Vivekanand Education Society's College of Pharmacy (Autonomous)

Hashu Advani Complex, Near Collector's Colony, Chembur (E) Mumbai 400074

Affiliated to University of Mumbai

Syllabus for Approval

Sr. No.	Heading	Particulars
1	Title of the Course	Master of Pharmacy (M. Pharm.)
2	Eligibility for Admission	B. Pharm. / GPAT
3	Passing Marks	50%
4	Ordinance/ Regulations if any	
5	No. of Years / Semesters	Two Years / Four Semester
6	Level	PG
7	Pattern	Semester
8	Status	Revised
9	To be implemented from Academic Year	From Academic year 2024-25

Date: 18/05/2024

Signature: sshidhaye

Name of BOS Chairperson Dr Supriya Shidhaye

Vivekanand Education Society's College of Pharmacy (Autonomous)

Hashu Advani Complex, Near Collector's Colony, Chembur (E) Mumbai 400074

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Scheme and Syllabus for
CHOICE BASED CREDIT SYSTEM
Master of Pharmacy, M. Pharm.
for
Post graduate Programme

Revised Course (Revised 2024)

Effective from Academic Year 2024-25

INTRODUCTION

ALIGNING SYLLABUS WITH THE VISION OF NEP 2020

As an autonomous college, we are committed to staying at the forefront of educational reform and ensuring that our curriculum reflects the latest advancements in pedagogy and policy. In light of the National Education Policy (NEP) 2020, we have undertaken a comprehensive review and revision of our syllabus to align it with the guidelines set forth in the NEP.

Our revised syllabus reflects our commitment to excellence, innovation, and skill enhancement in education, in alignment with the goals and principles of the National Education Policy 2020. We believe that by embracing these changes, we can better prepare our students to thrive in a rapidly evolving global landscape and contribute meaningfully to society.

RECOMMENDATIONS OF NATIONAL REGULATORY AUTHORITIES

The University Grants Commission (UGC), the National Assessment and Accreditation Council (NAAC), the Distance Education Council (DEC) and the National Knowledge Commission (NKC) have time and again come out with recommendations for improving the quality and effectiveness of Higher education provisions in the country. The ministry of Human Resource Development at the Central level and the Ministry of Higher & Technical Education, Govt. of Maharashtra have also repeatedly stressed on the need for universities to pay prompt attention to improve the quality of education. The National Knowledge Commission (NKC), in its report to the Prime Minister on 29th November 2006) has also reiterated the importance of higher education and the contribution it has made to economic development, social progress and political democracy in independent India.

An important concern voiced more strongly in recent times, is the need to develop a Choice- Based Credit System (CBCS) in tune with global trends and the adoption of a sound grading system for reflecting learner performance. This is in line with the **recommendation of the UGC** in its Action Plan for Academic and Administrative Reforms (Ref. UGC letters January 2008; March 2009) "……. Curricular flexibility and learners' mobility are issues that warrant our urgent attention. These can be addressed by introducing credit based courses and credit accumulation. In order to

provide with some degree of flexibility to learners, we need to provide flexibility in course selection and also a minimum as well as a maximum permissible span of time in which a course can be completed by a learner… The Choice- Based Credit System (CBCS) imminently fits into the emerging socioeconomic milieu, and could effectively respond to the educational and occupational aspirations of the upcoming generations. In view of this, institutions of higher education in India would do well to invest thought and resources into introducing CBCS. Aided by modern communication and information technology, CBCS has a high probability to be operationalized efficiently and effectively — elevating learners, institutions and higher education system in the country to newer heights…".

RATIONALE FOR INTRODUCTION OF CREDIT AND GRADING SYSTEM

The UGC while outlining the several unique features of the Choice-Based Credit System (CBCS) has, in fact, given in a nutshell, the rationale for its introduction. Among the features highlighted by the UGC are: *Enhanced learning opportunities, ability to match learners' scholastic needs and aspirations, inter-institution transferability of learners (following the completion of a semester), part-completion of an academic programme in the institution of enrolment and part-completion in a specialized (and recognized) institution, improvement in educational quality and excellence, flexibility for working learners to complete the programme over an extended period of time, standardization and comparability of educational programmes across the country, etc.*

This Choice Based Credit System enables a much-required shift in focus from teacher-centric to learner-centric education since the workload estimated is based on the investment of time in learning, not in teaching. It also focuses on continuous evaluation which will enhance the quality of education. It can be concluded from the above discussion that it is very much essential to implement the Choice Based Credit System in higher education in India. Course credit structure, examination/assessment and grading are mainly focused aspects of this manual and discussed in subsequent chapters.

DIRECTIVES OF PHARMACY COUNCIL OF INDIA

The Pharmacy Council of India (PCI) in exercise of the powers conferred to it under the sections 10 and 18 of the Pharmacy Act 1948 (8 of 1948), with the approval of the Central Government, had made the Bachelor of Pharmacy (B. Pharm.) Course Regulations, 2014 and Master of Pharmacy (M. Pharm.) Course regulations vide Gazette dated December 10, 2014. Further as per regulations 6 and 8 of the above course regulations the PCI has also prescribed the Rules and Syllabus for B. Pharm. course and Scheme and Syllabus for M. Pharm., its letter Ref 14-136/2016-PCI and Ref 14-154/2015 PCI dated December 21, 2016, with the subject heading "Statutory Scheme/Rules and syllabus for B. Pharm and M. Pharm. courses". It is thus mandatory to implement the directives of PCI with regard to the Rules/Regulations/Syllabus for recognition and extension of approval of B. Pharm. and M. Pharm. programs of institutes/Universities by the PCI

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1. Short Title and Commencement

These regulations shall be called as "Academic Regulations for the Master of Pharmacy (Revised 2024) Choice Based Credit System (CBCS) of the Vivekanand Education Society's College of Pharmacy, Chembur, Mumbai (Autonomous). They shall come into effect from the Academic Year 2024-25. The regulations framed are subject to modifications from time to time by Board of studies & Academic Council of VESCOP & guidelines by Pharmacy Council of India.

2. Minimum qualification for admission

The candidate should be an Indian National; Passed Bachelor's Degree in Pharmacy from any or Pharmacy Council of India or Central or State Government approved institution, with at least 55% marks (at least 50% marks in case of Backward Class category, Economically weaker section and Persons with Disability Candidates belonging to Maharashtra State only); Obtained non zero positive score in Graduates Pharmacy Aptitude Test(GPAT) conducted by National Testing Agency; For sponsored candidates, minimum of two years of fulltime work experience in a registered firm/ company/industry/ educational and/ or research institute/ any Government Department or Government Autonomous Organization in the relevant field in which admission is being sought. Any other criterion declared from time to time by the appropriate authority as defined under the Act

All admissions will be done as per Rules and Regulations prescribed from time to time in the information brochure published by State CET Cell, Maharashtra State for the said academic year.

3. Duration of the program

The program of study for M. Pharm. 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 Pharmacy Council of India, New Delhi.

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4. Medium of instruction and examinations

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 June/July to November/December and the even semesters shall be conducted from December/January to May/June in every calendar year.

6. Attendance and progress

According to ordinance O.6086 (repealing O.119, O.120 and O.125), it is mandatory for every learner to have minimum 50% attendance for each course and average attendance of all the courses together has to be 75% in each semester. 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, 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/extra-curricular activities is dependent upon the quantum of work expected to be put in for each of these activities per week.

Credit assignment

Theory and Laboratory courses

Courses are broadly classified as Theory and Practical. Theory courses consist of lecture (L) and Practical (P) courses consist of hours spent in the laboratory. Credits (C) for a course is 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 and a multiplier of half (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 semester carries a credit of 2.

The contact hours of seminars, assignments and research work shall be treated as that of practical courses for the purpose of calculating credits. i.e., the contact hours shall be multiplied by 1/2.

Similarly, the contact hours of journal club, research work presentations and discussions with the supervisor shall be considered as theory course and multiplied by1.

Minimum credit requirements

The minimum credit points required for the award of M. Pharm. degree is **97**. However, based on the credit points earned by the students under the head of co-curricular activities, a student shall earn a maximum of **102** credit points. These credits are divided into Theory courses, Practical, Seminars, Assignments, Research work, Discussions with the supervisor, Journal club and Co-Curricular activities over the duration of four semesters. The credits are distributed semester-wise as shown in Table 6. Courses generally progress in sequence, building competencies and their positioning indicates 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 respective courses.

9. Course of study

The specializations in M. Pharm program is given in Table 1.

Table – 1: List of M. Pharm. Specializations and their Code

Sr. No.	Specialisation	Code
1	Pharmaceutics	MPH
2	Pharmaceutical Chemistry	MPC
3	Pharmaceutical Quality Assurance	MQA

The course of study for M. Pharm. specializations shall include Semester wise Theory & Practical as given in Tables 2 to 4. The number of hours to be devoted to each theory and practical course in any semester shall not be less than that shown in Table 2 to 4.

