



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 Quality Assurance

**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.

P. K. K. K.

REGISTRAR



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PHARMACY COUNCIL OF INDIA NOTIFICATION

New Delhi, the 10th December, 2014

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

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

CHAPTER I: REGULATIONS

1. Short title and commencement

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

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

2. Minimum qualification for admission

A pass in the following examinations

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

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

3. Duration of the program

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

4. Medium of instruction and examination

Medium of instruction and examination shall be in English.

5. Working days in each semester

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

6. Attendance and progress

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

7. Program/Course credit structure

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

7.1. Credit assignment

7.1.1. Theory and laboratory courses

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

7.2. Minimum credit requirements

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

8. Academic work

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

9. Course work of study

The specializations in MPharm program are given in Table 1.

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
<p>Note: International conference: Held outside India</p> <p>International journal: The editorial board outside India</p> <p>*The credit points assigned for extracurricular and or co-curricular activities shall be given by the principal of the college and the same shall be submitted to the university. The criteria to acquire this credit point shall be defined by the college from time to time.</p>	

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
	Continu- ous 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		
<u>MPharm Theory Sessional Examinations, Month and Year</u>		
<u>Course Code. Course Title</u>		
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 <u>MPharm Practical Sessional Examinations, Month and Year</u> <u>Course Code. Course Title</u>		
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		
<u>MPharm Theory End-Semester Examinations, Month and Year</u>		
<u>Course Code. Course Title</u>		
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		
<u>MPharm Practical End-Semester Examinations, Month and Year</u>		
Manipal Academy of Higher Education, Manipal		
<u>Course Code. Course Title</u>		
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)

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

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

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

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

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

12.5. Cumulative Grade Point Average (CGPA)

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

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

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

12.6. Conversion of GPA/CGPA into a percentage

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

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

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

Percentage secured by the candidate = GPA or CGPA \times 10

13. Make-up/Supplementary examination

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

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

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

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

14. Improvement of internal assessment

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

15. Promotion to the next higher class

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

16. Declaration of class

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

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

17. Research project work

17.1 Dissertation submission

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

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

17.2 Dissertation evaluation

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

Internal Assessment			University Examination				Grand Total	
Presentation 1 (III semester)	Presentation 2 (IV semester)	Total	Dissertation Evaluation (300) by Examiners		Viva Voce Joint Evaluation by Internal and External Examiners (100)			Total
			Internal	External	Presenta- tion	Viva- voce		
i	ii	i+ii=A	i	ii	iii	iv	i+ii+i ii+iv =B	A+B
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.

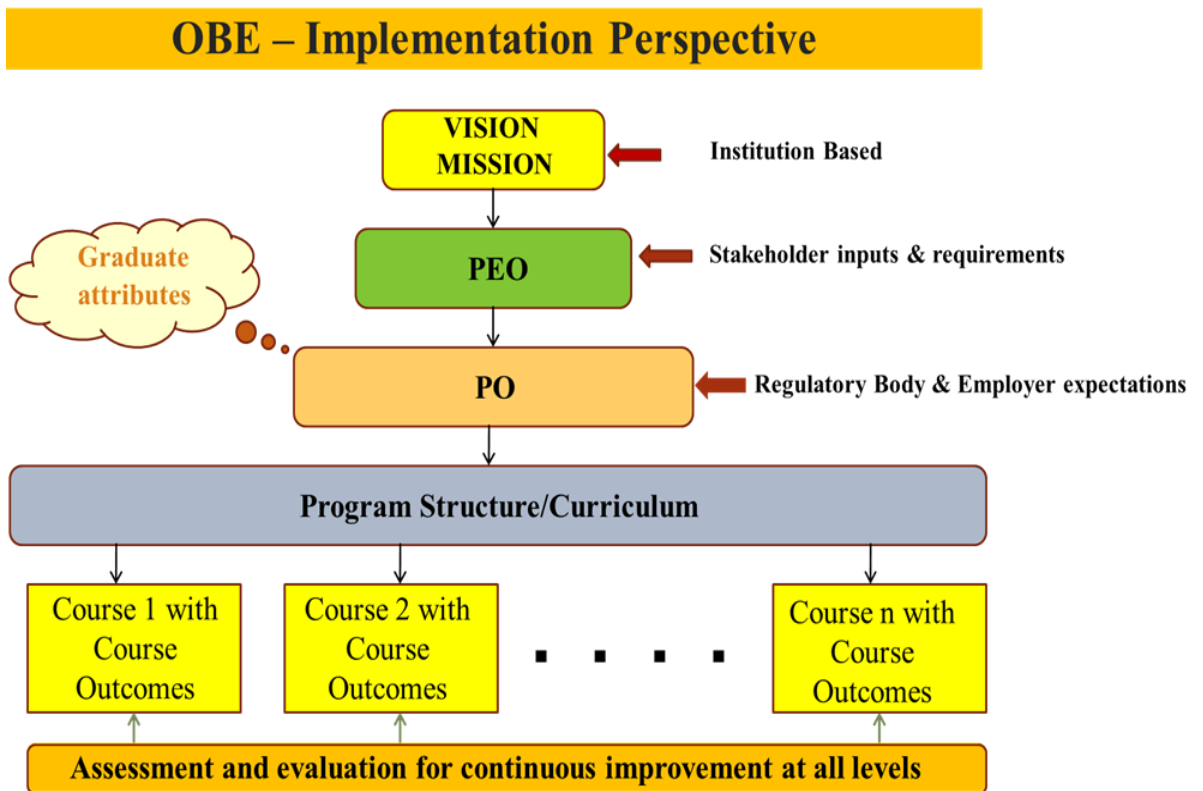
21. Re-admission after break of study

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.**



MANIPAL COLLEGE OF PHARMACEUTICAL SCIENCES

MANIPAL

(A constituent unit of MAHE, Manipal)

MPharm Pharmaceutical Quality Assurance

Program Educational Objectives

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

PEO No	Educational Objectives
PEO 1	Build an education leading to a Masters' degree in Pharmaceutical Quality Assurance with integrated professional knowledge and skills in pharmaceutical analysis, validation, calibration, with research competencies to work in the domain of pharmaceutical quality assurance.
PEO 2	Equip the Masters' students with comprehensive knowledge and skills to deliver quality management services in pharmaceutical industry with a critical thinking to face the challenges in Good Global Practices (GxP).
PEO 3	Cultivate an inclination for higher education and entrepreneurship.
PEO 4	Foster the best in-class experimental hands-on training in pharmaceutical analysis using sophisticated instruments.
PEO 5	Empower and sensitize the quality assurance professionals to serve the pharmaceutical industry, academia, society and the business.



MANIPAL COLLEGE OF PHARMACEUTICAL SCIENCES

MANIPAL

(A constituent unit of MAHE, Manipal)

MPharm Pharmaceutical Quality Assurance

Program Outcomes (POs)

After successful completion of MPharm Pharmaceutical Quality Assurance program, students will be able to:

PO No.	Attribute	Competency
PO 1	Domain knowledge	Demonstrate competency in the area of pharmaceutical quality systems, drug development research, and drug regulations.
PO 2	Problem analysis	Develop competency in quality related problem identification, root cause analysis and solving.
PO 3	Design/develop solutions	Demonstrate competency in designing and using various quality tools for trouble shooting.
PO 4	Conduct investigations of complex problems	Implement knowledge for conducting audits and investigations on quality issues in every stage of drug development and manufacturing.
PO 5	Modern tool usage	Demonstrate competency in implementing modern tools like Quality by Design (QbD), Process Analytical Technology (PAT), Design of Experiments (DoE), technology transfer etc.
PO 6	Business and society	Evolve as entrepreneurs in the pharmaceutical field to serve the society.
PO 7	Environment and sustainability	Comprehend the impact of pharmaceutical industry operations on the environment and strive to make the pharmaceutical manufacturing sustainable.
PO 8	Ethics	Inculcate a sense of fair play, social values and professional ethics.
PO 9	Individual/ Teamwork	Cultivate a sense of compliant partnering collaborative spirit in professional duties; develop transdisciplinary approaches in the area of pharmaceutical sciences through choice / problem-based learning.
PO 10	Communication	Conceptualize research ideas, develop oral and written communication skills including soft skills, frame and evaluate hypothesis by collating and interpreting data to draw meaningful conclusions.
PO 11	Project management and finance	Acquire skills in managing human, financial and other resources efficiently to achieve the project objectives and stake holder's satisfaction.
PO 12	Life-long learning	Cultivate a temperament that would enable individuals to work towards self-driven performance-goals, entrepreneurial ventures and overall leadership to tackle future challenges through lifelong learning and staying ahead of times.

