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

Academic Program Regulations – 2017

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

Program Title: MPharm (Master of Pharmacy)

CBCS (Choice Based Credit System)

Specialization: Pharmaceutical Biotechnology

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

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

July 1, 2023

Academic Program Regulations – 2017 : MPharm, CBCS – Approval

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

REGISTRAR

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

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PHARMACY COUNCIL OF INDIA

NOTIFICATION

New Delhi, the 10th December, 2014

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

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

CHAPTER I: REGULATIONS

1. Short title and commencement

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

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

2. Minimum qualification for admission

A pass in the following examinations

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

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

3. Duration of the program

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

4. Medium of instruction and examination

Medium of instruction and examination shall be in English.

5. Working days in each semester

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

6. Attendance and progress

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

7. Program/Course credit structure

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

7.1. Credit assignment

7.1.1. Theory and laboratory courses

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

7.2. Minimum credit requirements

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

8. Academic work

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

9. Course work of study

The specializations in MPharm program are given in Table 1.

Table 1. List of MPharm specializations and their codes

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

10. Program committee

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

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

3. Duties of the program committee:

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

11. Examinations/Assessments

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

Table 16. Schemes for internal assessments and end semester examinations

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

11.1. Internal assessment: Continuous mode

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

11.1.1. Sessional exams

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

Question paper pattern – MPharm Theory sessional examinations

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

MPharm Theory Sessional Examinations, Month and Year

Course Code. Course Title

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

Instructions: Answer ALL questions

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

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

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

11.2 End-semester examination

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

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

Question paper pattern – MPharm theory end-semester examinations

Manipal Academy of Higher Education, Manipal

MPharm Theory End-Semester Examinations, Month and Year

Course Code. Course Title

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

Instructions: Answer ALL questions.

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

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

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

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

Question paper pattern – MPharm practical end-semester examinations

MPharm Practical End-Semester Examinations, Month and Year

Manipal Academy of Higher Education, Manipal

Course Code. Course Title

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

Instructions: Answer ALL questions.

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

12. Pass and award of performance grades

12.1: Minimum for a pass in a course

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

in a 10-Point-Relative-Letter Grading-Scheme. Accordingly, no candidate shall be declared to have passed in any course unless he/she obtains a grade not less than E-grade.

12.2 Award of performance grades

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

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

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

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

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

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

Note the following:

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

obtained in that course. Eventually each letter grade of the course is converted into a specific grade point associated with the letter grade as given in the table above.

12.4 The Semester Grade Point Average (SGPA)

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

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

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

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

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

12.5. Cumulative Grade Point Average (CGPA)

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

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

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

12.6. Conversion of GPA/CGPA into a percentage

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

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

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

Percentage secured by the candidate = GPA or CGPA × 10

13. Make-up/Supplementary examination

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

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

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

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

14. Improvement of internal assessment

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

15. Promotion to the next higher class

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

16. Declaration of class

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

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

17. Research project work

17.1 Dissertation submission

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

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

17.2 Dissertation evaluation

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

Table 19. MPharm dissertation evaluation scheme

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

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

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

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

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

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

18. Award of degree

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

19. Duration for completion of the program

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

20. Revaluation of answer papers

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

21. Re-admission after break of study

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

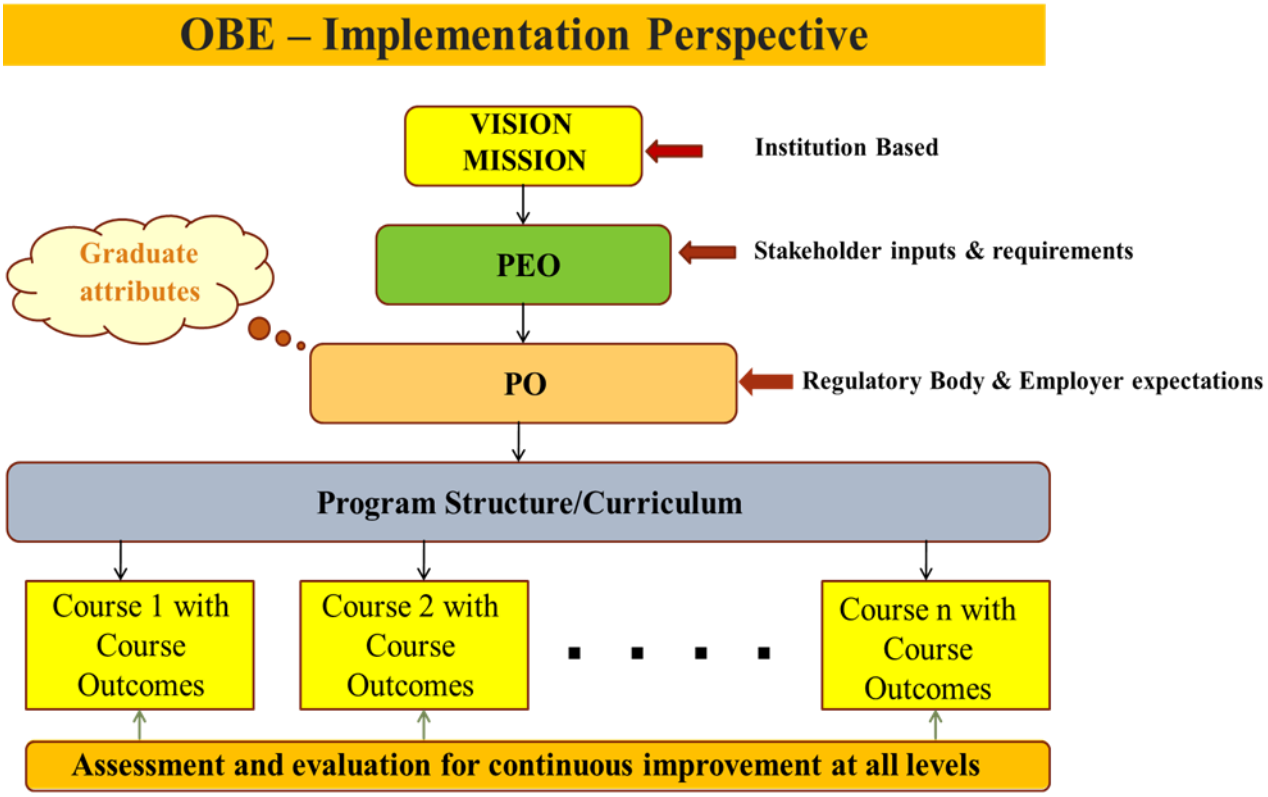
*****

OUTCOME BASED EDUCATION (OBE)

FRAMEWORK

Chapter II

Outcome Based Education (OBE) Framework



MCOPS Vision Mission

Vision:

“Excellence in Pharmaceutical Education and Research”

Mission:

“Marching with the Times”

Quality Policy

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

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

MPharm Pharmaceutical Biotechnology
Program Educational Objectives

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

PEO No	Education Objectives
PEO 1	Apply basic principles and technological advances of life sciences to impart education leading to a Masters' degree in Pharmaceutical Biotechnology and to integrate knowledge, skills and research competencies in the development of biological products having therapeutic and industrial use.
PEO 2	Train with sound theoretical knowledge and practical skills to deliver the services in discovery, manufacture, analysis and data management of biologicals.Take up professional activities to meet the demands of academic, research and industrial needs of fast evolving Pharmaceutical Biotechnology field.
PEO 3	Inculcate entrepreneurial and leadership skills for effective management of drugs of biological origin.
PEO 4	Foster best in class hands on training in bioprocess technology, cell and molecular biology, proteomics, computational biology, immunology and advanced biotechnological sciences.
PEO 5	Empower and sensitize the professionals to employ ethical principles and good practices to cater for the needs of society and pharmaceutical industries for sustainable development.

MPharm Pharmaceutical Biotechnology
Program Outcomes (POs)

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

PO No	Attribute	Competency
PO 1	**Domain knowledge**	Apply the fundamental knowledge of pharmacy and biotechnology in drug discovery and development, manufacture, analysis and data management process.
PO 2	**Problem analysis**	Identify and analyze pharmaceutical problems related to protein expression, purification and delivery, Isolation of microorganisms, production of biologicals, gene cloning and delivery to reach substantiated conclusions.
PO 3	**Design/develop solutions**	Design to find innovative, economical and apt solutions for pharmaceutical problems through biotechnological strategies and rational drug designs.
PO 4	**Conduct investigations of complex problems**	Conceptualize research ideas, frame and evaluate hypothesis, data interpretation to draw meaningful conclusions facilitating practical solutions.
PO 5	**Modern tool usage**	Create, utilize and apply appropriate techniques or resources such as computational tools, gene editing, cloning etc., to aid in development of biological products.
PO 6	**Business and society**	Develop and facilitate multidisciplinary approach in allied fields of pharmacy and life sciences that facilitate the development of business strategies for the benefit of industries and society.
PO 7	**Environment and sustainability**	Comprehend the impact of usage of organisms, chemicals and biochemicals on ecosystem and apply the gained knowledge for sustainable development.
PO 8	**Ethics**	Apply ethical principles during execution of professional responsibilities.