Table-2: Course of study for M. Pharm. (Pharmaceutics)

Sr. No.	Course Code	Course	Credit Hours	Credit Points	Hrs./w k	Marks
	Semester I					
1	**MPH101T**	Modern Pharmaceutical Analytical Techniques	4	4	4	100
2	**MPH102T**	Drug Delivery System	4	4	4	100
3	**MPH103T**	Modern Pharmaceutics	4	4	4	100
4	**MPH104T**	Regulatory Affair	4	4	4	100
5	**MPH105P**	Pharmaceutics Practical I	12	6	12	150
6	-	Seminar/Assignment	7	4	7	100
7	**IKS_MP_101**	Yoga, a key to healthy life (IKS)	-	-	2	-
	Total		**35**	**26**	**37**	**650**
	Semester II					
1	**MPH201T**	Molecular Pharmaceutics (Nano Tech and Targeted DDS)	4	4	4	100
2	**MPH202T**	Advanced Biopharmaceutics& Pharmacokinetics	4	4	4	100
3	**MPH203T**	Computer Aided Drug Delivery System	4	4	4	100
4	**MPH204T**	Cosmetic and Cosmeceuticals	4	4	4	100
5	**MPH205P**	Pharmaceutics Practical II	12	6	12	150
6	-	Seminar/Assignment	7	4	7	100
7	**AEC_MX_102**	Multidisciplinary Subject (AEC)	-	-	2	-
		Total	**35**	**26**	**37**	**650**

IKS: Indian Knowledge System

AEC: Ability Enhancement Course

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Table – 3: Course of study for M. Pharm. (Pharmaceutical Chemistry)

Sr. No.	Course Code	Course	Credit Hours	Credit Points	Hrs./ w K	Marks
	Semester I					
1	**MPC101T**	Modern Pharmaceutical Analytical Techniques	4	4	4	100
2	**MPC102T**	Advanced Organic Chemistry -I	4	4	4	100
3	**MPC103T**	Advanced Medicinal chemistry	4	4	4	100
4	**MPC104T**	Chemistry of Natural Products	4	4	4	100
5	**MPC105P**	Pharmaceutical Chemistry Practical I	12	6	12	150
6	-	Seminar/Assignment	7	4	7	100
7	**IKS_MP_101**	Yoga, a key to healthy life (IKS)	-	-	2	-
	Total		**35**	**26**	**37**	**650**
	Semester II					
1	**MPC201T**	Advanced Spectral Analysis	4	4	4	100
2	**MPC202T**	Advanced Organic Chemistry -II	4	4	4	100
3	**MPC203T**	Computer Aided Drug Design	4	4	4	100
4	**MPC204T**	Pharmaceutical Process Chemistry	4	4	4	100
5	**MPC205P**	Pharmaceutical Chemistry Practical II	12	6	12	150
6	-	Seminar/Assignment	7	4	7	100
7	**AEC_MX_102**	Multidisciplinary Subject (AEC)	-	-	2	-
		Total	**29**	**23**	**30**	**650**

IKS: Indian Knowledge System

AEC: Ability Enhancement Course

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Table – 4: Course of study for M. Pharm. (Pharmaceutical Quality Assurance or Quality Assurance)

Sr. No.	Course Code	Course	Credit Hours	Credit Points	Hrs./ wk	Marks
	Semester I					
1	**MQA101T**	Modern Pharmaceutical Analytical Techniques	4	4	4	100
2	**MQA102T**	Quality Management System	4	4	4	100
3	**MQA103T**	Quality Control and Quality Assurance	4	4	4	100
4	**MQA104T**	Product Development and Technology Transfer	4	4	4	100
5	**MQA105P**	Pharmaceutical Quality Assurance Practical I	12	6	12	150
6	-	Seminar/Assignment	7	4	7	100
7	**IKS_MP_101**	Yoga, a key to healthy life (IKS)	-	-	2	-
		Total	**35**	**26**	**37**	**650**
	Semester II					
1	**MQA201T**	Hazards and Safety Management	4	4	4	100
2	**MQA202T**	Pharmaceutical Validation	4	4	4	100
3	**MQA203T**	Audits and Regulatory Compliance	4	4	4	100
4	**MQA204T**	Pharmaceutical Manufacturing Technology	4	4	4	100
5	**MQA205P**	Pharmaceutical Quality Assurance Practical II	12	6	12	150
6	-	Seminar/Assignment	7	4	7	100
7	**AEC_MX_102**	Multidisciplinary Subject (AEC)	-	-	2	-
		Total	**29**	**23**	**30**	**650**

IKS: Indian Knowledge System

AEC: Ability Enhancement Course

Table – 5: Course of study for M. Pharm. III and IV Semesters (Common for All Specializations)

Sr. No.	Course Code	Course	Credit Hours	Credit Points
1.	**MRM301T**	Research Methodology and Biostatistics	4	4
2.	**-**	Journal Club	2	2
3.	**AEC_MP_301**	Scientific Writing (AEC)	-	-
4.	**VSC_MP_301**	Practical Insights of HPLC Method Development (VSC)	-	-
5.	**-**	Discussion / Presentation (Proposal Presentation)	5	5
6.	**-**	Research Work	30	30
	Total		**41**	**41**

VSC: Vocational Skill Enhancement Course

Table – 6: Semester wise credits distribution

Semester	Credit Points
I	26
II	26
III and IV	41
Co-curricular Activities* (Attending Conference, Scientific Presentations and Other Scholarly Activities)	Minimum=04 Maximum=09
Total Credit Points	Minimum=97 Maximum=102

*Credit Points for Co-curricular Activities. Minimum number of contact hours per credit shall be 15 hours,

Table – 7: Guidelines for Awarding Credit Points for Co-curricular Activities

Name of the Activity	Maximum Credit Points Eligible / Activity
Participation in National/ International Level Seminar /Conference/ Workshop/ Symposium/ Training Programs (related to the specialization of the student) (1 Credit for each participation)	02
Academic Award/Research Award from State Level/National Agencies	01
Academic Award/Research Award from International Agencies	02
Research / Review Publication/ Book chapter in National / International Journals (Indexed in Scopus / Web of Science), Patent file or granted (2 credits for each publication)	04

*The credit points assigned for extracurricular and or co-curricular activities shall be given by the Principal of the Autonomous college. The criteria to acquire this credit point shall be defined by the autonomous colleges from time to time

10. Program Committee

1. The M. Pharm. 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 M. Pharm specialization and four student representatives (two from each academic year), nominated by the Principal of Autonomous college.

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 thrice in a semester preferably at the end of each Sessional exam (Internal Assessment) and before the end semester exam.

11. Examinations/Assessments

The schemes for internal assessment and end semester examinations are given in Tables – 8 to 11.

Tables – 8: Schemes for internal assessments and end semester examinations (Pharmaceutics- MPH)

Sr. No.	Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
			Continuous Mode	Sessional Exams		Total	Marks	Duration	
				Marks	Duration				
	SEMESTER I								
1.	**MPH101T**	Modern Pharmaceutical Analytical Techniques	10	15	1 Hr	25	75	3 Hrs	100
2.	**MPH102T**	Drug Delivery System	10	15	1 Hr	25	75	3 Hrs	100
3.	**MPH103T**	Modern Pharmaceutics	10	15	1 Hr	25	75	3 Hrs	100
4.	**MPH104T**	Regulatory Affair	10	15	1 Hr	25	75	3 Hrs	100
5.	**MPH105P**	Pharmaceutics Practical I	20	30	6 Hrs	50	100	6 Hrs	150
6.	-	Seminar /Assignment	-	-	-	-	-	-	100
7.	**IKS_MP_101**	Yoga, a key to healthy life (IKS)	-	-	-	-	-	-	-
	Total								**650**
	SEMESTER II								
1.	**MPH201T**	Molecular Pharmaceutics (Nano Tech and Targeted DDS)	10	15	1 Hr	25	75	3 Hrs	100
2.	**MPH202T**	Advanced Biopharmaceutics & Pharmacokinetics	10	15	1 Hr	25	75	3 Hrs	100
3.	**MPH203T**	Computer Aided Drug Delivery System	10	15	1 Hr	25	75	3 Hrs	100
4.	**MPH 204T**	Cosmetic and Cosmeceuticals	10	15	1 Hr	25	75	3 Hrs	100
5.	**MPH205P**	Pharmaceutics Practical I	20	30	6 Hrs	50	100	6 Hrs	150
6.	-	Seminar /Assignment	-	-	-	-	-	-	100
7.	**AEC_MX_102**	Multidisciplinary Subject (AEC)	-	-	-	-	-	-	-
	TOTAL								**650**