CHAPTER – III

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

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.						

. 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	PO10	PO11	PO12
1	PQA-MQA101T	Modern Pharmaceutical Analytical Techniques	4	CO1 CO2 CO3	CO1 CO2 CO3	CO1 CO2 CO3	CO1	CO1 CO2 CO3	CO1	CO1 CO2 CO3	CO1 CO2 CO3	CO3	CO1 CO2 CO3	CO1 CO2 CO3	CO1 CO3
2	PQA-MQA102T	Quality Management Systems	5	CO1 CO2 CO3 CO4 CO5 CO6	CO1 CO3 CO6	CO1 CO2 CO3 CO4 CO5	CO3 CO4 CO5	CO4 CO5		CO2 CO3 CO4 CO5	CO2 CO3 CO4 CO5	CO1 CO2 CO3 CO4 CO5	CO1 CO2 CO3 CO4 CO5 CO6	CO2 CO3 CO4 CO5	CO2 CO3 CO4 CO5
3	PQA-MQA103T	Quality Control and Quality Assurance	5	CO1 CO3 CO4	CO3 CO4	CO1 CO3 CO4	CO2 CO4			CO1	CO4		CO2 CO3	CO3 CO4	
4	PQA-MQA104T	Product Development and Technology Transfer	5	CO1 CO2 CO3 CO4	CO1 CO2 CO3 CO4	CO1 CO2 CO3	CO1 CO2 CO3 CO4	CO1 CO2 CO3 CO4	CO1 CO2 CO3 CO4	CO2 CO2 CO3	CO1 CO2	CO1 CO2 CO3 CO4			
5	PQA-MQA105P	Pharmaceutical Quality Assurance Practical I	6	CO1 CO2 CO3	CO1 CO2 CO3	CO1 CO2 CO3	CO1 CO2 CO3	CO1 CO2 CO3	CO3	CO1 CO2 CO3	CO1 CO2 CO3	CO3	CO1 CO2 CO3	CO2 CO3	CO1 CO2 CO3
6	PQA-MQA106S	Seminar*	1	CO2 CO3 CO4 CO5	CO3 CO4 CO5				CO2 CO3 CO4 CO5	CO2 CO3 CO4	CO4 CO5	CO4 CO5	CO1 CO2 CO3 CO4 CO5	CO3 CO4 CO5	CO1 CO4 CO5
7	PQA-MQA201T	Hazards and Safety Management	5	CO1 CO2 CO3 CO4 CO5	CO3 CO4 CO5	CO1 CO2 CO4 CO5	CO2 CO5	CO5	CO1 CO2 CO3 CO5	CO1 CO2 CO5	CO1 CO2 CO4 CO5	CO2 CO4 CO5	CO3 CO5	CO1 CO3 CO5	CO3 CO5
8	PQA-MQA202T	Pharmaceutical Validation	5	CO1 CO2 CO3 CO4	CO1 CO2 CO3 CO4	CO1 CO2 CO3 CO4	CO1 CO2 CO3 CO4			CO1 CO2 CO3 CO4		CO1 CO2 CO3 CO4			
9	PQA-MQA203T	Audits and Regulatory Compliance	5	CO1 CO2 CO3 CO4 CO5		CO1 CO2 CO3 CO4 CO5	CO1 CO2 CO3 CO4 CO5			CO2 CO3 CO4 CO5	CO2 CO3 CO4 CO5	CO1 CO2 CO3 CO4 CO5	CO1 CO2 CO3 CO4 CO5		CO2 CO3 CO4 CO5

S No	Course Code	Course Name	Credits	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11	PO12
10	PQA-MQA204T	Pharmaceutical Manufacturing Technology	5	CO1 CO2	CO2 CO3	CO2 CO3	CO3	CO3		CO1		CO1 CO2	CO2	CO1 CO2	
11	PQA-MQA205P	Pharmaceutical Quality Assurance Practical II	6	CO1 CO2 CO3	CO1 CO2 CO3	CO1 CO2 CO3	CO1 CO2 CO3	CO1 CO2 CO3		CO1 CO2 CO3	CO1 CO2 CO3			CO2 CO3	CO2 CO3
12	PQA-MQA206S	Seminar*	1	CO1	CO1 CO2		CO2 CO5					CO3	CO3 CO4 CO5		CO6
13	PHA-MRM301T	Research Methodology and Biostatistics*	4	CO1		CO1	CO2	CO2						CO1	
14	MJC302P	Journal Club*	1	CO1	CO1		CO1					CO2 CO3	CO3		CO4
15	MRW401P	Research Work	35	CO1	CO1	CO4	CO5	CO5	CO6	CO3	CO3		CO5 CO6	CO2	

Chapter III

MPHARM – PHARMACEUTICAL QUALITY ASSURANCE (MQA)

SEMESTER I

POA-MQA101T: MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES

COURSE CODE	PQA-MQA101T					
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						
SI .No	Course Content	Syllabus (Chapters or Units with hours)	Marks of assessment	Distribution of marks of assessment		End Sem exam (70% of marks of assessment)
				Sessional exam (30% of marks of assessment)		
				S1	S2	
1	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-MQA101T: MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES

THEORY

52 hrs

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

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

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

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

2. **NMR Spectroscopy:** Quantum numbers and their role in NMR, principle, instrumentation, solvent requirement in NMR, relaxation process, NMR signals in various compounds, chemical shift, factors influencing chemical shift, Spin-Spin coupling, coupling constant, nuclear magnetic double resonance, brief outline of principles of FT-NMR and 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, Douglas 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 QUALITY ASSURANCE (MQA)

SEMESTER I

PQA-MQA102T: QUALITY MANAGEMENT SYSTEMS

COURSE CODE		PQA- MQA102T				
COURSE TITLE		QUALITY MANAGEMENT SYSTEMS (Theory)				
SCOPE / SUMMARY			OBJECTIVES / COURSE OUTCOMES			
This course is designed to impart fundamental knowledge and concepts about various quality management principles and systems utilized in the manufacturing industry. It also aids in understanding the quality evaluation in the pharmaceutical industries.			After completion of this course it is expected that students will be able to understand- 1. The importance of quality 2. Quality management systems 3. Tools for quality improvement 4. Pharmaceutical development & stability studies. 5. Statistical approaches for quality 6. Regulatory compliance through QMS.			
Course Content and Assessment Plan						
Sl. No.	Course Content	Syllabus (Chapters or Units with hours)	Total Marks of assessment	Distribution of marks of assessment		
				Sessional exam (30 % of total marks of assessment)		End Sem exam (70 % of total marks of assessment)
				S1	S2	
1	Will know the concept of quality, its dimension, strategic quality management, mission and vision statements, strategic planning and implementation	Unit I (06 hrs)	15	5		10
2	Will understand the basics of quality management, TQM, six sigma, ISO 9000 series, ICH Q10, quality metrics, NABL certification, WHO GMP and CFR 21 part 11	Unit II (12hrs)	25	10		15
3	Will study in detail about six system inspection model for QMS, production system, laboratory control and other departments, Implementation of quality systems such as OOT, OOS, CAPA, concept of IPQC and self-inspection.	Unit III (12 hrs)	26		6	20