PO 9	**Individual / Teamwork**	Function effectively as an individual / team member or leader in diverse settings for efficient teamwork.
PO No	**Attribute**	**Competency**
PO 10	**Communication**	Communicate effectively with team members, scientific community and with society at large, so as to comprehend and write effective reports, scientific articles and design documentation, presentations and exchange information.
PO 11	**Project management and finance**	Apply the knowledge of the financial management to effectively manage and execute various projects.
PO 12	**Life-long learning**	Appreciate the need to engage oneself as a life-long learner in the profession.

CHAPTER – III

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

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

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

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

S No	Course Code	Course Name	Credits	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO1O	PO11	PO12
1	PQA-MPB101T	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 CO3	CO1 CO2 CO3	CO1 CO3
2	PBT-MPB102T	Microbial and Cellular Biology	5	CO1 CO2 CO3 CO4	CO2 CO3 CO4	CO4	CO2 CO3 CO4	CO4	CO2	CO2					
3	PBT-MPB103T	Bioprocess Engineering and Technology	5	CO1 CO2 CO3 CO4 CO5	CO1 CO2 CO3 CO4 CO5	CO1 CO2 CO3 CO4 CO5	CO1 CO2 CO3 CO4 CO5	CO1 CO3 CO4	CO2 CO3 CO4	CO3		CO3	CO3		CO1 CO3
4	PBT-MPB104T	Advanced Pharmaceutical Biotechnology	5	CO1 CO2 CO3 CO4 CO5	CO1 CO2 CO3 CO4 CO5	CO1 CO2 CO3 CO4	CO2 CO3 CO4 CO5	CO1 CO2 CO3 CO4	CO2 CO3 CO4	CO1 CO2 CO3 CO4	CO1 CO2 CO3 CO4			CO3	CO1 CO2 CO3 CO4
5	PBT-MPB105P	Pharmaceutical Biotechnology Practical I	6	CO1 CO2 CO3 CO4	CO1 CO4	CO2	CO2 CO3 CO4	CO1				CO1 CO2 CO3 CO4	CO1 CO2		
6	PBT-MPB106S	Seminar*	1	CO1	CO1 CO2		CO2 CO5					CO3	CO3 CO4 CO5		
7	PBT-MPB201T	Proteins and Protein Formulations	5	CO1 CO2 CO3 CO4 CO5	CO2 CO3 CO4 CO5	CO2 CO3 CO4 CO5	CO2 CO3 CO4 CO5	CO3 CO4	CO2 CO3 CO4 CO5	CO2				CO2 CO3 CO4 CO5	CO2 CO3 CO4 CO5
8	PBT-MPB202T	Immunotechnology	5	CO1 CO2 CO3 CO4	CO2 CO3 CO4	CO1 CO2 CO3 CO4	CO4	CO2 CO3 CO4		CO4	CO1 CO2 CO3 CO4				CO1 CO2 CO3 CO4

S No	Course Code	Course Name	Credits	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO1O	PO11	PO12
9	PBT-MPB203T	Bioinformatics and Computational Biotechnology	5	CO1 CO2 CO3 CO4	CO1 CO3 CO4	CO1 CO3 CO4	CO2 CO3 CO4	CO3 CO4	CO1 CO3	CO2					
10	PBT-MPB204T	Biological Evaluation of Drug Therapy	5	CO1 CO2 CO3 CO4	CO2 CO3 CO4	CO2 CO3 CO4	CO2 CO3 CO4	CO1 CO3	CO2 CO3 CO4	CO2	CO4	CO4	CO4	CO2 CO3 CO4	CO2 CO3 CO4
11	PBT-MPB205P	Pharmaceutical Biotechnology Practical II	6	CO1 CO2 CO3	CO1 CO3	CO2	CO1					CO1 CO2 CO3	CO1 CO2		
12	PBT-MPB206S	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 BIOTECHNOLOGY (MPB)

SEMESTER I
PQA-MPB101T: MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES

COURSE CODE	**PQA-MPB101T**
COURSE TITLE	MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES (Theory)

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

Course Content and Assessment Plan

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

PQA-MPB101T: MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES

THEORY **52 hrs**

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

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

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

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

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

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

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

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

5. Other Analytical Techniques

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

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

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

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

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

REFERENCES

1. Spectrometric Identification of Organic Compounds, Robert M Silverstein, 6th edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis, Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern Press, Bangalore, 1998.
3. Instrumental Methods of Analysis, Willards, 7th edition, CBS Publishers.
4. Practical Pharmaceutical Chemistry, Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi, 1997.
5. Organic Spectroscopy, William Kemp, 3rd edition, ELBS, 1991.
6. Quantitative Analysis of Drugs in Pharmaceutical Formulation, PD Sethi, 3rd edition, CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis-Modern Methods, Part B, J W Munson, Volume11, Marcel Dekker Series.
8. Introduction to Spectroscopy, Donald L Pavia. 8th edition, CENGAGE Learning, USA
9. Contemporary Practice of Chromatography, Poole, Colin F and Sheila A Schuette, Elsevier Science Publishers.
10. Remington: The Science and Practice of Pharmacy, latest edition, Pharmaceutical Press, UK.
11. Quantitative Analysis of Pharmaceutical Formulations by HPTLC, PD Sethi, CBS Publishers, New Delhi.

MPHARM – PHARMACEUTICAL BIOTECHNOLOGY (MPB)

SEMESTER I

PBT-MPB102T: MICROBIAL AND CELLULAR BIOLOGY

COURSE CODE	PBT-MPB102T
COURSE TITLE	MICROBIAL AND CELLULAR BIOLOGY (Theory)

SCOPE/SUMMARY	**OBJECTIVE/COURSE OUTCOME**
The course is designed to provide knowledge of microbiology to the students. This would help them to understand the role of microorganisms in human health and diseases, microbial genetics, antimicrobial chemotherapy and drug resistance.	At the completion of this course, it is expected that the students will get an understanding about the following aspects; • Fundamental aspects of microbiology • Beneficial microorganisms to human • Antimicrobial agents and evaluation • Microbial pathogenicity • Bacterial genetics

Course Contents and Assessment Plan

Sl. No.	**Course Contents**	**Syllabus (Chapters or Units with hours)**	**Marks of assessment**	**Distribution of marks of assessment**		
				Sessional exam (*30% of marks of assessment)*		**End Sem exam** (*70% of marks of assessment)*
				S1	S2	
1	Learn fundamental features and characteristics of several types of microorganisms	Unit I (10 hrs)	21	6		15
2	Understand the role of microorganisms in the normal functions of the human body and their role in prevention and treatment of diseases.	Unit II (10 hrs)	21		6	15
3	Learn the principles of action of antimicrobial agents and their evaluation.	Unit III (12 hrs)	21	3	3	15
4	Understand the threat and severity of microbial resistance and biofilms in treating infectious diseases.	Unit IV (10 hrs)	21		6	15
5	Gain in-depth understanding about the genetic organization, flow	Unit V (10 hrs)	21	6		15

	of genetic information, modes of gene transfer and mutations.					
Total Marks of Assessment			105	15	15	75

PBT-MPB102T: MICROBIAL AND CELLULAR BIOLOGY

THEORY **52 hrs**

UNIT I **10 hrs**

Biology of Microorganisms

Introduction – Prokaryotes and Eukaryotes. Fundamental features of bacteria, fungi, actinomycetes, and viruses. Cultural, physiological, and reproductive features of the above microorganisms. Methods of isolation, cultivation, maintenance and long-term preservation of pure cultures. Concept of bioburden.

UNIT II **10 hrs**

Human Microbiota **06 hrs**

Relationship between normal microbiota and the host, normal microbial flora, composition and modulation of human intestinal microbiota, effects of microbiota on human health, functions and dysfunctions of intestinal microflora.

Microbes and Human Healthcare **04 hrs**

Probiotics in prevention and treatment of diseases, recycling of vital elements, sewage treatment, bioremediation and insect pest control.

UNIT III **12 hrs**

Antimicrobial Agents **06 hrs**

Classification, mechanism of actions and uses of antimicrobial agents against bacteria, fungi and virus with specific examples. Principles of selective toxicity.

Evaluation of microbial products and disinfectants **06 hrs**

Microbiological assay of antibiotics, vitamins and amino acids. Evaluation of bacteriostatic and bactericidal activity of disinfectants.