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Tables – 9: Schemes for internal assessments and end semester examinations (Pharmaceutical Chemistry-MPC)

Sr. No.	Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
			Continuous Mode	Sessional Exams		Total	Marks	Duration	
				Marks	Duration				
	SEMESTER I								
1.	MPC101T	Modern Pharmaceutical Analytical Techniques	10	15	1 Hr	25	75	3 Hrs	100
2.	MPC102T	Advanced Organic Chemistry -I	10	15	1 Hr	25	75	3 Hrs	100
3.	MPC103T	Advanced Medicinal chemistry	10	15	1 Hr	25	75	3 Hrs	100
4.	MPC104T	Chemistry of Natural Products	10	15	1 Hr	25	75	3 Hrs	100
5.	MPC105P	Pharmaceutical Chemistry Practical I	20	30	6 Hrs	50	100	6 Hrs	150
6.	-	Seminar /Assignment	-	-	-	-	-	-	100
7.	IKS_MP_101	Yoga, a key to healthy life (IKS))	-	-	-	-	-	-	-
	Total								650
	SEMESTER II								
1.	MPC201T	Advanced Spectral Analysis	10	15	1 Hr	25	75	3 Hrs	100
2.	MPC202T	Advanced Organic Chemistry -II	10	15	1 Hr	25	75	3 Hrs	100
3.	MPC203T	Computer Aided Drug Design	10	15	1 Hr	25	75	3 Hrs	100
4.	MPC204T	Pharmaceutical Process Chemistry	10	15	1 Hr	25	75	3 Hrs	100
5.	MPC205P	Pharmaceutical Chemistry Practical II	20	30	6 Hrs	50	100	6 Hrs	150
6.	-	Seminar /Assignment	-	-	-	-	-	-	100
7.	AEC_MX_102	Multidisciplinary Subject (AEC)	-	-	-	-	-	-	-
	TOTAL								650

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Tables – 10: Schemes for internal assessments and end semester examinations (Pharmaceutical Quality Assurance or Quality Assurance -MQA)

Sr. No.	Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
			Continuous Mode	Sessional Exams		Total	Marks	Duration	
				Marks	Duration				
	SEMESTER I								
1.	**MQA1 01T**	Modern Pharmaceutical Analytical Techniques	10	15	1 Hr	25	75	3 Hrs	100
2.	**MQA102T**	Quality Management System	10	15	1 Hr	25	75	3 Hrs	100
3.	**MQA103T**	Quality Control and Quality Assurance	10	15	1 Hr	25	75	3 Hrs	100
4.	**MQA1 04T**	Product Development and Technology Transfer	10	15	1 Hr	25	75	3 Hrs	100
5.	**MQA1 05P**	Pharmaceutical Quality Assurance Practical I	20	30	6 Hrs	50	100	6 Hrs	150
6.	**-**	Seminar /Assignment	-	-	-	-	-	-	100
7.	**IKS_MP_101**	Yoga, a key to healthy life (IKS)	-	-	-	-	-	-	-
	Total								**650**
	SEMESTER II								
1.	**MQA201T**	Hazards and Safety Management	10	15	1 Hr	25	75	3 Hrs	100
2.	**MQA202T**	Pharmaceutical Validation	10	15	1 Hr	25	75	3 Hrs	100
3.	**MQA2 03T**	Audits and Regulatory Compliance	10	15	1 Hr	25	75	3 Hrs	100
4.	**MQA2 04T**	Pharmaceutical Manufacturing Technology	10	15	1 Hr	25	75	3 Hrs	100
5.	**MQA2 05P**	Pharmaceutical Quality Assurance Practical II	20	30	6 Hrs	50	100	6 Hrs	150
6.	**-**	Seminar /Assignment	-	-	-	-	-	-	100
7.	**AEC_MX_102**	Multidisciplinary Subject (AEC)	-	-	-	-	-	-	-
	TOTAL								**650**

Tables – 11: Schemes for internal assessments and end semester examinations (Semester III & IV)

Sr. No.	Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
			Continuous Mode	Sessional Exams		Total	Marks	Duration	
				Marks	Duration				
	SEMESTER III								
1.	**MRM301T**	Research Methodology and Biostatistics*	10	15	1 Hr	25	75	3 Hrs	100
2.	-	Journal club	-	-	-	25	-	-	25
3.	-	Discussion / Presentation (Proposal Presentation)	-	-	-	50	-	-	50
4.	-	Research work and colloquium	-	-	-	-	-	-	-
5.	**AEC_MP_301**	Scientific Writing (SEC)	-	-	-	-	-	-	-
6.	**VSC_MP_301**	Practical Insights of HPLC Method Development	-	-	-	-	-	-	-
	Total								**175**
	SEMESTER IV								
1.	-	Journal club	-	-	-	25	-	-	25
2.	-	Discussion / Presentation (Proposal Presentation)	-	-	-	75	-	-	75
3.	-	Research work and Colloquium	-	-	-	-	750	1 Hr	750
	Total								**850**

Total marks from Sem to Sem IV: 2325

11.1 Internal assessment: Continuous mode

The marks allocated for Continuous mode of Internal Assessment shall be awarded as per the scheme given below.

Table – 12: Scheme for awarding internal assessment: Continuous mode

Theory	
Criteria	**Maximum Marks**
Attendance (Refer Table – 13)	4
Quiz, Assignment/ open book test	2
Student – Teacher interaction	4
Total	**10**
Practical	
Attendance (Refer Table – 13)	05
Based on Practical Records, Regular viva voce, etc.	15
Total	**20**

Table – 13: Guidelines for the allotment of marks for attendance

Percentage of Attendance	Theory	Practical
90 – 100	4	5
85 – 89	3	4
80 – 84	2	3
75– 79	1	2
Less than 75	0	0

11.2 Sessional Exams

Two sessional exams shall be conducted for each theory / practical course as per the schedule fixed by the college(s). Final sessional marks shall be arrived at by considering the marks secured by the student in both the mid examinations with 80% weightage to the better mid examination and 20% to the other. If a learner is absent for any or both of the sessional examinations, the mark for that particular examination shall be considered as zero while calculating the final sessional marks. The re sessional examination shall not be conducted if any student misses the examination.

Question paper pattern for theory Sessional examinations For subjects having University examination

I. Multiple Choice Questions (MCQs)	=	5 x 1 = 05
OR		OR
Objective Type Questions 1 or 2 marks (5 x 1) (Answer all the questions)	=	5 x 1 = 05
I. Long Answers (Answer 1 out of 2)	=	1 x 05 = 05
II. Short Answers (Answer 2 out of 3)#	=	2 x 2.5 = 05
Total	=	15 marks

One of the sub questions should be case study or application based,

Question paper pattern for practical sessional examinations

I. Synopsis	=	6
II. Experiments	=	20
III. Viva voce	=	4
Total	=	30 marks

11.3 End Semester Exam:

The End Semester Examinations in Semesters I and II (Theory Courses) of the M. Pharm. degree, and the *viva-voce* examination of the thesis at the end of Semester IV for the M. Pharm. Degree course will be conducted by the autonomous college.

A time-table and question papers for all the theory examinations of Semesters I and II will be prepared/set by the Controller of Examination (COE) of Autonomous College as per the procedure.

All appointments (paper setters, examiners, moderators) are done by Controller of examination (COE) of autonomous college from panel approved by Board of studies of autonomous college.
External examiner for assessment of thesis is appointed by the Research Recognition committee constituted by the autonomous college.
Final Grade reports are to be sent by the Institute to the respective section of university on completion of the viva-voce. The university of Mumbai shall award the final degree certificate for M Pharm

Question paper pattern for end semester theory examinations For 75 marks paper

I. Multiple Choice Questions(MCQs)	=	20 x 1	= 20
OR		OR	
Objective Type Questions (10 x 2)	=	10 x 2	= 20
(Answer all the questions 1 or 2 marks)			
II. Long Answers (Answer 2 out of 3)	=	2 x 10	= 20
III. Short Answers (Answer 7 out of 9)#	=	7 x 5	= 35
	Total =	75 marks	

Three of the sub questions should be case study or application based,

Question paper pattern for end semester practical examinations

I. Synopsis	=	15
II. Experiments	=	75
III. Viva voce	=	10
Total	=	100 marks

12. Promotion and award of grades

A student shall be declared PASS and eligible for getting grade in a course of M. Pharm. programme if he/she secures at least 50% marks in that particular course including internal assessment.

13. Carry forward of marks

In case a student fails to secure the minimum **50%** in any Theory or Practical course, then 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 shall be entitled for grade obtained by him/her on passing.

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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. Reexamination of end semester examinations

Re-examination of end semester examination shall be conducted as per the schedule prepared by the autonomous college time to time.