4	Will study in detail about ICH guidelines on stability studies, ICH Q8, QbD, process development report and concept of quality risk management.	Unit IV (10 hrs)	20		5	15
5	Will study in detail about statistical quality control.	Unit V (8 hrs)	13		3	10
6	Will understand the concept of regulatory compliance through quality management and learn the concept of benchmarking.	Unit VI (4 hrs)	6		1	5
Total Marks of Assessment			105	15	15	75

PQA-MQA102T: QUALITY MANAGEMENT SYSTEMS

THEORY

52 hrs

1. Introduction to Quality: Evolution of Quality, Definition of Quality, Dimensions of Quality.

Quality as a Strategic Decision: Meaning of strategy and strategic quality management, mission and vision statements, quality policy, Quality objectives, strategic planning and implementation. **06 hrs**

2. Pharmaceutical quality Management: Basics of Quality Management, Total Quality Management (TQM), Principles of Six sigma, ISO 9001:2008, 9001:2015, ISO 14001:2004, Pharmaceutical Quality Management – ICH Q10, Knowledge management, Quality Metrics, Operational Excellence and Quality Management Review. NABL certification and accreditation, Role of 21 CFR-Part 11 in QMS, WHO-GMP requirements. **12 hrs**

3. Six System Inspection model: Quality Management System, Production system, Facility and Equipment system, Laboratory control system, Materials system, Packaging and labeling system. Concept of self-inspection.

Quality systems: Change Management/ Change control. Deviations, Out of Specifications (OOS), Out of Trend (OOT), Complaints - evaluation and handling, Investigation and determination of root cause, Corrective & Preventive Actions (CAPA), Returns and Recalls, Vendor Qualification, Annual Product Reviews. Concept of IPQC. **12 hrs.**

4. Drug Stability: ICH guidelines for stability testing of drug substances and drug products. Study of ICH Q8, Quality by Design and Process development report

Quality risk management: Introduction, risk assessment, risk control, risk review, risk management tools, risk ranking and filtering according to ICH Q9 guidelines. **10 hrs**

5. Statistical Process control (SPC): Definition and Importance of SPC, Quality measurement in manufacturing, Statistical control charts - concepts and general aspects, Advantages of statistical control, Process capability, Estimating Inherent or potential capability from a control chart analysis, Measuring process control and quality improvement, Pursuit of decreased process variability. **08 hrs**

6. Regulatory Compliance through Quality Management and development of Quality Culture

Benchmarking: Definition of benchmarking, Reasons for benchmarking, Types of Benchmarking, Benchmarking process, Advantages of benchmarking, Limitations of benchmarking. **04 hrs**

REFERENCES

1. Implementing Juran's Road Map for Quality Leadership: Benchmarks and Results, By Al Endres, Wiley, 2000
2. Understanding, Managing and Implementing Quality: Frameworks, Techniques and Cases, By Jiju Antony; David Preece, Routledge, 2002
3. Organizing for High Performance: Employee Involvement, TQM, Reengineering, and Knowledge Management in the Fortune 1000: The CEO Report By Edward E. Lawler; Susan Albers Mohrman; George Benson, Jossey-Bass, 2001
4. Corporate Culture and the Quality Organization By James W. FairfieldSonn, Quorum Books, 2001
5. The Quality Management Sourcebook: An International Guide to Materials and Resources By Christine Avery; Diane Zabel, Routledge, 1997
6. The Quality Toolbox, Second Edition, Nancy R. Tague, ASQ Publications
7. Juran's Quality Handbook, Sixth Edition, Joseph M. Juran and Joseph A. De Feo, ASQ Publications
7. Root Cause Analysis, The Core of Problem Solving and Corrective Action, Duke Okes, 2009, ASQ Publications.

MPHARM – PHARMACEUTICAL QUALITY ASSURANCE (MQA)

SEMESTER I

PQA-MQA103T: QUALITY CONTROL AND QUALITY ASSURANCE

COURSE CODE		PQA-MQA103T				
COURSE TITLE		QUALITY CONTROL AND QUALITY ASSURANCE (Theory)				
SCOPE / SUMMARY			OBJECTIVES / COURSE OUTCOMES			
This course deals with the various aspects of quality control and quality assurance in pharmaceutical industry. It covers the important aspects like cGMP, QC tests, documentation, quality certifications, GLP and regulatory affairs.			<p>Upon completion of this course the student should be able to understand.</p> <ol style="list-style-type: none"> 1. The concept & importance of quality in pharmaceutical industry. 2. cGMP principles. 3. Implementation of quality assurance through testing & significance of official compendium. 4. Importance of documentation & understanding the scope of quality certification in pharmaceutical industry. 5. The pharmaceutical manufacturing operations & controls. 			
Course Content and Assessment Plan						
SI No.	Course Contents	Syllabus (Chapters or Units with hours)	Marks of assessment	Distribution of marks of assessment		
				Sessional exam (30% of marks of assessment)		End Sem exam (70% of marks of assessment)
				S1	S2	
1	Will understand the concept, evolution and scope of Quality Assurance and Quality Control and an overview on Quality, safety, efficacy guidelines proposed by ICH.	Unit I (08 hrs)	17	7		10
2	Understand and comprehend different GMP guidelines proposed and practiced under various regulatory agencies such as USFDA, CDSCO, EMEA.	Unit II (08 hrs)	17	7		10
3	Will learn the current methods for analysis of raw materials, finished products, packaging materials including Quality control methods implemented for various dosage forms in	Unit III (14 hrs)	27	1	6	20

	Pharma industry with respect to Indian, US and British Pharmacopoeia.					
4	Will understand various documentation practices at different stages of life cycle of pharma products.	Unit IV (14 hrs)	27		7	20
5	Will assimilate the techniques of manufacturing operations and control and understand the significance of Intellectual Property Rights in Pharma Industry.	Unit V (8 hrs)	17		2	15
Total Marks of Assessment			105	15	15	75

PQA-MQA103T: QUALITY CONTROL AND QUALITY ASSURANCE

THEORY

52 hrs

1. Introduction: Concept, evolution and scopes of Quality Control and Quality Assurance.

Overview of ICH Guidelines - QSEM, with special emphasis on Q series guidelines.

Good Laboratory Practices: Scope of GLP, Definitions, Quality assurance unit, protocol for conduct of non-clinical testing, control on animal house, report preparation, documentation and overview of GCP.

08 hrs

2. cGMP guidelines according to schedule M, USFDA Pharmaceutical Inspection Convention (PIC), WHO and EMEA covering: Organization and personnel responsibilities, training, hygiene and personal records, drug industry location, design, construction and plant layout, maintenance, sanitation, environmental control, utilities and maintenance of sterile areas, control of contamination and Good Warehousing Practices.

08 hrs

3. Analysis of raw materials, finished products, packaging materials. Developing specification (ICH Q6 and Q3), purchase specifications and maintenance of stores for raw materials.

Structure and referencing of Pharmacopoeia. In process quality control and finished products quality control for following dosage forms in Pharma industry according to Indian, US and British pharmacopoeias: tablets, capsules, ointments, suppositories, creams, parenterals, ophthalmic and surgical products.

Quality control tests for containers, closures & secondary packaging materials. **14 hrs**

4. Documentation in pharmaceutical industry: Three tier documentation, Policy, Procedures and Work instructions, and records (Formats), Basic principles - maintenance, retention and retrieval of records. Content and structure of Standard operating procedures, Master Batch Record, Batch Manufacturing Record, Quality audit plan and reports. Specification and test procedures, Protocols and reports. Distribution records. Concept of controlled and uncontrolled documents.