Unit IV **10 hrs**

Microbial Biofilms **05 hrs**

Biofilms in nature and consequence to health. Tolerance of biofilms to antimicrobials, mechanisms of biofilm tolerance, treatment of chronic biofilm infections.

Microbial Resistance **05 hrs**

Origins of resistance, mechanism of resistance and multiple drug resistance. Prevention of MDR, antibiotic stewardship.

UNIT V **10 hrs**

Microbial Genetics, Gene Expression and Regulation

Differences in the genetic organization of prokaryotes and eukaryotes. DNA structure and replication, RNA synthesis and processing, Protein synthesis: transcription and translation, Genetic code and regulation of gene expression, Mutations and DNA repair mechanisms Plasmids and transposons. Methods of gene transfer in bacteria.

REFERENCES

1. Hugo and Russel's Pharmaceutical Microbiology: WB Hugo and AD Russel. 8th Edition, Blackwell Scientific publications.
2. Microbiology – An introduction: Gerard J Tortora, Berdell R Funke, Christine L Case. 12th Edition, Pearson Education.
3. Probiotic Bactria and Their Effect on Human Health and Wellbeing: Edited by A Guarino, EMM Quigley and WA Walker. Karger Medical and Scientific Publishers.
4. Prescott's Microbiology: Christopher J, Woolverton P, Sherwood L, Willey J. 10th Edition, McGraw-Hill Education.
5. Microbiology: Pelczar MJ, Chan ECS and Krieg NR. 7th Edition, Tata McGraw-Hill.

MPHARM – PHARMACEUTICAL BIOTECHNOLOGY (MPB)

SEMESTER I

PBT-MPB103T: BIOPROCESS ENGINEERING AND TECHNOLOGY

COURSE CODE	PBT-MPB103T
COURSE TITLE	BIOPROCESS ENGINEERING AND TECHNOLOGY (Theory)

SCOPE / SUMMARY	**OBJECTIVES / COURSE OUTCOMES**
The course is designed to provide knowledge to the students in invaluable areas of bioprocess technology. It enables us to develop skills to design and operate diverse types of fermenters and to understand and implement various fermentation procedures. It trains the students in scale up and scale down fermentation operations	Upon completion of this course the student should be able to understand: 1. The basics of fermentation technology and design of fermenters 2. The application in mass transfer and rheological behavior of fermented broth 3. The upstream and downstream operations, scale up and scale down processing 4. Use of microorganisms in the industrial production of nanoparticles, biotransformation and enzymology 5. The production of important microbial metabolites and recombinant products

Course Contents and Assessment Plan

Sl. No.	**Course Content**	**Syllabus (Chapters or Units with hours)**	**Marks of assessment**	**Distribution of marks of assessment**		
				Sessional exam (*30% of marks of assessment)*		**End Sem exam** (*70% of marks of assessment)*
				S1	**S2**	
1	Understand the fundamentals microbial growth, design of fermenters and types of fermenters.	Unit I (12 hrs)	23	8		15
2	Learn the basics of mass transfer including the theory, methods of measurement, factors that affect them. Appreciate and learn the rheological properties of fermented broth that affect bioprocessing.	Unit II (10 hrs)	21		6	15
3	Understand the theory of upstream and downstream processing.	Unit III (10 hrs)	20		5	15
4	Learn the sources, production, reusability of enzymes, microbial	Unit IV (10 hrs)	20	5		15

	production of nanoparticles and biotransformation.					
5	Understand the principle involved in production, recovery, and purification of pharmaceutically important microbial metabolites and recombinant proteins.	Unit V (10 hrs)	21	2	4	15
Total Marks of Assessment			105	15	15	75

PBT-MPB103T: BIOPROCESS ENGINEERING AND TECHNOLOGY

THEORY **52 hrs**

UNIT I **12 hrs**

Fundamental Aspects of Fermentation Technology **04 hrs**

Screening, strain improvement techniques, microbial growth kinetics, continuous vs batch cultures, the concept of continuous processing.

Engineering Aspects of Bioprocess **06 hrs**

Fermenters: Basic features with an emphasis on agitators, aeration systems, inoculation and sampling ports, pH, temperature and foam control devices, instrumentation, and control.

Configurations of Bioreactors **02 hrs**

CSTR, tower, airlift, packed bed, hollow fiber, fluidized bed, and mammalian cell culture fermenters.

UNIT II **10 hrs**

Mass Transfer **06 hrs**

Theory, diffusional resistance to oxygen requirements of microorganisms, measurement of mass transfer coefficient and factors affecting them, effects of aeration and agitation on mass transfer, supply of air, air compressing, cleaning and sterilization of air and plenum ventilation, air sampling and testing standards for air purity.

Rheology **04 hrs**

Rheological properties of fermentation broths and their importance in bioprocessing.

UNIT III **10 hrs**

Upstream Processing **05 hrs**

Media and inocula considerations, microbial product formation and kinetics, aeration and agitation requirements, scale up and scale down of fermentation process.

Downstream Processing **05 hrs**

Product separation and purification – the concepts, equipment and applications of different methods namely, filtration, centrifugation, extraction, precipitation, adsorption, dialysis, ultrafiltration, reverse osmosis, chromatography, crystallization and drying.

UNIT IV **10 hrs**

Enzyme Technology **05 hrs**

Sources of enzymes, enzyme stability and kinetic studies. Enzyme immobilization technique and its applications.

Microbial production of nanoparticles **03 hrs**

Introduction, biosynthesis of extracellular and intracellular nanoparticles, Metal capture, enzymatic reduction, and capping. Advantages of microbial nanoparticles.

Microbial Transformation **02 hrs**

Introduction, application of microorganisms in biotransformation of steroids and alkaloids.

UNIT V **10 hrs**

Industrial Production of Microbial Metabolites and Recombinant Products

a. Primary metabolites: Alcohol, Citric acid, Glutamic acid, and Lysine

b. Secondary metabolites: Penicillin and Streptomycin

c. Recombinant proteins: Erythropoiten and Monoclonal antibodies

d. Enzymes: Streptokinase and Asparaginase

REFERENCES

1. Principles of Fermentation Technology: Peter Stanbury, Allan Whitaker, Stephen Hall. 3rd Edition, Elsevier.
2. Industrial Microbiology: LE Casida. 3rd Edition, John Wiley & Sons Inc.
3. Pharmaceutical Biotechnology - Concepts and applications: Gary Walsh. Wiley Publications, 2007.
4. Bioprocess Engineering - Basic concepts: Michael L Shuler and Fikret Kargi. 3rd Edition, Pearson Education Inc., Indian reprint.
5. Biochemical Engineering – Fundamentals: James E Bailey and David F Ollis. 2nd Edition, Mc Graw Hill Book Company, Indian Edition.

6. Biotechnology - A textbook of industrial microbiology: Wulf Crueger and Anneliese Crueger. 3rd Edition, Panama Publishing Corporation, Indian reprint.
7. Biotechnology - The Biological Principles: MD Trevan, S Boffey, KH Goulding and P.F. Stanbury. Tata McGraw-Hill Edition.
8. Nanobiotechnology – Concepts, applications and prospective: CM Niemeyer and CA Mirkin. Wiley.

MPHARM – PHARMACEUTICAL BIOTECHNOLOGY (MPB)

SEMESTER I

PBT-MPB104T: ADVANCED PHARMACEUTICAL BIOTECHNOLOGY

COURSE CODE	PBT-MPB104T
COURSE TITLE	ADVANCED PHARMACEUTICAL BIOTECHNOLOGY (Theory)

SCOPE/Summary	**OBJECTIVES/Course Outcomes**
This course has been designed to provide the knowledge to the students to develop skills in recent advancements in pharmaceutical biotechnology and enrich students with status of development and economic importance of biotechnological products.	Upon completion of this course the student should be able to: 1. Understand and appreciate genetic engineering techniques in gene manipulation, rDNA technology and gene amplification. 2. Understand the overview of pharmacogenomics and SNPs. 3. Understand the concepts and newer developments in cell culturing including stem cells. 4. Learn the latest technologies in biotechnological products such as Biosensors, PCR, NGS and Microarray technology. 5. Learn the various stages involved in drug discovery and development.