16. Allowed to keep terms(ATKT):

No student shall be admitted to any examination unless he/she fulfils the norms of attendance. ATKT rules are applicable as follows:

A student shall be eligible to carry forward all the courses of I, II and III. The submission of synopsis and the holding of the viva voce examination shall be permitted only if the student has successfully cleared semester I, II and III.

A student shall be eligible to get his/her CGPA upon successful completion of the courses of I to IV semesters within the stipulated time period as per the norms.

Note: Grade AB should be considered as failed and treated as one head for deciding ATKT. Such rules are also applicable for those students who fail to register for examination(s) of any course in any semester.

17. Grading of performances

a. Letter grades and grade points allocations:

Based on the performances, each student shall be awarded a final letter grade at the end of the semester for each course. The letter grades and their corresponding grade points are given in Table – 14.

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Table – 14: Letter grades and grade points equivalent to Percentage of marks and performances

Percentage of Marks Obtained	Letter Grade	Grade Point	Performance
90.00 – 100	O	10	Outstanding
80.00 – 89.99	A	9	Excellent
70.00 – 79.99	B	8	Good
60.00 – 69.99	C	7	Fair
50.00 – 59.99	D	6	Average
Less than 50	F	0	Fail
Absent	AB	0	Fail

A learner who remains absent for any end semester examination shall be assigned a letter grade of AB and a corresponding grade point of zero. He/she should reappear for the said evaluation/examination in due course.

18. The Semester grade point average (SGPA)

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 five 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:

$$\text{SGPA} = \frac{C_1G_1 + C_2G_2 + C_3G_3 + C_4G_4}{C_1 + C_2 + C_3 + C_4}$$

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 ABS grade awarded in that semester. For example, if a learner has a F or ABS grade in course 4, the SGPA shall then be computed as:

$$\text{SGPA} = \frac{C_1G_1 + C_2G_2 + C_3G_3 + C_4 * 0}{C_1 + C_2 + C_3 + C_4}$$

19. 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 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:

$$\text{CGPA} = \frac{C_1S_1 + C_2S_2 + C_3S_3 + C_4S_4}{C_1 + C_2 + C_3 + C_4}$$

where C_1, C_2, C_3,…. is the total number of credits for semester I,II,III,…. and S_1,S_2, S_3,….is the SGPA of semester I,II,III,…. .

20. Declaration of class

Although the GPA system is a stand-alone system of grading and not amenable to facile conversion to percent marks, in general, the conversion of CGPA to percent marks is: CGPA x 9.5 = Percent marks.

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

- First Class with Distinction = CGPA of. 7.37 and above
- First Class = CGPA of 6.32 to 7.36
- Second Class = CGPA of 6.00 to 6.31

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21. Project work

All the students shall undertake a project under the supervision of a teacher in Semester III to IV and submit a report. Four copies of the project report shall be submitted.

- **Writing the thesis**

The thesis will be typed using Times New Roman font, size 11, 1.5 line spacing, with all headings/subheadings in bold.

The thesis will be of maximum 125 pages and composed in the following manner:

Chapter 1 – Introduction. This should be limited to about 30 pages and will describe all background information of the research described in the thesis.

Chapter 2 – Aims and objectives, limited to 2 pages.

Chapter 3 – Plan of Work, limited to 4 pages

Chapter 4 – Experimental. This section should preferably include only the optimized experiments from which the inferences and conclusions were drawn.

Chapter 5 – Results and Discussion, this should constitute 40 to 50 pages of the thesis.

Chapter 6 – References. This should be in ACS format. Refer to Ch. 14 *In The ACS Style Guide*; Coghill, A., et al.; American Chemical Society: Washington, DC, 2006.

If any deviations are found in the style of writing the thesis, the thesis is liable to be rejected by the College.

Table 15: Scheme of assessment for Thesis

Assessment	External Examiner	Internal (Guiding Teacher)	Total
	50% of marks	50% of marks	100%

The assessment of the thesis submitted at the end of Semester IV will done by both the internal (guiding) teacher and an external examiner chosen from the industry with established competence in the field or may be any recognized research guide from another recognized university. It is proposed that every learner will submit a synopsis of the research work carried out by him/her

during Semesters III and IV which forms the content of the thesis. A learner will be permitted to submit synopsis after completion of 75 % of research work or 75 % of Sem IV term, whichever is longer and will submit the final thesis not later than 24 months from the beginning of the M. Pharm program. The time between submission of synopsis and thesis should be at least one month. The learner must submit his thesis to the College in a format as prescribed by the University. The College will take all steps to conduct the *viva-voce* examination at the earliest after the submission of the thesis. It is expected that only the synopsis of the thesis submitted by the learner will be forward by the college to the external examiner at least one week before the conduct of the *viva-voce* examination. Only at the time of the *viva-voce* examination, the external examiner will be presented the thesis submitted by the candidate for the award of the degree.

The evaluation will be done by a pair of examiners (research guide and external examiner), appointed by autonomous college and at the College, based on the report and a viva-voce. The criteria of evaluation of Dissertation are given in the curriculum manual.

Any late submission of synopsis or thesis will result in the learner requiring keeping terms for the next semester and any subsequent semester/s till the learner finishes his/her degree.

The internal and external examiner appointed by the COE as per the procedure shall evaluate the project. The projects shall be evaluated as per the criteria given below.

Evaluation of Dissertation Book:

Objective(s) of the work done	**50**
Methodology adopted	**150**
Results and Discussions	**250**
Conclusions and Outcomes	**50**
Total	**500 Marks**

Evaluation of Presentation:

Presentation of work		**100**
Communication skills		**50**
Question and answers kills		**100**
	Total	**250 Marks**

22. Award of degree

Candidates who fulfil the requirements mentioned above shall be eligible for award of degree during the ensuing convocation at University of Mumbai.

23. Duration for completion of the program of study

The duration for the completion of the program shall be fixed as per the norms of the University of Mumbai.

24. Audit Courses

Audit courses are mandatory noncredit courses covering the subjects of developing desired attitude, imparting skills or giving value education to learner.

A faculty advisor/mentor shall be assigned to each Audit course to advise students on the program, A candidate is required to submit report at the end of the semester to the examining authority of the Autonomous college. Student must score minimum 50% marks as per the scheme given in Table 16 and Satisfactory report from the concerned faculty is required to declare him/her as pass with specific grade which will get reflected in particular semester grade card. .

Table 16: Scheme for awarding the Grade for Audit Course

Criteria	**Maximum Marks**
Attendance	40%
Academic activities : Case studies, presentation, Assignments	20%
Student – Teacher interaction	10%
Report	30%
Total	**100%**
Award of Grade as per the marks	
Percent Marks obtained	**Grade**
100%	O
90%	A
80%	B
70%	C
60%	D
50%	E
Less Than 50%	Fail

Syllabus

M. Pharm
Pharmaceutics
Semester 1

CourseCode	Course Name	Credits
MPH101T	Modern Pharmaceutical Analytical Techniques	4

- **Prerequisites:**
  - Knowledge of Liquid-liquid extraction- Partition coefficient, molecular diffusion, mass transfer
  - Knowledge of Adsorption, adsorption isotherms, quantum theory, difference between protons, neutrons, and electrons
  - Knowledge of Carbocation stability, fission and rearrangements.
  - Knowledge of the Difference between protons, neutrons, and electrons
- **Course Outcomes: After completion of this course students should be able to:**
  1. Recall with examples the terminologies associated with spectroscopy, chromatography, X-ray diffraction, electrophoresis, potentiometry, and thermalanalysis
  2. Explain and illustrate the theory, instrumentation, and applications of various techniques involved in spectroscopy, chromatography, X-ray diffraction, electrophoresis, potentiometry and thermal analysis, and chromatographic parameters.
  3. Apply the knowledge gained to calculate concentration by UV-visible spectroscopy, predict the IR frequencies, number of signals in NMR, and fragmentation pattern in MS for simple organic compounds.
  4. Predict the spectroscopic behavior of molecules.

