperazine. (an intermediate for cetirizine HCl).
12. Preparation of 4-iodotoluene from p-toluidine.
13. NaBH<sub>4</sub> reduction of vanillin to vanillyl alcohol
14. Preparation of umbelliferone by Pechhman reaction
15. Preparation of triphenyl imidazole
16. To perform the Microwave irradiated reactions of synthetic importance (Any two)
17. Determination of log P, MR, hydrogen bond donors and acceptors of selected drugs using softwares **6 hrs**
18. Calculation of ADMET properties of drug molecules and its analysis using software's **3 hrs**
19. Pharmacophore modeling **3 hrs**
20. 2D-QSAR based experiments **3 hrs**
21. 3D-QSAR based experiments **3 hrs**
22. Docking study based experiment **3 hrs**
23. Virtual screening based experiment **3 hrs**

**MPHARM – PHARMACEUTICAL CHEMISTRY (MPC)****SEMESTER II****PCH- MPC206S: SEMINAR IN PHARMACEUTICAL CHEMISTRY**

<b>COURSE CODE</b>	PCH- MPC206S			
<b>COURSE TITLE</b>	SEMINAR IN PHARMACEUTICAL CHEMISTRY			
<b>SCOPE/ SUMMARY</b>		<b>OBJECTIVES/COURSE OUTCOMES</b>		
The subject is designed to create an environment where teachers provide the students a critical eye and openness to fortify the presentation and academic writing skills of students in the field of Pharmaceutical Chemistry.		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 pharmaceutical chemistry 2. Learn to organize pharmaceutical chemistry 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 scientific writing skill. 6. Cultivate a sense of upgradation of knowledge through self and continuous learning		
<b>Course Content and Assessment Plan</b>				
<b>Sl No.</b>	<b>Course Content</b>	<b>Hours</b>	<b>Total Marks of assessment</b>	<b>Marks</b>
				<b>End Sem exam</b>
1	The students should be able to develop skills to gather, organize, communicate the scientific information, and defend a given topic in pharmaceutical chemistry.	2 hours/week	100	No end-semester examination. Only continuous mode.

**MPHARM –PHARMACEUTICAL CHEMISTRY (MPC)**

**SEMESTER III**

**PHA-MRM301T: RESEARCH METHODOLOGY AND BIOSTATISTICS**

<b>COURSE CODE</b>	PHA-MRM301T					
<b>COURSE TITLE</b>	RESEARCH METHODOLOGY AND BIOSTATISTICS (Theory)					
<b>SCOPE/ SUMMARY</b>			<b>OBJECTIVES/COURSE OUTCOMES</b>			
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. 1. Appreciate advanced statistical techniques in solving the research problems.			
<b>Course Content and Assessment Plan</b>						
Sl No.	Course Content	Syllabus (Chapters or Units with hours)	Marks of assessment	Distribution of marks of assessment		End Sem exam
				Sessional exam (80% of marks of assessment)		
				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	-

## **SEMESTER III**

### **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 –PHARMACEUTICAL CHEMISTRY (MPC)****SEMESTER III****MJC 302P: JOURNAL CLUB IN PHARMACEUTICAL CHEMISTRY**

<b>COURSE CODE</b>	MJC 302P			
<b>COURSE TITLE</b>	JOURNAL CLUB IN PHARMACEUTICAL CHEMISTRY			
<b>SCOPE/ SUMMARY</b>		<b>OBJECTIVES/COURSE OUTCOMES</b>		
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 scientific 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		
<b>Course Content and Assessment Plan</b>				
<b>Sl No.</b>	<b>Course Content</b>	<b>Hours</b>	<b>Total Marks of assessment</b>	<b>Marks</b>
				<b>End Sem exam</b>
1	The students should be able to develop skills to gather, organize, communicate scientific 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.	<b>2 hrs</b>
Theories of dissolution. Noyes & Whitney equation and Hixson & Crowell Cube root.	<b>2 hrs</b>
Compendial methods and official dissolution test apparatus.	<b>2 hrs</b>
Principles, concepts and requirements of new dissolution method developments.	<b>2 hrs</b>
Alternative methods for drug release studies.	<b>1 hr</b>
Recommended apparatus for drug release studies of suppositories, topical, transdermal, powder dosage forms, controlled release products, etc.	<b>1 hr</b>
Computation of dissolution data with statistical approaches, model dependent approaches and model independent approaches.	<b>2 hrs</b>
Development of IVIVC models.	<b>1 hr</b>
Brief account on Biosimilar, Biowaiver, ICH Q4B and new regulatory prospective in dissolution.	<b>2 hrs</b>