Course Contents and Assessment Plan

Sl. No.	**Course Contents**	**Syllabus (Chapters or Units with hours)**	**Marks of assessment**	**Distribution of marks of assessment**		
				Sessional exam (*30% of marks of assessment)*		**End Sem exam** (*70% of marks of assessment)*
				S1	S2	
1	Understand the technique of recombinant DNA technology to produce pharmaceutically important proteins and transgenic animals.	Unit I (12 hrs)	23	8		15
2	Appreciate and understand the principle, importance and applications of pharmaco-genomics and gene therapy in modern pharmaceutical biotechnology.	Unit II (10 hrs)	22	7		15
3	Learn the basics of culturing of animal, plant and stem cells and their applications.	Unit III (10 hrs)	21		6	15
		Unit IV (5 hrs)	8		3	5
4	Understand the theory and applications of	Unit IV (5 hrs)	12		2	10

	polymerase chain reaction and biosensors.					
5	Advanced biotechnological methods used in drug development processes	Unit V (10 hrs)	19		4	15
Total marks of assessment			105	15	15	75

PBT-MPB104T: ADVANCED PHARMACEUTICAL BIOTECHNOLOGY

THEORY

52 hrs

UNIT I **12 hrs**

Genetic Engineering **10 hrs**

Techniques of gene manipulation, cloning strategies, procedures, cloning vectors, restrictive endonucleases, DNA ligases, recombinant clone selection strategies, prokaryotic and eukaryotic hosts. Applications of genetic engineering in the production of;

- Regulatory proteins: Interferon, Interleukins
- Blood products: Erythropoietin
- Vaccines: Hepatitis-B
- Hormones: Insulin

Transgenic Technology **02 hrs**

Principles and applications of transgenic animals.

UNIT II **10 hrs**

Pharmacogenomics **08 hrs**

The human genome project: a brief study. Overview and advances in Pharmacogenomics, individual's variabilities to drug response, polymorphisms, types, detection of single nucleotide polymorphism (SNP), SNP in drug metabolizing enzymes, applications. Personalized medicines Gene therapy: Gene augmentation therapy (GAT), gene inhibition therapy, gene editing using CRISPR-Cas9.

Analysis of SNP **02 hrs**

RFLP, RAPD, AFLP and SNP genotyping by fragment analysis.

UNIT III **10 hrs**

Animal Cell Culture **06 hrs**

Fundamentals of animal cell culture, primary, established and transformed cell cultures, growth requirements, facilities required and applications of cell culture in drug discovery, development and pharmaceutical research. Growth of viruses in cell culture and its applications. Screening techniques; cytotoxicity, anti-tumor and anti-viral assays.

Plant Tissue Culture **04 hrs**

Introduction to the concept, explant preparation, callus induction, regeneration, morphogenesis, and applications.

UNIT IV **10 hrs**

Stem Cell Biology **05 hrs**

Fundamentals of stem cell biology, types, cell differentiation, identification methods, induced pluripotent stem cells, application in therapeutics. Concept and application of tissue engineering.

Biosensors: Overview, types, biological recognition elements and applications. **02 hrs**

Polymerase Chain Reaction: **03 hrs**

Theory, types, designing of primers, melting point determination, instrumentation, analysis of results and applications.

UNIT V **10 hrs**

Nucleotide Sequencing Methods **05 hrs**

Sequencing genes and short stretches: Sanger sequencing, microarray-based sequencing, 16s rRNA sequencing, 18s rRNA sequencing.

Genome sequencing: Next generation sequencing (NGS), polony sequencing, pyrosequencing, shotgun metagenomics sequencing.

Microarray Technology **02 hrs**

Principle, types, instrumentation, and applications

Drug Development Process **03 hrs**

Drug discovery and development, preclinical studies, phases of clinical trials.

REFERENCES

1. Principles of Gene Manipulation and Genomics: S.B. Primrose and R.M. Twyman, 7th Edition, Blackwell Publishing.
2. Biotechnology - The Biological Principles: MD Trevan, S Boffey, KH Goulding and P.F. Stanbury. Tata McGraw-Hill Edition.

3. Molecular Biotechnology – Principle and applications of recombinant DNA: Bernard R. Glick, Jack J. Pasterank, Cheryl L. Patten, 4th Edition, ASM Press.
4. Culture of Animal Cells – A manual of basic technique: R. Ian Freshney, 6th Edition, Willy Blackwell Publishing.
5. Pharmaceutical Biotechnology - Concepts and applications: Gary Walsh, 2007, Wiley Publications.
6. Plant Tissue Culture – Techniques and experiments: Roberta Smith, 3rd Edition, Academic Press.
7. Stem Cells – From bench to bedside: Edited by Ariff Bongso and Eng Hin Lee, World Scientific.

MPHARM – PHARMACEUTICAL BIOTECHNOLOGY (MPB)

SEMESTER I

PBT-MPB105P: PHARMACEUTICAL BIOTECHNOLOGY PRACTICAL I

COURSE CODE	PBT-MPB105P
COURSE TITLE	PHARMACEUTICAL BIOTECHNOLOGY PRACTICAL – I

SCOPE/SUMMARY	**OBJECTIVE/COURSE OUTCOMES**
This subject is designed to gain practical skills on various basic and analytical microbiological techniques which are helpful in the drug discovery and development. This subject also helps the students to understand the practical aspects of bioprocess technology which includes up-stream and down-stream processing.	Upon completion of this course the student should be able to: 1. Understand the importance of analytical techniques in identification and analysis of drugs and biological products. 2. Experiment that helps in the isolation, identification, estimation of microorganisms from various sources 3. Learn microbial techniques used in the analysis of pharmaceutical preparations. 4. Analyze the basic fermentation techniques of pharmaceutically important microbial products including their up and down stream process techniques.

Course Contents and Assessment Plan

Sl No.	**Course Contents**	**Syllabus (Chapters or Units with hours)**	**Total Marks of assessment**	**Distribution of assessment marks**	
				Sessional exam (25 *% of total marks of assessment)* **S1**	**End Sem exam** (75 *% of total marks of assessment)*
1	Experiment to identify or analyze or estimate pharmaceutical active ingredients / formulations and biological samples. Determination of MIC and thermal death kinetics.	Experiments 1 to 6, 9 and 16 (40 hrs)	33	5	28
2	Inculcate best practices and skills to isolate, identify and maintain industrially important microorganisms. Develop skills of analyzing microorganisms in pharmaceutical products, water and milk. Use of	Experiments 7 to 11 (60 hrs)	50	13	37

	microorganisms in analyzing pharmaceutical preparations.				
3	Develop skills for studying growth curve and doubling time of microorganisms, fermentative production of useful microbial products, whole cell immobilization, replica plating and bioautography techniques.	Experiments 12 to 15, 17 and 18 (56 hrs)	47	12	35
Total Marks of Assessment			130	30	100

PBT-MPB105P: PHARMACEUTICAL BIOTECHNOLOGY PRACTICAL I

1. Good laboratory practice in microbiology.
2. Analysis of Pharmacopeial compounds and their formulations by UV Vis spectrophotometer
3. Simultaneous estimation of multi components containing formulations by UV spectrophotometry
4. Experiments based on HPLC
5. Experiments based on Gas Chromatography
6. Estimation of riboflavin/quinine sulphate by fluorimetry
7. Estimation of sodium/potassium by flame photometry
8. Evaluation of aseptic area
9. Primary and secondary screening of soil microorganisms
10. Microbial contamination of water and biochemical parameters.
11. Determination of Minimum Inhibitory Concentration by gradient plate technique and serial dilution method.
12. Construction of growth curve and determination of specific growth rate and doubling time
13. Fermentation process of alcohol and wine production
14. Fermentation of vitamins and antibiotics
15. Whole cell immobilization engineering
16. Thermal death kinetics of bacteria

17. Replica plating
18. Bio-autography.

References:

1. Principles of Instrumental Analysis, Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern Press, Bangalore, 1998.
2. Introduction to Spectroscopy, Donald L Pavia. 8th edition, CENGAGE Learning, USA
3. Contemporary Practice of Chromatography, Poole, Colin F and Sheila A Schuette, Elsevier Science Publishers.
4. Indian Pharmacopeia 2018: Vol. 1., Published by Indian Pharmacopoeia Commission, 2017
5. Microbiology – An introduction: Gerard J Tortora, Berdell R Funke, Christine L Case. 12th Edition, Pearson Education.
6. Microbiology: Pelczar MJ, Chan ECS and Krieg NR. 7th Edition, Tata McGraw-Hill.
7. Principles of Fermentation Technology: Peter Stanbury, Allan Whitaker, Stephen Hall. 3rd Edition, Elsevier.
8. Industrial Microbiology: LE Casida. 3rd Edition, John Wiley & Sons Inc.
9. Bioprocess Engineering - Basic concepts: Michael L Shuler and Fikret Kargi. 3rd Edition, Pearson Education Inc., Indian reprint.
10. Biochemical Engineering – Fundamentals: James E Bailey and David F Ollis. 2nd Edition, Mc Graw Hill Book Company, Indian Edition.
11. Biotechnology - A textbook of industrial microbiology: Wulf Crueger and Anneliese Crueger. 3rd Edition, Panama Publishing Corporation, Indian reprint.
12. Biotechnology - The Biological Principles: MD Trevan, S Boffey, KH Goulding and P.F. Stanbury. Tata McGraw-Hill Edition.