Sr. No.	Content	Hours
Unit 1:		**8**
1.1	**UV-Visible spectroscopy**: • *Principle,* Instrumentation of UV-Visible Spectroscopy **(Self-study:1 hr)** • Instrumentation associated with UV-Visible spectroscopy, Choice ofsolvents and solvent effect and **(Self-study)** • Applications of UV-Visible spectroscopy: Case study-based applications for single component and multicomponent analysis • Interpretation of UV-visible spectra of a simple organic compound • Difference/Derivative spectroscopy	2
1.2	**IR spectroscopy**: • Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier -Transform IR Spectrometer, Factors affecting vibrational frequencies **(Self-study)** • Applications of IR spectroscopy: Including case-study for use of Near IR as a PAT tool, Data interpretation of IR spectra of a simpleorganic compound	2
1.3	**Spectroflourimetry**: • Theory of Fluorescence, Factors affecting fluorescence, Quenchers **(Self-study)** • Instrumentation and Applications of fluorescence spectrophotometer	2
1.4	**Flame emission spectroscopy and Atomic absorption spectroscopy**: • Principle, Instrumentation, Interferences and Applications **(Self-study)**	2

	• Use of AAS for analysis of elemental impurities	
Unit 2:		**9**
2.1	**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	7
2.2	Interpretation of ^{1}H NMR spectrum of simple organic compounds	2
Unit 3:		**9**
3.1	**Mass Spectrometry:** Principle, Theory, Instrumentation of Mass Spectroscopy. Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI. Analyzers - Quadrupole and Time of Flight. Mass fragmentation and its rules, Metastable ions, Isotopic peaks. Applications of Mass spectroscopy	7
3.2	Interpretation of mass spectrum of simple organic compounds	2
Unit 4:		**10**
4.1	Introduction to chromatography and classification of chromatographic methods based on the mechanism of separation **(Self-study)**	1
4.2	Numericals based on calculation of chromatographic parameters	2
4.3	**Chromatography:** Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution and applications of the following: a. Thin Layer chromatography b. High Performance Thin Layer chromatography c. Paper chromatography d. Ion exchange chromatography e. Column chromatography f. Gas chromatography g. High Performance Liquid chromatography h. Affinity chromatography i. Gel chromatography j. Ultra-High Performance Liquid chromatography	7
Unit 5:		**10**
5.1	**Electrophoresis** - Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following: i.Paper electrophoresis i.Gel electrophoresis i.Capillary electrophoresis .Zone electrophoresis .Moving boundary electrophoresis i.Iso electric focusing	4
5.2	**X-ray Crystallography** - Production of X rays, Different X ray diffraction methods, Bragg 's law, Rotating crystal technique, X ray	3

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	powder technique, Types of crystals and applications of X- ray diffraction.	
5.3	**Immunological assays**: RIA (Radioimmunoassay), ELISA, RT-PCR, Bioluminescence assays	3
Unit 6:		**14**
6.1	**ICP-MS:** Principle and Instrumentation, Sample preparation techniques and method development strategies, Pharmaceutical Applications	2
6.2	**Hyphenated techniques:** Principle, interfaces used and applications of: LC-MS, GC-MS and HPTLC-MS	4
6.3	**Advanced Microscopic techniques:** Principle, Instrumentation and Applications of: SEM & TEM	3
6.4	**Potentiometry:** Principle, working, Ion selective Electrodes and Application of potentiometry **(Self-study)**	1
6.5	**Thermal Techniques:** • **Differential Scanning Calorimetry (DSC):** Principle, thermal transitions and Instrumentation (Heat flux and power-compensation and designs), Modulated DSC, Hyper DSC, experimental parameters (sample preparation, experimental conditions, calibration, heating and cooling rates, resolution, source of errors) and their influence, advantage and disadvantages, pharmaceutical applications. • **Differential Thermal Analysis (DTA):** Principle, instrumentation and advantage and disadvantages, pharmaceutical applications, derivative differential thermal analysis (DDTA) • **Thermogravimetric Analysis TGA:** Principle, instrumentation, factors affecting results, advantage and disadvantages, pharmaceutical applications	4
	Total Hours	**60**

Reference material:

. **Books**:**

1. D. A. Skoog, F. J. Holler and S. R. Crouch, Principles of Instrumental Analysis, Saunders College Publishing, USA.
2. K. A. Connors, A Textbook of Pharmaceutical Analysis, John Wiley and Sons, Canada.
3. A. H. Beckett and J. B. Stenlake, Practical Pharmaceutical Chemistry, ,Vol. 6, Part I and II, CBS Publishers and Distributors, India.
4. D. A. Skoog, D. M. West, F. J. Holler and S. R. Crouch, Fundamentals of Analytical Chemistry, Saunders College Publishing, USA.
5. G. D. Christian, Analytical Chemistry, John Wiley & Sons, Singapore, reprint by Wiley India Pvt. Ltd.
6. H.H. Willard, L. L. Merrit and J. A. Dean, Instrumental Method of Analysis, CBS Publishers & Distributors, New Delhi.
7. Ashutosh. Kar, Pharmaceutical Drug Analysis, New Age International (P) Ltd. Publishers, India.
8. S. S. Mahajan, Instrumental Methods of Analysis, Popular Prakashan Pvt Ltd., India.
9. G. R. Chatwal and S. K. Anand, Instrumental methods of chemical analysis, Himalaya Publishing House Pvt. Ltd.

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10. Indian Pharmacopoeia, The Indian Pharmacopoeia Commission, Ghaziabad, Government of India. Latest Edition
11. J. Mendham, R. C. Denney, J. D. Barnes, M. J. K. Thomas, Vogel's Textbook of Quantitative Chemical Analysis, Pearson Education Ltd.
12. D. G. Watson, Pharmaceutical Analysis –A textbook for pharmacy students and pharmaceutical chemists. Churchill Livingstone Elsevier.
13. J. W. Robinson, E. M. S. Frame and G. M. Frame II, Undergraduate Instrumental Analysis, Marcel Dekker, New York, USA.
14. R. Kellnar, J. M. Mermet, M. Otto, M. Valcarceland, H. M. Widmer, Analytical Chemistry: A modern approach to analytical science, Wiley-VCH, USA.
15. J. W. Munson, Pharmaceutical Analysis: Modern methods (in two parts), Marcel Dekker Inc., USA.
16. W. Kemp, Organic Spectroscopy, Palgrave Publishers Ltd., New York, USA.
17. R. M. Silverstein, F. X. Webster and D. J. Kiemle, Spectrometric identification of organic compounds, John Wiley & Sons, Inc. (Indian edition), New Delhi.
18. D. B. Troy and P. Beringer, Remington-The Science and Practice of Pharmacy, Vol-I & II, Wolters Kluwer/ Lippincott Williams & Wilkins (Indian edition), New Delhi.
19. J. W. Robinson, E. M. S. Frame and G. M. Frame II, Undergraduate Instrumental Analysis, Marcel Dekker, New York, USA.
20. J. R. Dyer, Applications Of Absorption Spectroscopy Of Organic Compounds, Prentice- Hall of India Pvt Ltd, New Delhi, India.
21. D. L. Pavia, G. M. Lampman, G. S. Kriz and J. R. Vyvyan, Introduction to Spectroscopy, Brooks/Cole Cengage Learning, Australia.
22. Y. R. Sharma, Elementary organic spectroscopy-Principles and Chemical Applications, S. Chand & Company Ltd, New Delhi, India

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Course Code	Course Name	Credits
MPH102T	**Drug Delivery Systems**	**4**

- **Prerequisites:**
  - Have foundational knowledge in the area of modified release dosage forms and polymers
- **Course Outcomes: After completion of this course students should be able to:**
  1. Understand the concepts and various approaches for development of novel drug delivery systems.
  2. Understand criteria for selection of drugs and polymers for the development of delivery systems.
  3. Understand formulation and evaluation of Novel drug delivery systems.

Sr. No.	Content	Hours
Unit 1:	**Subtopic**	**10**
1.1	**Sustained Release (SR) and Controlled Release (CR) formulations:** Introduction & basic concepts, advantages/ disadvantages, factors influencing, Physicochemical & biological approaches for SR/CR formulation, Mechanism ofDrug Delivery from SR/CR formulation.	4
1.2	**Polymers:** Introduction, definition, classification based on biodegradable, non-biodegradable and bio-erodible, propertiesand applications in controlled drug delivery, bio-responsive polymers	3
1.3	**Dosage Forms for Personalized Medicine:** Introduction, Definition, Pharmacogenetics, Categories of Patients for Personalized Medicines: Customized drug delivery systems, Bioelectronic Medicines, 3D printing of pharmaceuticals, Telepharmacy.	3
Unit 2:		**10**
2.1	**Rate Controlled Drug Delivery Systems:** Principles & Fundamentals, Types, Activation; Modulated Drug Delivery Systems; Mechanically activated, pH activated,Enzyme activated, and Osmotic activated Drug Delivery Systems	7
2.2	Feedback regulated Drug Delivery Systems; Principles & Fundamentals.	3
Unit 3:		**10**
3.1	**Gastro-Retentive Drug Delivery Systems:** Principle, concepts advantages and disadvantages, Modulation of GI transit time approaches to extend GI transit. Different approaches: High density systems, floating systems, mucoadhesive systems, expandable systems, magnetic systems, superporous hydrogels.	6