## **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. Nanotechnology 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 pharmaceuticals: 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, Pharmacophore, 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:	<b>2 hrs</b>
Personal protection	<b>1 hr</b>
Radioactive materials: Regulatory requirements, hazards, handling, storage, disposal, emergency procedures.	<b>2 hrs</b>
Fire safety	<b>1 hr</b>

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

**(15 hrs)**

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

**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	<b>3 hrs</b>
2. Basic levels of documentation	<b>6 hrs</b>
a. Level -1, Level-2, Level-3 and Level-4 documentation	
3. Case studies in each level	<b>3 hrs</b>
4. Open lab and e-documentation concept	<b>3 hrs</b>

## **PQA-003E: TROUBLE SHOOTING IN HIGH PERFORMANCE LIQUID**

### **CHROMATOGRAPHY**

(15 hrs)

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

## **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, nanofibrous 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, 4<sup>th</sup> 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 WRITING 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.



- 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)**

- Introduction to pharmacokinetic parameters: Elimination rate constant ( $k_e$ ), Elimination half-life, Bioavailability & AUC, Volume of distribution, Clearance, Bioequivalence 2 hrs
- Bioavailability studies: In animal & human **2 hrs**
- 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**
- Introduction Phoenix WinNonlin: Data entry and data tools, graphs **2 hrs**
- Non-compartmental analysis using (NCA) Phoenix WinNonlin: For Oral, IV, IV infusion, Sparse sampling and urinary excretion data **3 hrs**
- Pharmacokinetic modeling: Compartment modelling, choosing the right compartment model, Simulating using PK model **2 hrs**
- Bioequivalence data analysis: Parallel, Cross-over study data analysis **2 hrs**

#### **REFERENCES**

- Gibaldi M, Perrier D. Pharmacokinetics. 2<sup>nd</sup> edition. Informa Healthcare; 2007.
- Rowland M, Tozer TN. Clinical Pharmacokinetics: Concepts & Applications. 4<sup>th</sup> edition. Lippincott Williams & Wilkins; 2011.
- Phoenix WinNonlin examples guide. Pharsight. A Certara Company; 2012
- Phoenix WinNonlin Users guide. Pharsight. A Certara Company; 2012.
- 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 anti-anxiety drugs
14. Screening methods for anti-parkinsonian 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 ( <i>Ginkgo biloba</i> , Tea, Citrus fruits, Grape, Soy); Carotene and fatty acids: (Curcuma, Tomato, Flax seed, Olive oil) | <b>5 hrs</b> |
| 7. Current market scenario of nutraceuticals  | <b>1 hr</b>  |
| 6. Regulatory requirements for nutraceuticals   | <b>1 hr</b>  |

## **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.	<b>1 hr</b>
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.	<b>5 hrs</b>
3	Phytochemical screening of natural products	<b>2 hrs</b>
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 chromatography and electrochromatography (Electrophoresis).	<b>7 hrs</b>

## **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 Nanotechnology, 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   | <b>3 hrs</b>  |
| 2. Systematic study of the following important plants for their monographs;<br>Leaf: Vasaka ( <i>Adhatoda zeylanica</i> )<br>Root: Shatavari ( <i>Asparagus racemosus</i> )<br>Rhizome: Rasna ( <i>Alpinia galanga</i> )<br>Bark: Cinchona ( <i>Cinchona officinalis</i> )<br>Fruit: Pepper ( <i>Piper nigrum</i> )<br>Entire herb: Kalmegh ( <i>Andrographis paniculata</i> ). | <b>12 hrs</b> |

### **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 | <b>3 hrs</b> |
| 2. Strategies in Retailing           | <b>3 hrs</b> |
| 3. Retail Marketing in rural areas   | <b>3 hrs</b> |
| 4. Pharmacy Store Management         | <b>4 hrs</b> |
| 5. Online Pharmacy Retailing         | <b>2 hrs</b> |

### **REFERENCES**

1. Retail Management by Barry Berman. Person Education 11<sup>th</sup> Edition.
2. Retail Management by Chetan Bajaj. Oxford 2<sup>nd</sup> 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.

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

### **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.

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|---|--------------|
| 1. Introduction to management concepts  | <b>3 hrs</b> |
| 2. Decision Making                      | <b>3 hrs</b> |
| 3. Leadership and Motivation            | <b>4 hrs</b> |
| 4. Conflict Management                  | <b>3 hrs</b> |
| 5. Ethical Issues related to Management | <b>2 hrs</b> |

### **REFERENCES**

1. Organisational Behaviour by Stephen P. Robbins, Prentice – Hall, India
2. Management, A global Perspective by Heinz, Wehrich 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.

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

### **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)*