MPHARM – PHARMACEUTICAL BIOTECHNOLOGY (MPB)

SEMESTER I

PBT-MPL106S: SEMINAR IN PHARMACEUTICAL BIOTECHNOLOGY

COURSE CODE	PBT- MPL106S
COURSE TITLE	SEMINAR IN PHARMACEUTICAL BIOTECHNOLOGY

SCOPE/SUMMARY	**OBJECTIVE/COURSE OUTCOMES**
The subject is designed to create an environment where teachers trains the students to critically think about a research problem and develop and fine tune presentation and academic writing skills in the field of Pharmaceutical Biotechnology.	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 biotechnology. 2. Learn to organize complex pharmaceutical biotechnology concepts using audio-visual aids. 3. Acquire communication and presentation skills. 4. Effectively answer the questions raised by peers and stand scientific scrutiny. 5. Develop a write-up on the subject of seminar presentation. 6. Cultivate a sense of upgradation of knowledge through self and continuous learning

Course Contents and Assessment Plan

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

MPHARM – PHARMACEUTICAL BIOTECHNOLOGY (MPB)

SEMESTER II

PBT-MPB201T: PROTEINS AND PROTEIN FORMULATIONS

COURSE CODE	PBT-MPB201T
COURSE TITLE	PROTEINS AND PROTEIN FORMULATIONS (Theory)

SCOPE/SUMMARY	**OBJECTIVE/COURSE OUTCOMES**
This course is designed to impart knowledge and skills necessary for understanding the fundamental aspects of proteins and their formulations. Basic theoretical discussions of the structures of proteins, analysis of proteins, protein purifications and development of peptide and protein-based drugs and formulations are included in this course. This would help the students to clarify the various concepts of biopharmaceuticals.	At the completion of this course, it is expected that students will be able to understand, 1. Protein structure identification and characterization 2. Various methods of purification and analysis of proteins 3. Peptide and protein-based drugs 4. Protein formulation and delivery 5. Basics of biosimilars, Pharmacokinetics, and Pharmacodynamics of biologics

Course Contents and Assessment Plan

Sl. No.	**Course Contents**	**Syllabus (Chapters or Units with hours)**	**Marks of assessment**	**Distribution of marks of assessment**		
				Sessional exam (*30% of marks of assessment)*		**End Sem exam** (*70% of marks of assessment)*
				S1	S2	
1	Understand the basics of protein structure and methods used in protein characterization.	Unit I (12 hrs)	25	5		20
2	Learn various techniques that are commonly used in protein purification and analysis.	Unit II (10 hrs)	20		10	10
3	Understand the basics of peptide and protein-based therapeutics.	Unit III (10 hrs)	20	5		15
4	Understand the formulation and delivery of proteins and peptide formulations.	Unit IV (10 hrs)	20	5		15
5	Understand the pharmacokinetic and pharmacodynamic properties of peptide and protein formulations. Appreciate the importance of biosimilars and approaches used in characterizing them.	Unit V (10 hrs)	20		5	15
		Total Marks of Assessment	105	15	15	75

PBT-MPB201T: PROTEINS AND PROTEIN FORMULATIONS

THEORY **52 hrs**

UNIT I **10 hrs**

Protein Engineering **05 hrs**

Overview: Amino acids - types, peptide bond chemistry. Protein structure - primary, secondary, tertiary and quaternary structures. Protein folding and stability.

Proteomics **05 hrs**

Protein identification and characterization: Methods/strategies for protein identification, determination of amino acid composition, sequence and molecular mass of protein. Sanger degradation, Edman degradation, proteolytic cleavage and peptide digestion. Mass spectroscopic methods for protein analysis, protein quantification techniques.

UNIT II **12 hrs**

Protein Purification **08 hrs**

Cell separation, cell lysis techniques and removal of nucleic acids. Initial and final protein purification and concentration techniques: protein precipitation, gel filtration, ion-exchange, affinity and hydrophobic interaction chromatography, two liquid phase separation, ultrafiltration and dialysis.

Analysis of Proteins **04 hrs**

Electrophoresis: SDS-PAGE, 2-Dimensional gel electrophoresis and isoelectric focusing. HPLC, Circular Dichroism (CD) spectroscopy, and fluorescence spectroscopy.

UNIT III **10 hrs**

Peptide-Based Drugs **04 hrs**

Overview of peptide chemistry, peptidomimetics and approaches, classification, pseudopeptides, and design of conformationally restricted peptides and their therapeutic applications.

Protein-Based Products **06 hrs**

Study on the source, mechanism of action and therapeutic application of following categories of products: Cytokines – interferons, interleukins and TNF. Growth factors – erythropoietin, epidermal growth factor (EGF), asparaginase. Therapeutic hormones – insulin and glucagon. Monoclonal antibodies and vaccines.

UNIT IV **10 hrs**

Protein Formulations **06 hrs**

Stability of proteins: Chemical and physical stability, protein destabilization (denaturation), aggregation and precipitation. Selection of protein stabilizers and excipients. Biopharmaceutical considerations such as sterility, viral decontamination and pyrogen removal, shelf life of protein and peptide-based formulations.

Delivery of Biologicals **04 hrs**

Routes of administration, absorption enhancement, approaches for rate controlled and target specific delivery of peptides and proteins.

UNIT V **10 hrs**

Pharmacokinetics and Pharmacodynamics **06 hrs**

Pharmacokinetics: ADME of peptide and protein-based formulation. Pharmacodynamics: direct and indirect effects, PK-PD models, dose response and concentration response curves, protein binding and immunogenicity.

Biosimilars or Follow-on Biologicals **04 hrs**

Characteristics of biologicals, introduction to biogenerics and biosimilars, advent of biosimilars and its importance. Approaches for the characterization of biosimilars and problems associated with its characterization.

REFERENCES

1. Biotechnology - The biological principles: MD Trevan, S Boffey, KH Goulding and P.F. Stanbury. Tata McGraw-Hill Edition.
2. Pharmaceutical Biotechnology - Concepts and applications: Gary Walsh, Wiley Publications.
3. Molecular Cell Biology: Harvey Lodish, Arnold Berk, S Lawrence Zipursky, Paul Matsudaira, David Baltimore, and James Darnell. 7th Edition, W.H. Freeman and Company.
4. Pharmaceutical Biotechnology - Fundamentals and applications: Crommelin DJA, Sindelar RD, Meibohm B. Springer New York, 2013.
5. Therapeutic Peptides and Proteins - Formulation, processing and delivery systems: Banga AK. 3rd Edition. CRC Press.
6. Pharmaceutical Formulation Development of Peptides and Proteins: Hovgaard L, Frokjaer S, van de Weert M. 2nd Edition. Taylor & Francis.
7. Protein Formulation and Delivery: McNally EJ, McNally E, Hastedt JE. 2nd Edition, CRC Press.
8. Biosimilars and Interchangeable Biologics - Strategic elements: Niazi SK. CRC Press, 2016.

MPHARM – PHARMACEUTICAL BIOTECHNOLOGY (MPB)

SEMESTER II

PBT-MPB202T: IMMUNOTECHNOLOGY

COURSE CODE	PBT-MPB202T
COURSE TITLE	IMMUNOTECHNOLOGY (Theory)

SCOPE/SUMMARY	**OBJECTIVES/COURSE OUTCOMES**
This course is designed to impart knowledge on basics of Immunology and immune system, biochemistry of antigens, vaccine technology, production and applications of monoclonal antibodies, immunological disorders and immunodiagnosis.	On completion of this course, the students will be able to; 1. Understand the basics of immunology and natural immune system 2. Appreciate the composition and functioning of adaptive immune system 3. Develop knowledge on antigens and vaccine technology 4. Assess immunological disorders and cancer immunology 5. Understand the concept of immunodiagnostics and monoclonal antibodies

Course Contents and Assessment Plan

Sl. No.	**Course Contents**	**Syllabus (Chapters or Units with hours)**	**Marks of assessment**	**Distribution of marks of assessment**		
				Sessional exam (*30% of marks of assessment)*		**End Sem exam** (*70% of marks of assessment)*
				S1	S2	
1	Understand the organization and cells involved in our immune system. Also to learn the mechanism and importance of inflammation process.	Unit I (12 hrs)	25	5		20
2	Learn the mechanism and phases of adaptive immune system.	Unit II (10 hrs)	20		5	15
3	Understand the properties of immunogens, antigen-antibody interactions and conventional and novel methods of vaccine production.	Unit III (10 hrs)	20		5	15
4	Understand the mechanism and consequences of different immunological disorders and to appreciate the role of immune system in cancer.	Unit IV (10 hrs)	20	5		15
5	Appreciate and learn the mechanism and applications of hybridoma technology and immunodiagnostics	Unit V (10 hrs)	20	5	5	10
		Total Marks of Assessment	105	15	15	75

PBT-MPB202T: IMMUNOTECHNOLOGY

THEORY **52 hrs**

UNIT I **12 hrs**

Cells, Organs and Micro-environments of Immune System **04 hrs**

Cells of the immune system, primary and secondary lymphoid organs, functions of lymphoid organs.