	Self Study: Structure and physiology of GIT, concept of absorption window, need for GRDDS, gastric motility	
3.2	**Buccal Drug Delivery Systems:** Principle of mucoadhesion, advantages and disadvantages, theories of mucoadhesion, Mechanism of drug permeation, Methods of formulation andits evaluations.	4
Unit 4:		**6**
4.1	**Ocular Drug Delivery Systems:** Barriers of drug permeation, Methods to overcome barriers. Methods to prolong ocular drug residence with emphasis on mucoadhesive systems. Ocular penetration enhancers. Intraocular inserts: Nonerodible inserts/Erodible inserts. Novel ophthalmic drug delivery systems, nanoparticles and liposomes. **Self Study:** Structure and physiology of eye, drug absorptionand disposition in the eye	6
Unit 5:		**10**
5.1	**Transdermal Drug Delivery Systems:** Skin barriers, kineticsof skin permeation and penetration enhancers, types of formulations: gels, films and patches, *in vitro-in vivo* evaluation. **Self Study:** Structure and physiology of skin	7
5.2	Iontophoresis, recent advances-use of microneedles in transdermal drug delivery	3
Unit 6:		**8**
6.1	**Protein and Peptide Delivery:** Barriers to transport protein delivery and approaches to circumvent metabolic barriers. Routes for delivery of proteins and peptides with emphasis onoral and mucosal delivery, pulmonary delivery, nasal delivery, and parenteral delivery	4
6.2	Formulation and evaluation of delivery systems of proteins and other macromolecules. **Self Study:** Structure of proteins and peptides, analysis of proteins and peptides, Physical and chemical stability aspects,protein degradation pathways, techniques of stabilization of proteins and peptides	4
Unit 7:		**6**
7.1	Vaccine delivery systems: Vaccines, uptake of antigens, singleshot vaccines, mucosal and transdermal delivery of vaccines.	6
	Total Hours	**60**

Reference material:

Books:

1. Y W. Chien, Novel Drug Delivery Systems, 2nd edition, revised and expanded, Marcel Dekker, Inc., New York, 1992.
2. Robinson, J. R., Lee V. H. L, Controlled Drug Delivery Systems, Marcel Dekker,Inc., New York, 1992.
3. Encyclopedia of controlled delivery, Editor- Edith Mathiowitz, Published by WileyInterscience Publication, John Wiley and Sons, Inc, New York! Chichester/Weinheim

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4. N.K. Jain, Controlled and Novel Drug Delivery, CBS Publishers & Distributors, New Delhi, First edition 1997 (reprint in 2001).
5. S.P.Vyas andR.K.Khar, Controlled Drug Delivery- concepts and advances, Vallabh Prakashan, New Delhi, First edition 2002

Journals:

1. Indian Journal of Pharmaceutical Sciences (IPA)
2. Indian drugs (IDMA)
3. Journal of controlled release (Elsevier Sciences) desirable
4. Drug Development and Industrial Pharmacy (Marcel & Decker)

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CourseCode	Course Name	Credits
MPH103T	**Modern Pharmaceutics**	**4**

- **Prerequisites:**
  - Basic knowledge about pre-formulation, validation, GMP and scale-up techniques
- **Course Outcomes: After completion of this course students should be able to:**
  1. Understand the concepts of pre-formulation, tablet compression, optimization, validation, and cGMP.
  2. Apply the preformulation knowledge for proper selection of formulation excipients.
  3. Investigate various qualification parameters for equipment and validation parameters for dosage forms.
  4. Analyze the formulation parameters, apply optimization techniques and device suitable formulation composition.

Sr. No.	Content	Hours
Unit 1:		**20**
a.	**Preformulation Concepts**	
1.1	Role of preformulation in drug development: Preformulation as a support for formulation development, identification of 'developmental challenges' during pharmaceutical development, (Example of Oral Solid Dosage Form)	3
1.2	Salt selection: Role of salt selection in drug discovery and development, theoretical concepts for selection of counter ions for salt formation, 'pKa rule' for salt formation, decision tree for salt selection, appropriate case studies.	3
1.3	Solubilization: Solubility and solubilization of non-electrolyte, drug solubilization in surfactant systems, use of co-solvents for development of liquid formulations, solid-state manipulations including use of metastable solid forms like amorphous state.	2
1.4	SMEDDS preparation and stability **Self-Study**: Theories of dispersion and pharmaceutical dispersion (Emulsion and Suspension, Large and small volume parenteral – physiological and formulation consideration, Manufacturing, and evaluation	2
b.	**Optimization techniques in Pharmaceutical Formulation**	
1.5	Concept and parameters of optimization. Optimization techniques in pharmaceutical formulation and processing	5
1.6	Statistical design, Response surface method, Contour designs, Factorial designs and application in formulation	5
Unit 2:	**Validation**	**10**
2.1	Introduction to Pharmaceutical Validation. Scope & merits of validation.	1
2.2	Validation and calibration of master plan.	2
2.3	ICH & WHO guidelines for calibration and validation of equipment.	2
2.4	Validation of specific dosage form, types of validation.	2

2.5	Government regulation, manufacturing process model, URS.	2
2.6	DQ, IQ, OQ & P.Q. of facilities.	1
Unit 3:	**cGMP & Industrial Management**	**10**
3.1	Objectives and policies of current good manufacturing practices, layout of buildings, services, equipment, and their maintenance.	5
3.2	Production management: Production organization, materials management, handling and transportation, inventory management and control, production and planning control, sales forecasting, budget and cost control, industrial and personal relationship. **Self Study**: Concept of Total Quality Management.	5
Unit 4:	**Compression and compaction**	**10**
4.1	Tablet compression Tooling. Advancement in tablet tooling.	3
4.2	Effect of friction, distribution of forces, compaction profiles.	3
4.3	Pressure volume relationship (Heckel plots), Study of consolidation parameters	4
Unit 5:	**Study of consolidation parameters**	**10**
5.1	Solubility, Diffusion parameters	3
5.2	Selection of discriminatory dissolution media and QC release media, bio-relevant media (FaSSIF & FeSSIF). IVIVC	3
5.3	Similarity factors – f2 and f1	1
5.4	Mechanisms of drug release from conventional and controlled release dosage forms	1
5.5	Linearity concept of significance, standard deviation, Chi square test, student's T-test, ANOVA test.	2
	Total Hours	**60**

References:

1. Theory and Practice of Industrial Pharmacy by Lachmann and Libermann
2. Pharmaceutical dosage forms: Tablets Vol. 1-3 by Leon Lachmann.
3. Pharmaceutical Dosage forms: Disperse systems, Vol, 1-2; By Leon Lachmann.
4. Pharmaceutical Dosage forms: Parenteral medications Vol. 1-2; By Leon Lachmann.
5. Modern Pharmaceutics; By Gillbert and S. Banker.
6. Remington"s Pharmaceutical Sciences.
7. Advances in Pharmaceutical Sciences Vol. 1-5; By H.S. Bean & A.H. Beckett.
8. Physical Pharmacy; By Alfred martin
9. Bentley"s Textbook of Pharmaceutics – by Rawlins.
10. Good manufacturing practices for Pharmaceuticals: A plan for total quality control, Second edition; By Sidney H. Willig.
11. Quality Assurance Guide; By Organization of Pharmaceutical producers of India.
12. Drug formulation manual; By D.P.S. Kohli and D.H. Shah. Eastern publishers, New Delhi.
13. How to practice GMPs; By P.P. Sharma. Vandhana Publications, Agra.
14. Pharmaceutical Process Validation; By Fra. R. Berry and Robert A. Nash.

15. Pharmaceutical Preformulations; By J.J. Wells.
16. Applied production and operations management; By Evans, Anderson, Sweeney and Williams.

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Course ode	Course Name	Credits
MPH104T	**Regulatory Affairs**	**4**

- **Prerequisites:**
  - Have foundational knowledge in pharmaceutical science, pharmaceutical management and communication skills.
- **Course Outcomes: After completion of this course students should be able to:**
  1. Understand the concepts of innovator and generic drugs, drug development process andthe Regulatory guidance and guidelines for filing and approval process.
  2. Develop and submit the dossiers in CTD/ eCTD formats and the post approval regulatory requirements for actives and drug products
  3. Understand the requirements in the clinical trials settings and pharmacovigilance activities
  4. To correlate theoretical knowledge with the professional and practical need of thepharmaceutical industry.