Submission documents for regulators: DMFs, Common Technical Document and Electronic Common Technical Documentation (CTD, eCTD). Concept of regulated and non-regulated markets. **14 hrs**

5. Manufacturing operations and controls: Sanitation of manufacturing premises, mix-ups and cross contamination, processing of intermediates and bulk products, packaging operations, IPQC, process deviations, time limitations on production, drug product inspection, expiry date calculation, calculation of yields, production record review, change control, sterile products, aseptic process control, packaging, reprocessing, salvaging, handling of waste and scrap disposal. **08 hrs**

REFERENCES

1. Quality Assurance Guide by organization of Pharmaceutical Procedures of India, 3rd revised edition, Volume I & II, Mumbai, 1996.
2. Good Laboratory Practice Regulations, 2nd Edition, Sandy Weinberg Vol. 69, Marcel Dekker Series, 1995.
3. Quality Assurance of Pharmaceuticals- A compedium of Guide lines and Related materials Vol I & II, 2nd edition, WHO Publications, 1999.
4. How to Practice GMP's – P P Sharma, Vandana Publications, Agra, 1991.
5. The International Pharmacopoeia – vol I, II, III, IV & V - General Methods of Analysis and Quality specification for Pharmaceutical Substances, Excipients and Dosage forms, 3rd edition, WHO, Geneva, 2005.
6. Good laboratory Practice Regulations – Allen F. Hirsch, Volume 38, Marcel Dekker Series, 1989.
7. ICH guidelines
8. ISO 9000 and total quality management
9. The drugs and cosmetics act 1940 – Deshpande, Nilesh Gandhi, 4th edition, Susmit Publishers, 2006.
10. QA Manual – D.H. Shah, 1st edition, Business Horizons, 2000.

11. Good Manufacturing Practices for Pharmaceuticals a plan for total quality control – Sidney H. Willig, Vol. 52, 3rd edition, Marcel Dekker Series.
12. Steinborn L. GMP/ISO Quality Audit Manual for Healthcare Manufacturers and Their Suppliers, Sixth Edition, (Volume 1 - With Checklists and Software Package). Taylor & Francis; 2003.
13. Sarker DK. Quality Systems and Controls for Pharmaceuticals. John Wiley & Sons; 2008.
14. Packaging of Pharmaceuticals.
15. Schedule M and Schedule N.
16. Pharmaceutical Packaging technology by D.A. Dean. E.R. Evans, I.H. Hall. 1st Edition (Reprint 2006). Taylor and Francis. London and New York.

MPHARM – PHARMACEUTICAL QUALITY ASSURANCE (MQA)

SEMESTER I

PQA-MQA104T: PRODUCT DEVELOPMENT AND TECHNOLOGY TRANSFER

COURSE CODE	PQA-MQA104T					
COURSE TITLE	PRODUCT DEVELOPMENT AND TECHNOLOGY TRANSFER (Theory)					
SCOPE / SUMMARY			OBJECTIVES / COURSE OUTCOMES			
This course deals with activities related to drug product development and Technology transfer.			Upon completion of this course the student should be able to understand: <ol style="list-style-type: none"> 1. The new drug development process and related regulations (Unit I). 2. Development & regulatory approval guidelines for biologics, biosimilars & medical devices and data analysis (Unit II). 3. The concept of pre-formulation studies, solubility studies, crystal properties and polymorphism (Unit III). 4. The necessary information to transfer technology from R&D to actual manufacturing and related documentation and importance of IPR (Unit IV). 			
Course Content and Assessment Plan						
Sl No.	Course Content	Syllabus (Chapters or Units with hours)	Marks of assessment	Distribution of marks of assessment		
				Sessional exam (30% of marks of assessment)		End Sem exam (70% of marks of assessment)
				S1	S2	
1	Students should be able to learn the principles and regulations of drug discovery and development process.	Unit I (20 hrs)	40	10		30
2	Students should be able to learn the important process and procedure of technology transfer & IPR.	Unit IV (08 hrs)	15	5		10
3	Development and approval of biologics, biosimilars & medical devices and data analysis.	Unit II (12hrs)	25		7	15
4	Students should be able to learn the concepts and aspects of pre-formulation and analyse the factors affecting them.	Unit III (12 hrs)	25		8	20
Total Marks of Assessment			105	15	15	75

POA-MQA104T: PRODUCT DEVELOPMENT AND TECHNOLOGY TRANSFER

THEORY

52 hrs

Unit I:

Principles of Drug discovery and development: Introduction, Clinical research process. Development and informational content for Investigational New Drugs Application (IND), New Drug Application (NDA), Abbreviated New Drug Application (ANDA), Supplemental New Drug Application (SNDA), Scale Up Post Approval Changes (SUPAC) and Bulk active chemical Post approval changes (BACPAC), Post marketing surveillance.

Product registration guidelines of CDSCO.

20 hrs

Unit II:

Principle, development and approval of biologics, biosimilars & medical devices (510K, PMA & IDE).

Pharma Analytics: data extraction (SQL), data transportation (Python) & data visualization (Power BI).

12 hrs

Unit III:

Pre-formulation studies: Introduction/concept, organoleptic properties, purity, impurity profiles, particle size, shape and surface area. Solubility, Methods to improve solubility of Drugs: Surfactants & its importance, co-solvency. Techniques for the study of Crystal properties and polymorphism. Pre-formulation protocol, Stability testing during product development.

12 hrs

Unit IV:

Technology transfer: Development and transfer of process and analytical methods by R&D. Documentation in technology transfer: Development report, technology transfer plan and Exhibit.

Introduction, scope and importance of intellectual property rights. Concept of trade mark, copyright and patents.

08 hrs

REFERENCES

1. The process of new drug discovery and development. I and II Edition (2006) by Charles G. Smith, James T and O. Donnell. CRC Press, Group of Taylor and Francis.
2. Leon Lac Lachman, Herbert A. Liberman, Theory and Practice of Industrial Pharmacy. Marcel Dekker Inc. New York.

3. Sidney H Willing, Murray M, Tuckerman. Williams Hitchings IV, Good manufacturing of pharmaceuticals (A Plan for total quality control) 3rd Edition. Bhalani publishing house Mumbai.
4. Tablets Vol. I, II, III by Leon Lachman, Herbert A. Liberman, Joseph B. Schwartz, 2nd Edn. (1989) Marcel Dekker Inc. New York.
5. Text book of Bio- Pharmaceutics and clinical Pharmacokinetics by Milo Gibaldi, 3rd Edn, Lea & Febriger, Philadelphia.
6. Pharmaceutical product development. Vandana V. Patrevala. John I. Disouza. Maharukh T.Rustomji. CRC Press, Group of Taylor and Francis.
7. Dissolution, Bioavailability and Bio-Equivalence by Abdou H.M, Mack Publishing Company, Eastern Pennsylvania.
8. Remingtons Pharmaceutical Sciences, by Alfonso & Gennaro, 19th Edn.(1995)OO2C Lippincott; Williams and Wilkins A Wolters Kluwer Company, Philadelphia.
9. The Pharmaceutical Sciences; the Pharma Path way 'Pure and applied Pharmacy' by D. A Sawant, Pragathi Books Pvt. Ltd.

MPHARM – PHARMACEUTICAL QUALITY ASSURANCE (MQA)

EMESTER I

PQA-MQA105P: PHARMACEUTICAL QUALITY ASSURANCE PRACTICAL I

COURSE CODE		PQA-MQA 105P			
COURSE TITLE		PHARMACEUTICAL QUALITY ASSURANCE PRACTICAL – I			
SCOPE / SUMMARY			OBJECTIVES / COURSE OUTCOMES		
This course is designed to gain practical skills on assay of drugs, formulations, quality control of packaging materials, pre-formulation studies and QA case studies.			Upon completion of this course the student should be able to: 1. Analyze the API and formulations using various analytical instruments 2. Solve the case studies on QA related issues 3. Perform the Pre-formulation studies		
Course Content and Assessment Plan					
Sl No.	Course Content	Syllabus (Chapters or Units with hours)	Total Marks of assessment	Distribution of assessment marks	
				Sessional exam (25 % of total marks of assessment)	End Sem exam (75 % of total marks of assessment)
				S1	
1	Analyze pharmacopeial compounds in bulk and formulations by UV-Visible Multi drug component analysis, experiments based on HPLC, GC, fluorimetry, flame photometry.	Experiments 1 to 6 (60 hrs)	44	10	34
2	Case studies on TQM, Six sigma, Change management, OOS, OOT, CAPA, Deviations	Experiments 7 to 12 (31 hrs)	34	8	26
3	Development of stability protocol, IPQC for tablets, capsules, parenterals and semisolid dosage form, raw material analysis as per official monograph, testing related and foreign substances in raw materials, pre-formulation studies for tablets, parenterals, effect of pH on solubility of drugs, QC test for primary and secondary packaging materials, accelerated stability studies, improved solubility using surfactants, co-solvency, and determination of pKa and Log p for drugs.	Experiments 13 to 19 (65 hrs)	52	12	40
Total Marks of Assessment			130	30	100