Innate Immunity **04 hrs**

Factors affecting infection, first line of defense - anatomical barriers of infection, second line of defense - phagocytosis, induced cellular innate response, natural killer cells.

Complementary System **02 hrs**

Components, activation, function in biological aspect and pathogenic effect of complements system.

Inflammation **02 hrs**

Introduction, phases, types and importance of inflammation in immunity process.

UNIT II **10 hrs**

Adaptive Immune System **02 hrs**

Third line of defense, active and passive immunity, cells involved and cytokines.

Humoral and Cell Mediated Immunity **08 hrs**

Humoral immunity: Activation, hematopoiesis, cell development and maturation of B – Lymphocytes. Structure, classes, theories of antibody formation, affinity and function of immunoglobulins. Cell mediated immunity: T-lymphocytes - types, activation, development, selection and maturation.

UNIT III **10 hrs**

Antigens **04 hrs**

Properties of immunogens, structure, antigen-antibody interaction mechanisms, MHC role and types.

Vaccine Technology **06 hrs**

Introduction, types, conventional and novel methods of vaccines, conjugate or multivalent vaccines, vaccine adjuvants. Routes of vaccination and the significance of vaccination program.

UNIT IV **10 hrs**

Immunological Disorders **06 hrs**

Autoimmune disorders and treatment, hypersensitivity reaction, transplantation immunity, immunodeficiency disorders.

Cancer and the Immune System **04 hrs**

Tumor antigens, the immune response to cancer and cancer immunotherapy.

UNIT V **10 hrs**

Hybridoma Technology **05 hrs**

Cell fusion methods, selection and screening techniques. Production and purification of monoclonal antibodies and their applications.

Immunodiagnostics **05 hrs**

Principles and applications of ELISA, Radio-immuno Assay, Blotting techniques, immuno-electrophoresis, immunofluorescence and chemiluminescence assay.

REFERENCES

1. Kuby Immunology: Owen, Punt and Stranford. 7th Edition, W.H. Freeman and Company.
2. Immunodiagonstics: SC Rastogi, New Age International, 1996.
3. Immunology and Immunotechnology: Ashim Chakravarthy. Oxford University Press, 2006.
4. Immunology - A short course: Richard Coico and Geoffrey Sunshine. 7th Edition, Wiley Blackwell.

MPHARM – PHARMACEUTICAL BIOTECHNOLOGY (MPB)

SEMESTER II

PBT-MPB203T: BIOINFORMATICS AND COMPUTATIONAL BIOTECHNOLOGY

COURSE CODE	PBT-MPB203T
COURSE TITLE	BIOINFORMATICS AND COMPUTATIONAL BIOTECHNOLOGY (Theory)

SCOPE/Summary	**OBJECTIVES/Course Outcomes**
This paper has two components; the first part deals with the molecular biology of eukaryotic cells. A sound knowledge of these processes is essential for students to apply in bioinformatics and computational biotechnology. The second part - bioinformatics has been designed to provide the necessary knowledge to the students in applied aspects of bioinformatics, which strengthens the student's ability to make use of databases and computational tools in the drug discovery and design.	At the completion of this course, it is expected that the students will be able to understand; 1. Protein expression and its regulation in higher organisms 2. Cell communication, cell cycle and molecular basis of cancer. 3. Concepts for bioinformatics, data mining and data analysis. 4. Bioinformatics approaches to analyze proteins diversity and drug designing.

Course Contents and Assessment Plan

Sl. No.	**Course Contents**	**Syllabus (Chapters or Units with hours)**	**Marks of assessment**	**Distribution of marks of assessment**		
				Sessional exam (*30% of marks of assessment)*		**End Sem exam** (*70% of marks of assessment)*
				S1	S2	
1.	Learn the importance of gene expression regulation in higher organisms	Unit I (10 hrs)	20	5		15
2.	Understand various signal transduction pathways, receptors and cell messengers. Learn the events in a cell division, regulation of cell cycle and molecular basis of cancer.	Unit II (10 hrs)	20	5	5	10

	Cell communication, cell cycle and molecular basis of cancer.	Unit III (10 hrs)	20		5	15
3.	Understand the tools and techniques used in data mining and data analysis.	Unit IV (12 hrs)	25	5		20
4.	Learn to analyse proteins diversity and drug designing using basic bioinformatics tools.	Unit V (10 hrs)	20		5	15
Total Marks of Assessment			105	15	15	75

PBT-MPB203T: BIOINFORMATICS AND COMPUTATIONAL BIOTECHNOLOGY

THEORY **52 hrs**

Molecular Biology

Unit I **10 hrs**

Molecular Genetics

Eukaryotic cell morphology and structure, chromosomal and mitochondrial DNA, genome organization in eukaryotes, mutations and repair mechanisms. Transcription, RNA processing, translation, post-translational processing in eukaryotes.

UNIT II **10 hrs**

Overview of Cell Cycle **5 hrs**

Overview of the cell-cycle: Phases of cell-cycle, checkpoints, cyclins, cyclin-dependent kinases (CDKs).

Cell cycle regulation **5 hrs**

Cell-cycle regulation, abnormalities, oncogenes and tumor suppressor genes. Detection of DNA damage, apoptosis and necrosis. Pathways of apoptosis. Manipulating cell-cycle for therapeutic strategies.

UNIT III **10 hrs**

Basic Cancer Biology **05 hrs**

Hallmarks of cancer, multitep process of carcinogenesis, tumor heterogeneity and clonal evolution. Key factors contributing to cancer progression and metastasis.

Overview of Cell Signaling **05 hrs**

Signal transduction pathways, signaling molecules, receptors and second messengers.

Receptor tyrosine kinases and their downstream signaling cascades, role of intracellular signaling molecules in cellular processes. Study of the following cell signaling pathways: Notch signaling pathway, Wnt signaling pathway and Hedgehog signaling pathway.

Bioinformatics

UNIT IV **12 hrs**

Introduction to Bioinformatics **01 hrs**

Definition, history, information theory and biology, applications of bioinformatics.

Biological Databases **03 hrs**

Protein and nucleic acid sequence databases, structural databases, primary and secondary databases, genome databases, introduction to data mining.

Sequence Analysis **08 hrs**

Sequence alignment: Pairwise and Multiple sequence alignment methods. Sequence similarity searching: FASTA and BLAST, genome annotation techniques, gene prediction methods, evolutionary change in nucleotide sequences, amino acid substitution matrices, and phylogenetic analysis.

UNIT V **10 hrs**

Protein Informatics **02 hrs**

Protein structure levels, secondary structure elements, structural representation and various styles of protein display, buried and exposed residues.

Protein Structure Prediction **03 hrs**

Secondary and tertiary structure prediction methods. Homology modeling: evaluation and applications. Threading and Ab initio methods.

Target Searching and Drug Designing **03 hrs**

Targets in a diseases, target discovery and target modulators. Drug designing process, timeline for drug development, leads, and drugs, lead discovery, libraries of ligands, prediction of drug quality, ADMET prediction and analysis.

Docking **02 hrs**

Rational drug design, target-ligand interactions, active site analysis, methods for protein-ligand docking, screening small molecule databases, high throughput and virtual screening, scoring, analyzing docking results, validation studies and applications.

REFERENCES

1. Bioinformatics Sequence and Genome Analysis: David W Mount. 2nd Edition, CBS Publishers and Distributors.
2. Bioinformatics - Concepts skill and applications: SC Rastogi et. al. 1st Edition, CBS Publishers and Distributors.
3. Protein Structure and Molecular Properties: TE Creighton. 2nd Edition, W. H. Freeman and Company.
4. Bioinformatics - A practical guide to the analysis of genes and proteins: Andreas D Baxevanis, BF Francis Ouellette. 2nd Edition. John Wiley & Sons, Inc.
5. Introduction to Bioinformatics: Arthur M. Lesk, Oxford University Press 2002.
6. Bioinformatics for DNA Sequence Analysis: David Posada. Humana press, 2008.
7. Biochemistry and Molecular Biology: Papachristodoulou D, Snape A, Elliott WH, Elliott DC. 5th Edition, OUP Oxford.
8. Essentials of Molecular Biology: Malacinski GM. 4th Edition, Jones & Bartlett Learning, LLC.
9. The Cell - A molecular approach: Cooper GM and Hausman RE. 7th Edition. Sinauer.
10. Molecular Cell Biology: Berk A, Kaiser CA, Lodish H, Amon A, Ploegh H, Bretscher A. 8th Edition. Macmillan Learning.
11. Cell and Molecular Biology - Concepts and experiments; Karp G. 6th Edition. John Wiley & Sons.