Sr. No.	Content	Hours
Unit1:	**Documentation in pharmaceutical industry and regulatory requirement for product approval**	**24**
1.1	Documentation in Pharmaceutical industry: Master formula record,DMF (Drug Master File), Distribution records, Generic drugs product development Introduction **Self study topic:** Hatch- Waxman act and amendments, CFR (CODE OF FEDERAL REGULATION)	5
1.2	Drug product performance, In-vitro, ANDA regulatory approvalprocess, NDA approval process	5
1.3	BE and drug product assessment, in-vivo, scale up process approval changes, post marketing surveillance, outsourcing BAand BE to CRO	6
1.4	Regulatory requirement for product approval: API, biologics, novel, therapies obtaining NDA, ANDA for generic drugs waysand means of US registration for foreign drugs	6
1.5	Country-wise specialist dossier checklist	2
Unit2:	**CMC, post approval regulatory affairs**	**12**
2.1	Regulation for combination products and medical devices.CTD and ECTD format, industry and FDA liaison.	4
2.2	ICH - Guidelines of ICH-Q, S E, M. Regulatory requirementsof EU, MHRA, TGA and ROW	4
2.3	Country wise post approval changes in regulated, semi-regulated and ROW	2
2.4	Classification of medical devices, Registration process ofmedical devices worldwide	2
Unit3:	**Nonclinical drug development**	**12**
3.1	Non clinical drug development: Global submission of IND, NDA,ANDA	5

3.2	Investigation of medicinal products dossier, dossier (IMPD) andinvestigator brochure (IB).	5
3.3	Submission of pharmacological and toxicological documentationdata	2
Unit4:	**Clinical trials**	**12**
4.1	Developing clinical trial protocols. Institutional review board/ independent ethics committee Formulation and working procedures informed Consent process and procedures.	7
4.2	HIPAA- new, requirement to clinical study process, pharmacovigilance safety monitoring in clinical trials.	3
4.3	Case report form and individual patient listings	2
Unit5:	**Indian and International regulations for Herbal medicines,cosmetics, food, and nutraceutical**	2
5.1	Regulatory guidelines for submission of herbal medicines,cosmetics, food and nutraceutical and its filling process	2
	Total Hours	**60**

Reference material:

Books:**

1. Generic Drug Product Development, Solid Oral Dosage forms, Leon Shargel and Isader Kaufer, Marcel Dekker series, Vol.143
2. The Pharmaceutical Regulatory Process, Second Edition Edited by Ira R. Berry and Robert P. Martin, Drugs and the Pharmaceutical Sciences, Vol.185, Informa Health care Publishers.
3. New Drug Approval Process: Accelerating Global Registrations by Richard A Guarino, MD,5th edition, Drugs and the Pharmaceutical Sciences, Vol.190.
4. Guidebook for drug regulatory submissions / Sandy Weinberg. By John Wiley & Sons. Inc.
5. FDA regulatory affairs: a guide for prescription drugs, medical devices, and biologics/edited By Douglas J. Pisano, David Mantus.
6. Clinical Trials and Human Research: A Practical Guide to Regulatory Compliance by Fay A. Rozovsky and Rodney K. Adams
7. Jeffery DB. The regulation of medical devices and the role of the medical devices agency. Br J Clin Pharmacol 2001;52:229-35.
8. Anuja R Shah, Goyal RK. Status of the regulation for medical devices. Indian J Pharmal Sci 2008;70:695-700.
9. Verma B, Popli H. Regulations of nutraceuticals in India & us. Pharma Innovation J 2018; 7(7): 811–816.
10. www.ich.org/
11. www.fda.gov/
12. europa.eu/index_en.htm
13.https://www.tga.gov.au/tga-basics

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CourseCode	Course Name	Credits
MPH105P	Pharmaceutics Practical's - I	6

- **Prerequisites:**
  - Basic knowledge of pharmaceutics and pharmaceutical analysis
- **Course Outcomes: After completion of this course students should be able to:**
  1. Estimate the active pharmaceutical ingredients in formulations by using different modern analytical techniques.
  2. Apply the concepts of pre-formulation in formulation development.
  3. Understand the formulation and evaluation methods of different novel drug delivery systems.
  4. Plan and execute the experiments using various methodologies and systematically summarize the findings verbally and in written communication.

Exp.No.	Title of the Experiment
1	Analysis of pharmacopoeial compounds and their formulations by UV Vis spectrophotometer
2	Simultaneous estimation of multi-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
7	To perform *In-vitro* dissolution profile of CR/ SR marketed formulation
8	Formulation and evaluation of sustained release matrix tablets
9	Formulation and evaluation osmotically controlled DDS
10	Preparation and evaluation of Floating DDS- hydro dynamically balanced DDS
11	Formulation and evaluation of Muco adhesive tablets.
12	Formulation and evaluation of transdermal patches.
13	To carry out preformulation studies of tablets.
14	To study the effect of compressional force on tablets disintegration time.
15	To study Micromeritic properties of powders and granulation.
16	To study the effect of particle size on dissolution of a tablet.
17	To study the effect of binders on dissolution of a tablet.
18	To plot Heckel plot. Higuchi and peppas plot and determine similarity factors.
19	Design of modified drug delivery system like film forming gel

Course code	Course Name	Credits
IKS_MP_101	Yoga: A key to healthy life	-

- **Prerequisites**
  - Basic knowledge of Yoga and human health
- **Course Outcomes: After the completion of course, learner will be able to:**
  1. Improvement in mental and physical health
  2. Provide improved attention in studies and better interpersonal relationships

Sr. No.	Content	Hours
1	**UNIT 1: INTRODUCTION**	**10**
1.1	Yoga-Meaning and definition, yoga misconceptions and comparison between yoga and exercise, Introduction to Ashtanga yoga (eight limbs of yoga), Pranav sadhana, Mudra and Bandh	6
1.2	Yoga therapy	2
1.3	Yoga and diet	2
2	**UNIT 2: AASANA (Introduction, contraindications, benefits and demonstration of following asanas**	**12**
2.1	**Sitting postures**: Swastikasana, padmasana, Marjarasana, Bhadrasana, Vajrasana, Ustrasana, Sasakasana, Vakrasana, Paschimatanasana, Parvatasana	3
2.2	**Standing postures**: Tadasana, Vrksasana, Pada-hastasana, Ardha chakrasana, Trikonasana	3
2.3	**SUPINE POSTURES**: Setubandhasana, Uttana padasana, Ardha halasana, Pavana muktasana, Savasana, Viparit karni, tadagi mudra	3
2.4	**Prone postures**: Makarasana, Bhujangasana, Salabhasana, Naukasana, Matsyasana	2
2.5	Suryanamaskar	1
3	**UNIT 3: PRANAYAMA (Introduction, contraindications, benefits and demonstration of following pranayama)**	**02**
3.1	Kapalabhati, Anulom vilom, Sitali, Sitakari, Bhramari, Ujiayi, Bhastrika, Uddiyana bandha	2
4	**UNIT 4: STRESS MANAGEMENT**	**06**
4.1	Meditation, Yog nidra, Shavasana, Mindfulness, Prayers	4
4.2	Yogic lifestyle	2
	TOTAL	**30**

Recommended Books (Latest Editions)

1. Websites: https://ayush.gov.in/ Ministry of Ayurveda, Yoga & Naturopathy, Unani, Siddha and Homoeopathy (AYUSH)

Books: Know yoga Live Yoga, By ShriKrishna Mhaskar

Pharmaceutics
Semester 2

Course ode	Course Name	Credits
MPH 201T	**Molecular Pharmaceutics (Nano Tech and TargetedDDS)**	**4**

- **Prerequisites:**
  - Prior knowledge of Pharmaceutics in B. Pharmacy
- **Course Outcomes: After completion of this course students should be able to:**
  1. Understand the concept of drug targeting, its application, pulmonary drug deliverysystems and gene therapy.
  2. Apply the knowledge for selection of appropriate Nanotechnology and deliverysystem for given class of drug and route of administration.
  3. Analyze the parameters for evaluation of Nano and Micro drug delivery systems.
  4. Construct composition of NDDS, encompassing Micro and Nano drug deliverysystems.