PQA-MQA105P: PHARMACEUTICAL QUALITY ASSURANCE PRACTICAL I

1. Analysis of Pharmacopoeial compounds in bulk and in their formulations (tablet/capsules/ semisolids) by UV Vis spectrophotometer
2. Simultaneous estimation of multi-drug component containing formulations by UV spectrophotometry
3. Experiments based on HPLC
4. Experiments based on Gas Chromatography
5. Estimation of riboflavin/quinine sulphate by fluorimetry
6. Estimation of sodium/potassium by flame photometry or AAS
7. Case studies on
 - Total Quality Management
 - Six Sigma
 - Change Management/ Change control. Deviations,
 - Out of Specifications (OOS)
 - Out of Trend (OOT)
 - Corrective & Preventive Actions (CAPA)
 - Deviations
8. Development of Stability study protocol
9. Estimation of process capability
10. In process and finished product quality control tests for tablets, capsules, parenterals and semisolid dosage forms.
11. Assay of raw materials as per official monographs
12. Testing of related and foreign substances in drugs and raw materials
13. To carry out pre formulation study for tablets, parenterals (2 experiment).
14. To study the effect of pH on the solubility of drugs, (1 experiment)
15. Quality control tests for Primary and secondary packaging materials
16. Accelerated stability studies (1 experiment)
17. Improved solubility of drugs using surfactant systems (1 experiment)
18. Improved solubility of drugs using co-solvency method (1 experiment)
19. Determination of pKa and Log p of drugs.

MPHARM – PHARMACEUTICAL QUALITY ASSURANCE (MQA)**SEMESTER I****PQA-MQA106S: SEMINAR IN PHARMACEUTICAL QUALITY ASSURANCE**

COURSE CODE	PQA- MQA 106S			
COURSE TITLE	SEMINAR IN PHARMACEUTICAL QUALITY ASSURANCE			
SCOPE / SUMMARY		OBJECTIVES / COURSE OUTCOMES		
The course is designed to create an environment where student gather information about an assigned topic in the relevant field. Students will develop writing skills, presentation skills and defend their presentation effectively.		Upon completion of the course the student shall be able to: 1. Acquire knowledge to gather, organize, deliver information, and defend a given topic in the Pharmaceutical Quality Assurance area. 2. Acquire knowledge on concepts using audio-visual aids. 3. Acquire communication and presentation skills. 4. Effectively defend the presentation. 5. Develop a write-up about seminar topic. 6. Cultivate a sense of upgradation of knowledge through self and continuous learning		
Course Content and Assessment Plan				
Sl. No.	Course Content	Hours	Total Marks of assessment	Marks
				End Sem exam
1	The students should be able to develop skills to gather, organize, deliver information, and defend a given topic in Pharmaceutical Quality Assurance	2 hours/week	100	No end-semester examination. Only continuous mode.

MPHARM – PHARMACEUTICAL QUALITY ASSURANCE (MQA)

SEMESTER II

PQA-MQA201T: HAZARDS AND SAFETY MANAGEMENT

COURSE CODE	PQA-MQA201T					
COURSE TITLE	HAZARDS AND SAFETY MANAGEMENT (Theory)					
SCOPE / SUMMARY			OBJECTIVES / COURSE OUTCOMES			
This course is designed to convey the knowledge necessary to understand issues related to different kinds of hazard and their management. Basic theoretical and practical discussions integrate the proficiency to handle the emergency in the pharmaceutical product development process and provides the principle based approach to solve the complex tribulations.			After completion of this course it is expected that students will be able to: 1. Impart basic knowledge about the environment and its allied problems. 2. Develop an attitude of concern for the industry environment. 3. Ensure safety from chemical hazards & explosion in pharmaceutical industry. 4. Ensure safety from fire hazards & fire protection. 5. Implement the Hazard assessment procedure, methodology to provide safe industrial atmosphere.			
Course Content and Assessment Plan						
Sl. No.	Course Content	Syllabus (Chapters or Units with hours)	Marks of assessment	Distribution of marks of assessment		End Sem exam (70% of marks of assessment)
				Sessional exam (30% of marks of assessment)		
				S1	S2	
1	Will know about the multidisciplinary nature of environment and eco system.	Unit I (10 hrs)	22	8		20
2	Will be able to comprehend the types of fire and respective preventive measures.	Unit II (07 hrs)	18	7		10
3	Will know about various air-based hazards	Unit III (10 hrs)	20		5	15
4	Will know about various chemical hazards & chemical explosion	Unit IV (10 hrs)	20		5	15
5	Will know about the various hazards and risk management plans, factory act and rules, and waste management methods. Biosafety hazards & management	Unit V (13 hrs)	25		5	15
Total Marks of Assessment			105	15	15	75

PQA-MQA201T: HAZARDS AND SAFETY MANAGEMENT

THEORY

52 hrs

1. Multidisciplinary nature of environmental studies: Natural Resources, Renewable and non-renewable resources, Natural resources and associated problems: a) Forest resources b) Water resources c) Mineral resources d) Energy resources e) Land resources.

Ecosystems: Concept of an ecosystem and Structure and function of an ecosystem.

Environmental hazards: Hazards based on Air, Water, Soil and Radioisotopes. **10 hrs**

2. Air based hazards: Sources, Types of Hazards, Air circulation maintenance in industry for sterile area and non-sterile area, Preliminary Hazard Analysis (PHA). **07 hrs**

3. Chemical based hazards: Sources of chemical hazards, Hazards of Organic synthesis, sulphonating hazard, Organic solvent hazard, Control measures for chemical hazards, Management of combustible gases, Toxic gases and Oxygen displacing gases management, Regulations for chemical hazards, Management of over-Exposure to chemicals and TLV concept.

Mechanical & chemical explosion, multi-phase reactions, transport effects and global rates.

12 hrs

4. Fire and Explosion: Introduction, Industrial processes and hazards potential, mechanical electrical, thermal and process hazards. Safety and hazards regulations. Preventive and protective management from fires and explosion- electricity passivation, ventilation, and sprinkling, proofing, relief systems -relief valves, flares, scrubbers.

Fire protection system: Fire prevention, types of fire extinguishers and critical Hazard management system. **10 hrs**

5. Hazard and risk management: Self-protective measures against workplace hazards. Critical training for risk management, Process of hazard management, ICH guidelines on risk assessment and Risk management methods and Tools.

Factory act and rules, fundamentals of accident prevention, elements of safety program and safety management, Physicochemical measurements of effluents, BOD, COD, Determination of some contaminants, Effluent treatment procedure, Role of emergency services.

Biosafety hazards & management.

13 hrs

REFERENCES

1. Y.K. Sing, Environmental Science, New Age International Pvt, Publishers, Bangalore
2. “Quantitative Risk Assessment in Chemical Process Industries” American Institute of Chemical Industries, Centre for Chemical Process safety.
3. Bharucha Erach, The Biodiversity of India, Mapin Publishing Pvt. Ltd., Ahmedabad – 380 013, India,
4. Hazardous Chemicals: Safety Management and Global Regulations, T.S.S. Dikshith, CRC Press.