MPHARM – PHARMACEUTICAL BIOTECHNOLOGY (MPB)

SEMESTER II

PBT-MPB204T: BIOLOGICAL EVALUATION AND DRUG THERAPY

COURSE CODE	PBT-MPB204T
COURSE TITLE	BIOLOGICAL EVALUATION AND DRUG THERAPY (Theory)

SCOPE/SUMMARY	**OBJECTIVES/COURSE OUTCOMES**
The course is designed to provide knowledge to the students in the areas of quality assurance, control, formulation and regulatory aspects of biotechnological products.	Upon completion of this course the student should be able to: 1. Understand the general concept of standardization of biologicals. 2. Understand the quality control of biological products. 3. Learn the concept of clean room and evaluation of biotechnological formulations 4. Appreciate the bioavailability and pharmacokinetic parameters of biopharmaceuticals. 5. Regulations governing the approval of biological products, documentation and batch release procedures

Course Contents and Assessment Plan

Sl. No.	**Course Contents**	**Syllabus (Chapters or Units with hours)**	**Marks of assessment**	Distribution of marks of assessment		
				Sessional exam (*30% of marks of assessment)*		**End Sem exam** (*70% of marks of assessment)*
				S1	S2	
1	Understand the general principles involved in Quality testing of biologicals viz., standardization, toxicity testing and preclinical studies	Unit I (12 hrs)	25	5		20
		Unit II (10 hrs)	20	5		15
2	Clean room concepts and evaluation of biotechnological formulations	Unit III (10 hrs)	20		5	15
3	Bioavailability and pharmacokinetic parameters of biopharmaceuticals	Unit IV (10 hrs)	20	5	5	10
4	Understand the regulations governing the approval of biopharmaceuticals, documentation and batch release procedures	Unit V (10 hrs)	20		5	15
Total marks of assessment			105	15	15	75

PBT-MPB204T: BIOLOGICAL EVALUATION AND DRUG THERAPY

THEORY **52 hrs**

UNIT I **12 hrs**

Biological Standardization **04 hrs**

General principles, scope and limitation of bio-assay, bioassay of some official drugs.

Preclinical Drug Evaluation **06 hrs**

Preclinical drug evaluation of its biological activity, potency and toxicity, toxicity test in animals including acute, sub-acute and chronic toxicity, ED_{50} and LD_{50} determination, special toxicity tests like teratogenecity and mutagenecity.

Guidelines for Toxicity Studies **02 hrs**

Various guidelines for toxicity studies. Animal experiments assessing safety of biopharmaceuticals.

UNIT II **10 hrs**

Quality Control and Analysis of Biological Products

Concepts and protocols of sterility testing, pyrogen testing, and microbial limit tests. Detection of protein contaminants in protein formulations by analytical and immunological methods.

UNIT III **10 hrs**

Clean Room Concepts **04 hrs**

Layout, facilities, HEPA and ULPA filters, biosafety cabinets and various classes, biosafety levels, personnel controls and air sampling.

Evaluation of Biotechnological Formulations **06 hrs**

Protein based contaminants, removal of altered forms of proteins, detection of impurities, immunological considerations, microbial contamination and their analysis. Analysis of biological activity, stability testing, shelf-life determination, biophysical characterization and forced degradation studies of biopharmaceuticals.

UNIT IV **10 hrs**

Bioavailability **05 hrs**

Objectives and consideration in bio-availability studies, concept of equivalents, measurements of bio-availability. Determination of the rate of absorption, bioequivalence and its importance, regulatory aspects of bio-availability and bioequivalence studies for conventional dosage forms and controlled drug delivery systems of Biopharmaceuticals.

Pharmacokinetics **05 hrs**

Pharmacokinetics: Basic consideration, pharmacokinetic models, application of pharmacokinetics in new drug development and designing of dosage forms and Novel drug delivery systems of Biopharmaceuticals.

UNIT V **10 hrs**

Regulatory Consideration **06 hrs**

An introduction to the regulations and documents necessary for approval of a medical product. Regulatory consideration for pre-clinical testing and clinical testing of drugs, biologics and medical devices. New drug applications for global pharmaceutical product approvals.

Documentation Requirements for Quality Assurance **02 hrs**

Batch manufacturing records (BMRs), Standard operating procedures (SOPs), Good documentation Practices (GDPs), and data integrity

Batch Release and Disposition **02 hrs**

Criteria for batch release and disposition decisions, release testing and acceptance criteria, deviation management and investigations.

REFERENCES

1. Standardization and Control of Biologicals Produced by Recombinant DNA Technology: Perkins FT, Hennessen W. International Association of Biological Standardization.
2. Biological Standardization: JH Burn. Oxford University Press.
3. Drug Discovery and Evaluation in Pharmacological Assay: HG Vogel and WH Vogel. Springer Publications.
4. Screening Methods in Pharmacology (Vol I & II): RA Turner and P Hebborn. Academic Press.
5. Pharmaceutical Biotechnology - Concepts and applications: Gary Walsh. Wiley Publications, 2007.

6. Biotechnology - The biological principles: MD Trevan, S Boffey, KH Goulding and P.F. Stanbury. Tata McGraw-Hill Edition.
7. Molecular Biotechnology - Principle and applications of recombinant DNA: Bernard R. Glick, Jack J. Pasterank, Cheryl L. Patten, 4th Edition, ASM Press.
8. Essentials of Biopharmaceutics and Pharmacokinetics: Ashutosh Kar. Elsevier.

MPHARM – PHARMACEUTICAL BIOTECHNOLOGY (MPB)

SEMESTER II

PBT-MPB205P: PHARMACEUTICAL BIOTECHNOLOGY PRACTICAL II

COURSE CODE	PBT-MPB205P
COURSE TITLE	PHARMACEUTICAL BIOTECHNOLOGY PRACTICAL – II

SCOPE/SUMMARY	**OBJECTIVE/COURSE OUTCOMES**
This subject is designed to gain practical skills on various basic and analytical techniques which are helpful in the study of basic life sciences, drug discovery and development. This subject also helps the students to understand the practical aspects of genetics, cell and molecular biology.	Upon completion of this course the student should be able to: 1. Impart the skills in isolation and analysis of biological macromolecules. 2. Apply experimental and analytical skills in use of modern biotechnological tools and cell culturing. 3. Learn the skill of using microorganisms to analyze antibiotics, vitamins, pharmaceutical preparations. 4. Analyze and comprehend the immunodiagnostic and pharmacokinetics of biological preparations

Course Contents and Assessment Plan

Sl. No.	**Course Contents**	**Syllabus (Chapters or Units with hours)**	**Total Marks of assessment**	**Distribution of assessment marks**	
				Sessional exam (25 *% of total marks of assessment)* **S1**	**End Sem exam** (75 *% of total marks of assessment)*
1	Experiment to learn the skills of isolation, estimation, amplify and analysis of biological macromolecules.	Experiments 1 to 3 (40 hrs)	34	6	28
2	Inculcate best practices and skills to understand the principles and applications of bacterial genetics, gene transfer, cloning	Experiments 4 and 5 (40 hrs)	33	8	25
3	Develop skills of use and applications of bioinformatics tools such as database searching, sequence analysis, gene annotation, protein structure prediction and phylogenetic analysis.	Experiments 6 to 10 (30 hrs)	25	8	17
4	Understand and learn the techniques of culturing of animal cells, immunodiagnosis, microbiological methods used in analysis of	Expt 11 to 15 (46 hrs)	38	8	30

	pharmaceutical products, pharmacokinetics of biological products.				
Total Marks of Assessment			130	30	100

PBT-MPB205P: PHARMACEUTICAL BIOTECHNOLOGY PRACTICAL II

1. Good laboratory practices in molecular biology and cell culturing
2. Isolation and estimation of nucleic acids
3. Analysis of proteins and nucleic acids by electrophoresis
4. Polymerase chain reaction.
5. Bacterial gene transfer through transformation
6. Artificial ways of gene transfer in bacteria: Gene cloning
7. UV survival curve and Dark repair
8. Sterility testing of pharmaceutical preparations
9. Database searching
10. Sequence alignment tools
11. Protein structure prediction
12. Genome annotation methods
13. Phylogenetic analysis
14. OMICS in cancer (multi-omic data analysis)
15. Microbiological methods as per Indian Pharmacopoeia
16. Evaluation of aseptic area
17. Immunodiagnostic experiments
18. Culturing and maintenance of animal cells and cytotoxicity analysis
19. Pharmacokinetic and formulation considerations for biotechnological products

References:

1. Indian Pharmacopeia 2018: Vol. 1., Published by Indian Pharmacopoeia Commission, 2017
2. Protocols for nucleic acid analysis by non-radioactive probes. Edited by Elina Hilario and John Mackey, 2nd Edition, Humana Press, 2007.
3. Cleanroom Microbiology for the Non-microbiology by David M. Carlberg, Second Edition CRC press, 2005.

4. Biopharmaceutical, Biochemistry and Biotechnology, Second Edition, Gary Walsh, Wiley Publishers, 2003.
5. Bioinformatics - A practical guide to the analysis of genes and proteins: Andreas D Baxevanis, BF Francis Ouellette. 2nd Edition. John Wiley & Sons, Inc.
6. Introduction to Bioinformatics: Arthur M. Lesk, Oxford University Press 2002.
7. Bioinformatics for DNA Sequence Analysis: David Posada. Humana press, 2008.
8. Protein Structure and Molecular Properties: TE Creighton. 2nd Edition, W. H. Freeman and Company.
9. Immunology and Immunotechnology: Ashim Chakravarthy. Oxford University Press, 2006.
10. Culture of Animal Cells – A manual of basic technique: R. Ian Freshney, 6th Edition, Willy Blackwell Publishing.

MPHARM – PHARMACEUTICAL BIOTECHNOLOGY (MPB)

SEMESTER II

PBT-MPL206S: SEMINAR IN PHARMACEUTICAL BIOTECHNOLOGY

COURSE CODE	PBT- MPL206S
COURSE TITLE	SEMINAR IN PHARMACEUTICAL BIOTECHNOLOGY

SCOPE/SUMMARY	**OBJECTIVE/COURSE OUTCOMES**
The subject is designed to create an environment where teachers trains the students to critically think about a research problem and develop and fine tune presentation and academic writing skills in the field of Pharmaceutical Biotechnology.	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 biotechnology. 2. Learn to organize complex pharmaceutical biotechnology concepts using audio-visual aids. 3. Acquire communication and presentation skills. 4. Effectively answer the questions raised by peers and stand scientific scrutiny. 5. Develop a write-up on the subject of seminar presentation. 6. Cultivate a sense of upgradation of knowledge through self and continuous learning

Course Contents and Assessment Plan

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

MPHARM – PHARMACEUTICAL BIOTECHNOLOGY (MPB)

SEMESTER III

PHA-MRM301T: RESEARCH METHODOLOGY AND BIOSTATISTICS

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

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

Course Contents and Assessment Plan

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

PHA-MRM301T: RESEARCH METHODOLOGY AND BIOSTATISTICS

THEORY **52 hrs**

UNIT – I

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

UNIT – II

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

UNIT – III

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

UNIT – IV

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

UNIT – V

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

MPHARM – PHARMACEUTICAL BIOTECHNOLOGY (MPB)

SEMESTER III

MJC302P: JOURNAL CLUB IN PHARMACEUTICAL BIOTECHNOLOGY

COURSE CODE	MJC 302P
COURSE TITLE	JOURNAL CLUB IN PHARMACEUTICAL BIOTECHNOLOGY

SCOPE/SUMMARY	**OBJECTIVE/COURSE OUTCOMES**
The subject is designed to enhance presentation, analytical and communication skills in students. Each student will be guided to present a published research article after understanding the background and critical thinking.	Upon completion of the course the student shall be able to: 1. Learn to understand and present complex research concepts using audio-visual aids. 2. Enhance communication and presentation skills. 3. Learn to effectively respond to the questions raised by peers. 4. Cultivate a sense of upgradation of knowledge through self and continuous learning

Course Contents and Assessment Plan

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

MPHARM – CHOICE BASED INTERDISCIPLINARY COURSES

PCE-001E: GENERIC DRUG DEVELOPMENT

(15 hrs)

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

REFERENCES

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

PCE-002E: PHARMACEUTICAL DISSOLUTION TECHNOLOGY

(15 hrs)

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

REFERENCES

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

PCE-003E: PARTICULATE DRUG DELIVERY SYSTEMS

(15 hrs)

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

6 hrs

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

9 hrs

REFERENCES

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

PCE-004E: 3D PRINTING IN PHARMACEUTICAL MANUFACTURING

(15 hrs)

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

REFERENCES

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

PCH-001E: PREPARATIVE SEPARATION TECHNIQUES

(15 hrs)

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

PCH-002E: MOLECULAR MODELLING AND DRUG DESIGN

(15 hrs)

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

PCH-003E: HYPHENATED TECHNIQUES

(15 hrs)

Principle and applications of following hyphenated techniques

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

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

(15 hrs)

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

First aid procedures **1 hr**

Good laboratory practices: **2 hrs**

Personal protection **1 hr**

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

Fire safety **1 hr**

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

(15 hrs)

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

Evaluation

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

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

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

(15 hrs)

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

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

(15 hrs)

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

PQA-004E: PROFESSIONAL DEVELOPMENT

(15 hrs)

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

Assessments:

- assignments
- case studies
- portfolios
- presentations

PQA-005E: STABILITY TESTING OF DRUGS AND BIOLOGICALS

(15 hrs)

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

PQA-006E: USFDA DRUG REGULATORY AFFAIRS

(15 hrs)

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

PQA-007E: REST OF THE WORLD DRUG REGULATIONS

(15 hrs)

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

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

PQA-008E: EVALUATION OF MEDICAL DEVICES

(15 hrs)

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

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

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

Importance, scope, clinical evaluation in brief

PBT-001E: CLEAN ROOM CONCEPTS

(15 hrs)

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

Morphology, Microscopy, Growth and Controlling Growth of Microorganisms.

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

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

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

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

REFERENCES

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

PBT-002E: BIOSIMILARS

(15 hrs)

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

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

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

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

REFERENCES

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

PBT-003E: PRINCIPLES OF GENE CLONING

(15 hrs)

Unit I **3 hrs**

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

Unit II **6 hrs**

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

Unit III **6 hrs**

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

REFERENCES

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

PBT-004E: TISSUE ENGINEERING

(15 hrs)

Unit I **5 hrs**

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

Unit II **5 hrs**

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

Unit III **5 hrs**

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

REFERENCES

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

PPR-001E: RETAIL PHARMACY PRACTICE

(15 hrs)

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

REFERENCES

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

PPR-002E: FUNDAMENTALS OF MEDICAL WRITING

(15 hrs)

I. Introduction **2 hrs**

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

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

- Language and Style in Medical Writing
- Literature search

  -Data bases (Medline, PubMed, Cochrane)

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

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

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

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

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

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

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

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

REFERENCES

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

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

PPR-003E: SYSTEMATIC REVIEW AND META-ANALYSIS

(15 hrs)

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

REFERENCES:

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

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

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

Evaluation: Based on Assignments

PPR-004E: PHARMACOKINETICS DATA ANALYSIS

(Employing WinNonlin)

(15 hrs)

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

REFERENCES

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

Pre-requisites: Knowledge of basic pharmacokinetics.

Evaluation: Based on Assignments.

PHA-001E: CANCER BIOLOGY

(15 hrs)

Objectives/Course Outcomes

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

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

PHA-002E: SCREENING METHODS FOR DRUG DEVELOPMENT

(15 hrs)

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

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

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

PHA-003E: FREE RADICAL BIOLOGY AND MEDICINE

(15 hrs)

Objectives

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

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

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

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

(15 hrs)

Objectives

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

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

Guidelines for safety testing

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

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

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

PCO-001E: NUTRACEUTICALS

(15 hrs)

Scope

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

Objectives

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

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

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

REFERENCES

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

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

(15 hrs)

Scope

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

Objectives

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

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

REFERENCES

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

PCO-003E: NANOPHYTOPHARMACEUTICALS

(15 hrs)

Scope

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

Objectives

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

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

REFERENCES

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

PCO-004E: HERBAL MONOGRAPHS

(15 hrs)

Scope

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

Objectives

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

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

   Leaf: Vasaka (*Adhatoda zeylanica)*

   Root: Shatavari (*Asparagus racemosus)*

   Rhizome:Rasna *(Alpinia galanga)*

   Bark: Cinchona (*Cinchona officinalis)*

   Fruit: Pepper (*Piper nigrum)*

   Entire herb: Kalmegh *(Andrographis paniculata).*

REFERENCES

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

PRM-001E: RETAIL BUSINESS MANAGEMENT

(15 hrs)

Scope

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

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

REFERENCES

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

PRM-002E: INTELLECTUAL PROPERTY MANAGEMENT

(15 hrs)

Scope

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

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

REFERENCES

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

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

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

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

PRM-003E: GENERAL MANAGEMENT PRINCIPLES

(15 hrs)

Scope

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

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

REFERENCES

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

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

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

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

PRM-004E: ENTREPRENEURSHIP DEVELOPMENT

(15 hrs)

Scope

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

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

REFERENCES

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

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

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

MPHARM – CHOICE BASED MULTIDISCIPLINARY COURSE

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

(As prescribed from time to time)