MPHARM – PHARMACEUTICAL QUALITY ASSURANCE (MQA)

SEMESTER II

PQA-MQA202T: PHARMACEUTICAL VALIDATION

COURSE CODE		PQA-MQA202T				
COURSE TITLE		PHARMACEUTICAL VALIDATION (Theory)				
SCOPE / SUMMARY			OBJECTIVES / COURSE OUTCOMES			
The main purpose of the course is to understand about validation and how it can be applied to industry and thus to improve the quality of the products. The course covers the complete information about validation, types, methodology and application.			Upon completion of this course the student should be able to understand: <ol style="list-style-type: none"> 1. The concepts of calibration and validation. Calibration of various equipment's and analytical method validation (Unit I). 2. The qualification of equipment's used in pharmaceutical industry (Unit II). 3. Process validation of different dosage forms (Unit III). 4. The concepts of cleaning, facility & computer system validation (Unit IV). 			
Course Content and Assessment Plan						
SL .No.	Course Content	Syllabus (Chapters or Units with hours)	Marks of assessment	Distribution of marks of assessment		
				Sessional exam (30% of marks of assessment)		End Sem exam (70% of marks of assessment)
				S1	S2	
1	Students should be able to learn the importance and concepts of validation, calibration and qualification.	Unit I (10 hrs)	21	6		15
2	Students should be able to learn the concept, principle and procedure of pharmaceutical process validation.	Unit III (15hrs)	31	9		22
3	Students should be able to learn the principle and procedure for qualification of selected advanced analytical and laboratory equipments.	Unit II (15hrs)	31		8	22
4	Students should be able to learn the concept, principle and procedure of facility, cleaning and computer system validation.	Unit IV (12 hrs)	22		7	16
Total marks of assessment			105	15	15	75

PQA-MQA202T: PHARMACEUTICAL VALIDATION

THEORY

52 hrs

Unit I:

Introduction to validation: Definition of Calibration, Qualification and Validation, Scope, frequency and importance. Difference between calibration and validation. Calibration of weights and measures, electronic balance, pH meter, DSC, UV & HPLC equipments. Advantages of Validation, scope of Validation, Organization for Validation, Validation Master plan, Types of Validation, Streamlining of qualification & Validation process and Validation Master Plan. Analytical & bioanalytical method validation. **10 hrs**

Unit II:

Qualification: User requirement specification, Design qualification, Factory Acceptance Test (FAT)/Site Acceptance Test (SAT), Installation qualification, Operational qualification, Performance qualification, Re-Qualification (Maintaining status- Calibration Preventive Maintenance, Change management).

Qualification of analytical equipment's (UV, HPLC, GC).

Qualification of laboratory equipments (Hardness tester, Friability test apparatus, tap density tester, Disintegration tester, Dissolution test apparatus, Stability testing chamber)

Validation of Utility systems (HVAC, Water, Air)

15 hrs

Unit III:

Process Validation: Concept, Process and documentation of Process Validation. Prospective, Concurrent & Retrospective Validation, Re validation criteria, Process Validation of various formulations (Granules, Coated and uncoated including sustained and modified release tablets, Capsules, Ointment/Creams, Liquid Orals and aerosols.), Aseptic filling: Media fill validation, USFDA guidelines on Process Validation- A life cycle approach.

Validation of biopharmaceutical process.

15 hrs

Unit IV:

Cleaning Validation: Cleaning Method development, Validation of analytical method used in cleaning, Cleaning of Equipment, Cleaning of Facilities. Cleaning in place (CIP).

Validation of facilities in sterile and non-sterile plant.

Computer system validation: Electronic records and digital signature - 21 CFR Part 11 and GAMP 5. **12 hrs**

REFERENCES

1. B. T. Loftus & R. A. Nash, "Pharmaceutical Process Validation", Drugs and Pharm Sci. Series, Vol. 129, 3rd Ed., Marcel Dekker Inc., N.Y.
2. The Theory & Practice of Industrial Pharmacy, 3rd edition, Leon Lachman, Herbert A. Lieberman, Joseph. L. Karig, Varghese Publishing House, Bombay.
3. Validation Master Plan by Terveeks or Deeks, Davis Harwood International publishing.
4. Validation of Aseptic Pharmaceutical Processes, 2nd Edition, by Carleton & Agalloco,
5. (Marcel Dekker).
6. Michael Levin, Pharmaceutical Process Scale-Up", Drugs and Pharm. Sci. Series, Vol. 157, 2nd Edn., Marcel Dekker Inc., N.Y.
7. Validation Standard Operating Procedures: A Step by Step Guide for Achieving Compliance in the Pharmaceutical, Medical Device, and Biotech Industries, Syed Imtiaz Haider
8. Pharmaceutical Equipment Validation: The Ultimate Qualification Handbook, Phillip A. Cloud, Interpharm Press
9. Validation of Pharmaceutical Processes: Sterile Products, Frederick J. Carlton (Ed.) and James Agalloco (Ed.), Marcel Dekker
10. Analytical Method validation and Instrument Performance Verification by Churg Chan, Heiman Lam, Y.C. Lee, Yue. Zhang, Wiley Interscience.
11. Huber L. Validation and Qualification in Analytical Laboratories. Informa Healthcare
12. Wingate G. Validating Corporate Computer Systems: Good IT Practice for Pharmaceutical Manufacturers. Interpharm Press
13. LeBlanc DA. Validated Cleaning Technologies for Pharmaceutical Manufacturing. Interpharm Press.

MPHARM – PHARMACEUTICAL QUALITY ASSURANCE (MQA)

SEMESTER II

PQA-MQA203T: AUDITS AND REGULATORY COMPLIANCE

COURSE CODE		PQA- MQA203T				
COURSE TITLE		AUDITS AND REGULATORY COMPLIANCE (Theory)				
SCOPE / SUMMARY			OBJECTIVES / COURSE OUTCOMES			
This course deals with the understanding and process for auditing in pharmaceutical industries.			Upon completion of this course the student should be able: 1. To understand the importance of auditing, auditing process, checklist preparation & reporting. 2. To understand the methodology of auditing 3. To carry out the audit of vendors and production departments. 4. To carryout auditing of microbiology laboratory and clinical trial facilities. 5. To carryout auditing of QA & engineering departments.			
Course Content and Assessment Plan						
Sl No.	Course Content	Syllabus (Chapters or Units with hours)	Total Marks of assessment	Distribution of marks of assessment		
				Sessional exam (30 % of total marks of assessment)		End Sem exam (70 % of total marks of assessment)
				S1	S2	
1	Will know the concept of audit, management of audit, responsibilities, planning, information gathering for audit and types of deficiencies.	Unit I (10 hrs)	18	8		10
2	Will understand the role of quality systems in audits, management responsibilities and learn to prepare audit checklist.	Unit II (12 hrs)	22	7		15
3	Will know the auditing of vendors and every section of production department.	Unit III (08 hrs)	20		5	15
4	Will know the auditing of every section of microbiology laboratory and clinical trial facilities.	Unit IV (12 hrs)	24		4	20
5	Will learn the auditing of QA, engineering and ETP sections.	Unit V (10 hrs)	21		6	15
Total Marks of Assessment			105	15	15	75

PQA-MQA203T: AUDITS AND REGULATORY COMPLIANCE

THEORY

52 hrs

1. Introduction: Objectives, Management of audit, Responsibilities, Planning process, information gathering, and administration, Classifications of deficiencies. **10 hrs**

2. Role of quality systems and audits in pharmaceutical manufacturing environment: cGMP Regulations, Quality assurance functions, Quality systems approach, Management responsibilities, Resource, Manufacturing operations, Evaluation activities, transitioning to quality system approach, Audit checklist for drug industries. **12 hrs**

3. Auditing of vendors and production department: Bulk Pharmaceutical Chemicals and packaging material Vendor audit, Warehouse and weighing, Dry Production: Granulation, tableting, coating, capsules, sterile production and packaging. **08 hrs**

4. Auditing of Microbiological laboratory: Auditing the manufacturing process. General areas of interest in the building raw materials, Water, Packaging materials.
Auditing of Clinical Trial facilities **12 hrs**

5. Auditing of Quality Assurance and engineering department: Quality Assurance Maintenance, Critical systems: HVAC, Water, Water for Injection systems, ETP. **10 hrs**

REFERENCES

1. Compliance auditing for Pharmaceutical Manufacturers. Karen Ginsbury and Gil Bismuth, Interpharm/CRC, Boca Raton, London New York, Washington D.C.
2. Pharmaceutical Manufacturing Handbook, Regulations and Quality by Shayne Cox Gad. Wiley-Interscience, A John Wiley and sons, Inc., Publications.
3. Handbook of microbiological Quality control. Rosamund M. Baird, Norman A. Hodges, Stephen P. Denyar. CRC Press. 2000.
4. Laboratory auditing for quality and regulatory compliance. Donald C. Singer, Raluca-loana Stefan, Jacobus F. Van Staden. Taylor and Francis (2005).

MPHARM – PHARMACEUTICAL QUALITY ASSURANCE (MQA)

SEMESTER II

PQA-MQA204T: PHARMACEUTICAL MANUFACTURING TECHNOLOGY

COURSE CODE	PQA-MQA204T					
COURSE TITLE	PHARMACEUTICAL MANUFACTURING TECHNOLOGY (Theory)					
SCOPE / SUMMARY			OBJECTIVES / COURSE OUTCOMES			
This course is designed to impart knowledge and skills necessary to train the students with the industrial activities during Pharmaceutical Manufacturing.			At completion of this course it is expected that students will be able to understand: 1. The common practice in the pharmaceutical industry developments, plant layout and production planning. 2. The principles and practices of aseptic process technology and advanced sterile products. 3. Conventional and advanced non-sterile product manufacturing. 4. Pharmaceutical container, closure systems technology. 5. The principles and implementation of Quality by design (QbD) and process analytical technology (PAT) in pharmaceutical manufacturing.			
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 learn the layout of manufacturing unit and production planning	Unit I (12 hrs)	27	7		20
2	Will learn the intricacies of aseptic technology and latest developments in the same.	Unit II (12 hrs)	21	6		15
3	Will learn the intricacies and latest developments in non-sterile technology	Unit III (10 hrs)	21	2	4	15
4	Will acquire complete understanding of container closure system for pharmaceuticals	Unit IV (10 hrs)	21		6	15
5	Will understand the automation of the process and design of quality of pharmaceutical products	Unit V (8 hrs)	15		5	10
Total Marks of Assessment			105	15	15	75

POA-MQA204T: PHARMACEUTICAL MANUFACTURING TECHNOLOGY

THEORY

52 hrs

1. Pharmaceutical industry developments: Legal requirements and Licenses for API and formulation industry, Plant location - Factors influencing.

Plant layout: Factors influencing, Special provisions, Storage space requirements, sterile and aseptic area layout.

Production planning: General principles, production systems, calculation of standard cost, process planning, routing, loading, scheduling, dispatching of records, production control.

12 hrs

2. Aseptic process technology: Manufacturing, manufacturing flowcharts, in process-quality control tests for following sterile dosage forms: Ointment, Suspension and Emulsion, Dry powder, Solution (Small Volume & large Volume).

Advanced sterile product manufacturing technology: Area planning & environmental control, wall and floor treatment, fixtures and machineries, change rooms, personnel flow, utilities & utilities equipment location, engineering and maintenance.

Process Automation in Pharmaceutical Industry: With specific reference to manufacturing of sterile semisolids, Small Volume Parenterals & Large Volume Parenterals (SVP & LVP), Monitoring of Parenteral manufacturing facility, Cleaning in Place (CIP), Sterilization in Place (SIP), Prefilled Syringe, Powdered Jet, Needle Free Injections, and Form Fill Seal Technology (FFS).

Lyophilization technology: Principles, process and equipment.

12 hrs

3. Nonsterile manufacturing process technology: Manufacturing, manufacturing flowcharts, in process-quality control tests for following Non-Sterile solid dosage forms: Tablets (compressed & coated including sustained and modified release), Capsules (Hard & Soft).

Advanced non-sterile solid product manufacturing technology: Process Automation in Pharmaceutical Industry with specific reference to manufacturing of tablets and coated products, Improved Tablet Production: Tablet production process, granulation and pelletization equipments, continuous and batch mixing, rapid mixing granulators, rota granulators, spheronizers and marumerisers, and other specialized granulation and drying equipments. Problems encountered.

Coating technology: Process, equipment, particle coating, fluidized bed coating, application techniques. Problems encountered. **10 hrs**

4. Containers and closures for pharmaceuticals: Types, performance, assuring quality of glass; types of plastics used, Drug plastic interactions, biological tests, modification of plastics by drugs; different types of closures and closure liners; film wrapper; blister packs; bubble packs; shrink packaging; foil / plastic pouches, bottle seals, tape seals, breakable seals and sealed tubes; quality control of packaging material and filling equipment, flexible packaging, product package compatibility, transit worthiness of package, Stability aspects of packaging. Evaluation of stability of packaging material. **10 hrs**

5. Quality by design (QbD) and process analytical technology (PAT): Current approach and its limitations. Why QbD is required, Advantages, Elements of QbD, Terminology: QTPP. CMA, CQA, CPP, RLD, Design space, Design of Experiments, Risk Assessment and mitigation/minimization. Quality by Design, Formulations by Design, QbD for drug products, QbD for Drug Substances, QbD for Excipients, Analytical QbD. FDA initiative on process analytical technology. PAT as a driver for improving quality and reducing costs: quality by design (QbD), QA, QC and GAMP. PAT guidance, standards and regulatory requirements. **08 hrs**

REFERENCES

1. Lachman L, Lieberman HA, Kanig JL. The theory and practice of industrial pharmacy, 3rd ed., Varghese Publishers, Mumbai 1991.
2. Sinko PJ. Martin's physical pharmacy and pharmaceutical sciences, 5th ed., B.I. Publications Pvt. Ltd, Noida, 2006.
3. Lieberman HA, Lachman L, Schwartz JB. Pharmaceutical dosage forms: tablets Vol. I-III, 2nd ed., CBS Publishers & distributors, New Delhi, 2005.
4. Banker GS, Rhodes CT. Modern Pharmaceutics, 4th ed., Marcel Dekker Inc, New York, 2005.
5. Sidney H Willing, Murray M, Tuckerman. Williams Hitchings IV, Good manufacturing of pharmaceuticals (A Plan for total quality control) 3rd Edition. Bhalani publishing house Mumbai.
6. Indian Pharmacopoeia. Controller of Publication. Delhi, 1996.
7. British Pharmacopoeia. British Pharmacopoeia Commission Office, London, 2008.

8. United States Pharmacopoeia. United States Pharmacopoeial Convention, Inc, USA, 2003.
9. Dean D A, Evans E R and Hall I H. Pharmaceutical Packaging Technology. London, Taylor & Francis, 1st Edition. UK.
10. Edward J Bauer. Pharmaceutical Packaging Handbook. 2009. Informa Health care USA Inc. New York.
11. Shaybe Cox Gad. Pharmaceutical Manufacturing Handbook. John Willey and Sons, New Jersey, 2008.

MPHARM – PHARMACEUTICAL QUALITY ASSURANCE (MQA)

SEMESTER II

PQA-MQA205P: PHARMACEUTICAL QUALITY ASSURANCE PRACTICAL II

COURSE CODE	PQA-MQA 205P				
COURSE TITLE	PHARMACEUTICAL QUALITY ASSURANCE PRACTICAL – II				
SCOPE / SUMMARY			OBJECTIVES / COURSE OUTCOMES		
This course is designed to gain practical skills on qualification of analytical instruments, estimation of contaminants, and design of audit check lists.			Upon completion of this course the student should be able to: 1. Analyze the contamination in pharmaceutical products using various analytical instruments 2. Design audit check list for various pharmaceutical activities. 3. Understand the Qualification of analytical instruments, and importance of QbD and PAT.		
Course Content and Assessment Plan					
Sl. No.	Course Content	Syllabus (Chapters or Units with hours)	Total Marks of assessment	Distribution of marks of assessment	
				Sessional exam (25 % of total marks of assessment) S1	End Sem exam (75 % of total marks of assessment)
1	Analyze the contamination in pharmaceutical product using various analytical instruments.	Experiments 1 to 6 (60 hrs)	44	10	34
2	Design audit check list for various pharmaceutical activities.	Experiments 7 to 12 (31 hrs)	34	8	26
3	Qualification of analytical instruments and case studies on QbD and PAT.	Experiments 13 to 19 (65 hrs)	52	12	40
Total Marks of Assessment			130	30	100

PQA-MQA205P: PHARMACEUTICAL QUALITY ASSURANCE PRACTICAL II

1. Organic contaminants residue analysis by HPLC
2. Estimation of Metallic contaminants by Flame photometer
3. Identification of antibiotic residue by TLC
4. Estimation of Hydrogen Sulphide in Air.
5. Estimation of Chlorine in Work Environment.
6. Sampling and analysis of SO₂ using Colorimetric method
7. Qualification of following Pharma equipment
 - a. Autoclave
 - b. Hot air oven
 - c. Powder Mixer (Dry)
 - d. Tablet Compression Machine
8. Validation of an analytical method for a drug
9. Validation of a processing area
10. Qualification of at least two analytical instruments
11. Cleaning validation of one equipment
12. Qualification of Pharmaceutical Testing Equipment (Dissolution testing apparatus, Friability Apparatus, Disintegration Tester)
13. Check list for Bulk Pharmaceutical Chemicals vendors
14. Check list for tableting production.
15. Check list for sterile production area
16. Check list for Water for injection.
17. Design of plant layout: Sterile and non-sterile
18. Case study on application of QbD
19. Case study on application of PAT
20. Case study on statistical quality control
21. Qualification of dissolution apparatus.

MPHARM – PHARMACEUTICAL QUALITY ASSURANCE (MQA)

SEMESTER II

PQA-MQA206S: SEMINAR IN PHARMACEUTICAL QUALITY ASSURANCE

COURSE CODE	PQA- MQA 206S			
COURSE TITLE	SEMINAR IN PHARMACEUTICAL QUALITY ASSURANCE			
SCOPE / SUMMARY		OBJECTIVES / COURSE OUTCOMES		
The course is designed to create an environment where student gather information about an assigned topic in the relevant field. Students will develop writing skills, presentation skills and defend their presentation effectively.		Upon completion of the course the student shall be able to: <ol style="list-style-type: none"> 1. Acquire knowledge to gather, organize, deliver information, and defend a given topic in the Pharmaceutical Quality Assurance area. 2. Acquire knowledge on concepts using audio-visual aids. 3. Acquire communication and presentation skills. 4. Effectively defend the presentation. 5. Develop a write-up about seminar topic. 6. Cultivate a sense of upgradation of knowledge through self and continuous learning 		
Course Content and Assessment Plan				
Sl. No.	Course Content	Hours	Total Marks of assessment	Marks
				End Sem exam
1	The students should be able to develop skills to gather, organize, deliver information, and defend a given topic in pharmaceutical quality assurance	2 hours/ week	100	No end-semester examination. Only continuous mode.

MPHARM – PHARMACEUTICAL QUALITY ASSURANCE (MQA)

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 Content and Assessment Plan						
Sl. No.	Course Content	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)	15		15	-
4	Student will learn the history, principles and concepts of medical research.	Unit IV (10 hrs)	15		15	-
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 QUALITY ASSURANCE (MQA)

SEMESTER III

MJC 302P: JOURNAL CLUB IN PHARMACEUTICAL QUALITY ASSURANCE

COURSE CODE	MJC 302P			
COURSE TITLE	JOURNAL CLUB IN PHARMACEUTICAL QUALITY ASSURANCE			
SCOPE / SUMMARY		OBJECTIVES / COURSE OUTCOMES		
The course is designed to create an environment where students present a published research paper, and critically analyse it, that would enhance the communication, presentation and analytical skills of the students.		Upon completion of the course the student shall be able to: 1. Learn to organize complex research concepts using audio-visual aids. 2. Acquire communication and presentation skills. 3. Effectively respond to the questions raised by peers and stand scientific scrutiny. 4. Cultivate a sense of upgradation of knowledge through self and continuous learning		
Course Content and Assessment Plan				
Sl. No.	Course Content	Hours	Total Marks of assessment	Marks
				End Sem exam
1	The students should be able to develop skills to gather, organize, deliver information, and defend a given research topic in Pharmaceutical Quality Assurance	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. Nanotechnology in Drug Delivery, Melgardt M. De Villers, Pornanong Aramwit and Glen S Kwon, Springer.
5. Nanoparticulate Drug Delivery Systems, Deepak Thassu, Michel Delees and Yashwant Pathak, Informa Healthcare, NY, USA.
6. Nanoparticulates as Drug Carriers, Vladimir P Torchilin, Imperial College Press, London.

PCE-004E: 3D PRINTING IN PHARMACEUTICAL MANUFACTURING

(15 hrs)

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

REFERENCES

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

PCH-001E: PREPARATIVE SEPARATION TECHNIQUES

(15 hrs)

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

PCH-002E: MOLECULAR MODELLING AND DRUG DESIGN

(15 hrs)

1. Molecular Geometry, Molecular mechanics, Quantum mechanics, Molecular dynamics, 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, nanofibrous material as biomaterial.

Unit III **5 hrs**

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

REFERENCES

1. Principles of Tissue Engineering, 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 WRITING AND PUBLICATION 2 hrs

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

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

REFERENCES

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

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

PPR-003E: SYSTEMATIC REVIEW AND META-ANALYSIS

(15 hrs)

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

REFERENCES:

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

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 (k_e), 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 anti-anxiety drugs
14. Screening methods for anti-parkinsonian drugs
15. Screening methods for Alzheimer's disease related dementia

PHA-003E: FREE RADICAL BIOLOGY AND MEDICINE

(15 hrs)

Objectives

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

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

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

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

(15 hrs)

Objectives

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

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

Guidelines for safety testing

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

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

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

PCO-001E: NUTRACEUTICALS

(15 hrs)

Scope

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

Objectives

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

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

- | | |
|---|--------------|
| 6. Herbs as health foods: Poly phenols and flavonoids (<i>Ginkgo biloba</i> , Tea, Citrus fruits, Grape, Soy); Carotene and fatty acids: (Curcuma, Tomato, Flax seed, Olive oil) | 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 chromatography and electrochromatography (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 Nanotechnology, T. Pradeep, Tata McGraw-Hill Publishing Company Limited, New Delhi, 2008.
2. Nanocrystals: Synthesis, Properties and Applications, C. N. R. Rao, P. J. Thomas and G. U. Kulkarni, Springer (2007)
3. Nanostructures & Nanomaterials: Synthesis, Properties & Applications, Guozhong Cao, Imperial College Press (2004).
4. Nanoparticles as Drug carriers, Vladimir P Torchilin, Imperial College Press, USA, 2006
5. Multifunctional Pharmaceutical Nanocarriers, Vladimir Torchilin, Springer Publishing, New York, NY, 2008.

PCO-004E: HERBAL MONOGRAPHS

(15 hrs)

Scope

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

Objectives

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

- | | |
|---|---------------|
| 1. Introduction to monographs, purpose and content of the monographs, use of the monographs | 3 hrs |
| 2. Systematic study of the following important plants for their monographs;
Leaf: Vasaka (<i>Adhatoda zeylanica</i>)
Root: Shatavari (<i>Asparagus racemosus</i>)
Rhizome: Rasna (<i>Alpinia galanga</i>)
Bark: Cinchona (<i>Cinchona officinalis</i>)
Fruit: Pepper (<i>Piper nigrum</i>)
Entire herb: Kalmegh (<i>Andrographis paniculata</i>). | 12 hrs |

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, Wehrich and Harold Koontz. Mc Graw Hill publishing company.
3. Management, tasks, responsibilities and practices by Drucker. Peter. F., Alfied Publisher Pvt. Ltd.
4. Principles and Practice of Management by L M Prasad, Sultan Chand & Sons.

PRM-004E: ENTREPRENEURSHIP DEVELOPMENT

(15 hrs)

Scope

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

- | | |
|--|--------------|
| 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)