Sr. No.	Content	Hours
Unit 1:	**Targeted Drug Delivery Systems**	**12**
1.1	Concepts, events and biological process involved in drug targeting:	6
1.2	Tumor targeting: Stages of Tumor development, Tumor vasculature, EPR effect, Lymphatic targeting	3
1.3	Brain specific delivery: Blood Brain Barrier, Blood Cerebrospinal Fluid Barrier, Strategies to enhance brain Delivery: Neurosurgical, Pharmacologic and Physiologic	3
Unit 2:	**Targeting Methods**	**12**
2.1	Nano Particles: Introduction, types- Polymeric Nanoparticles Lipid-Based Nanoparticles, Protein-Based Nanoparticles Preparation: Polymerization based methods, Polymer precipitation methods, Evaluation Particle Size and Size Distribution, Charge determination, Morphology and Shape, Drug Loading Efficiency, Drug Release, Stability Applications	6
2.2	Liposomes: Introduction, types: on the basis of structure and method of preparation , Preparation: Mechanical Dispersion, Solvent dispersion, Detergent removal method Evaluation: Physical and Chemical, Applications	6
Unit 3:	**Micro Capsules / Micro Spheres**	**12**
3.1	Micro Capsules and Micro Spheres: Types, preparation: Single Emulsion, double emulsion, polymerization, phase separation coacervation,spray drying, spray congealing, solvent extraction, Polymers used, Evaluation: Physical and Chemical, Applications	5

3.2	Niosomes, Aquasomes, Phytosomes: Preparation, Evaluation and Applications Introduction to Electrosomes	4
3.3	Monoclonal Antibodies: Preparation and application.	3
Unit 4:	**Pulmonary and Nasal Drug Delivery Systems**	**12**
4.1	Nasal drug delivery systems: Anatomy and physiological aspects of Nose, Absorption pathways of intranasally administered drugs, permeation enhancers	2
4.2	Intranasal formulations types, devices and evaluation	2
4.3	Intranasal toxicity-animal and cell line models	1
4.4	Nose to brain delivery	1
4.5	Pulmonary Drug Delivery System: Weibul's model, aerosol deposition, mechanisms and pattern in lungs, Concept of MMAD, FPF	2
4.6	Delivery Systems: Nebulised systems, pMDIs: Aerosols, propellants, containers: DPIs, active and passive devices, evaluation methods.	4
Unit 5:		**12**
5.1	Gene therapy: Introduction (ex-vivo & in-vivo gene therapy).	2
5.2	Potential target diseases for gene therapy (inherited disorder and cancer).	2
5.3	Gene expression systems (viral and nonviral gene transfer).	2
5.4	Liposomal gene delivery systems.	2
5.5	Biodistribution and Pharmacokinetics.	2
5.6	Knowledge of therapeutic antisense molecules and aptamers as drugs of future	2
	Total Hours	**60**

Reference material:

1. Modern Pharmaceutics _ Gilbert Banker & Rhodes. Chapter 16
2. Targeted & Controlled Drug Delivery – Novel Carrier Systems- Vyas &Khar
3. For Brain Specific Delivery: Targeted & Controlled Drug Delivery – Novel Carrier Systems- Vyas &Khar Chapter 13
4. For Tumor Targeting - Targeted & Controlled Drug Delivery – Novel Carrier Systems- Vyas &Khar Chapter 14
5. Controlled Drug Delivery – Robinson and Lee Chapter 13
6. Controlled & Novel Drug Delivery – N K Jain
7. Advances in Controlled & Novel Drug Delivery
8. Engineering liposomal nanoparticles for targeted gene therapy, C Zylberberg, et.al., Gene Therapy (2017) 24, 441–452, doi:10.1038/gt.2017.41
9. Viral and nonviral delivery systems for gene delivery, Advanced Biomedical Research, . doi: 10.4103/2277-9175.98152
10. Aptamers as Therapeutic Agents: Has the Initial Euphoria Subsided?,Molecular Diagnosis & Therapy (2019) 23:301–309, https://doi.org/10.1007/s40291-019-00400-6

CourseCode	Course Name	Credits
MPH202T	**Advanced Biopharmaceutics & Pharmacokinetics**	**4**

- **Prerequisites:**
  - Have foundational knowledge in the area Biopharmaceutics and Pharmacokinetics at graduate level.
- **Course Outcomes: After completion of this course students should be able to:**
  1. Understand the basic concepts in biopharmaceutics and pharmacokinetics.
  2. Understand how to use raw data and derive the pharmacokinetic models and parameters that best describe the process of drug absorption, distribution, metabolismand elimination.
  3. Understand the critical evaluation of biopharmaceutic studies involving drug productequivalency...
  4. Understand the design and evaluation of dosage regimens of the drugs usingpharmacokinetic and biopharmaceutic parameters.
  5. Understand the potential clinical pharmacokinetic problems and application of basicsof pharmacokinetic.

Sr. No.	Content	Hours
Unit 1:	**Drug Absorption from the Gastrointestinal Tract**	**12**
1.1	Gastrointestinal tract, Mechanism of drug absorption,	2
1.2	Factors Affecting drug absorption, pH–partition theory of drug absorption.	1
1.3	Formulation and physicochemical factors: Dissolution rate,	1
1.4	Dissolution process, Noyes–Whitney equation and drug dissolution,Factors affecting the dissolution rate.	2
1.5	Gastrointestinal absorption: role of the dosage form: Solution (elixir, syrup,and solution) as a dosage form, Suspension as a dosage form,Capsule as a dosage form, Tablet as a dosage form,	2
1.6	Dissolution methods, Formulation and processing factors, Correlation of invivo data with in vitro dissolution data.	2
1.7	Transport model: Permeability-Solubility-Charge State and the pH Partition Hypothesis, Properties of the Gastrointestinal Tract (GIT),pHMicroclimate Intracellular pH Environment, Tight-Junction Complex	2
Unit 2:	**Biopharmaceutic considerations in drug product design and In VitroDrug Product Performance:**	**12**
2.1	Introduction, Biopharmaceutic factors affecting drug bioavailability,	2
2.2	Rate-limiting steps in drug absorption, physicochemical nature of the drug.	2
2.3	Formulation factors affecting drug product performance,In vitro: dissolution and drug release testing,	2
2.4	Compendial methods of dissolution, Alternative methods of dissolution testing, meeting dissolution requirements, Problems of variable control indissolution testing performance of drug products.	2
2.5	Invitro–invivo correlation,	1

2.6	Dissolution profile comparisons, drug product, Stability, considerations in the design of a drug product.	3
Unit 3:	**Pharmacokinetics:**	**14**
3.1	Basic considerations, pharmacokinetic models, compartment modeling: onecompartment model- IV bolus, IV infusion, extra-vascular.	8
3.2	Multi compartment model: two compartment - model in brief,	2
3.3	Non-linear pharmacokinetics: cause of non-linearity, Michaelis – Mentenequation, estimation of Kmax and Vmax	2
3.4	Drug interactions: introduction, the effect of protein- binding interactions,	1
3.5	The effect of tissue-binding interactions, cytochrome p450-based druginteractions, Drug interactions linked to transporters	1
Unit 4:	**Drug Product Performance, In Vivo: Bioavailability andBioequivalence:**	**12**
4.1	Drug product performance, purpose of bioavailability studies, relative andabsolute availability.	2
4.2	Methods for assessing bioavailability, bioequivalence studies,	2
4.3	Design and Evaluation of bioequivalence studies, Study designs, crossoverstudy designs, evaluation of the data, bioequivalence example, study submission and drug review process.	4
4.4	Biopharmaceutics classification system, methods.	2
4.5	Permeability: In-Vitro, In-situ and In-vivo methods, generic biologics (biosimilar drug products), clinical significance of bioequivalence studies,special concerns in bioavailability and bioequivalence studies, generic substitution.	2
Unit 5:	**Application of Pharmacokinetics:**	**10**
5.1	Modified-Release Drug Products, Targeted Drug Delivery Systems andBiotechnological Products.	2
5.2	Introduction to Pharmacokinetics and pharmacodynamic, druginteractions.	2
5.3	Pharmacokinetics and pharmacodynamics of biotechnology drugs.Introduction, Proteins and peptides, Monoclonal antibodies, Oligonucleotides, Vaccines (immunotherapy), Gene therapies.	6
	Total Hours	**60**

Reference material:

1. Biopharmaceutics and Clinical Pharmacokinetics by Milo Gibaldi, 4th edition, Philadelphia, Lea and Febiger,1991
2. Biopharmaceutics and Pharmacokinetics, A. Treatise, D.M. Brahmankar and Sunil B. Jaiswal., Vallab Prakashan, Pitampura, Delhi
3. Applied Biopharmaceutics and Pharmacokinetics by Shargel. Land YuABC, 2nd edition, Connecticut Appleton CenturyCrofts,1985
4. Textbook of Biopharmaceutics and Pharmacokinetics, Dr. Shobha Rani R. Hiremath, Prism Book
5. Pharmacokinetics by Milo Gibaldi and D. Perrier, 2nd edition, Marcel Dekker Inc., New York, 1982
6. Current Concepts in Pharmaceutical Sciences: Biopharmaceutics, Swarbrick. J, Leaand Febiger, Philadelphia, 1970

7. Clinical Pharmacokinetics, Concepts and Applications 3rd edition by Malcolm Rowland and Thom~ N. Tozer, Lea and Febiger, Philadelphia, 1995
8. Dissolution, Bioavailability and Bioequivalence, Abdou. H.M, Mack Publishing Company, Pennsylvania 1989
9. Biopharmaceutics and Clinical Pharmacokinetics, An Introduction, 4th edition, revised and expanded by Robert. E. Notari, Marcel Dekker Inc, New York, and Basel,1987. Biopharmaceutics and Relevant Pharmacokinetics by John. G Wagner and M. Pemarowski, 1st edition, Drug Intelligence Publications, Hamilton, llinois, 1971.
10. Encyclopaedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James. G. Boylan, Marcel Dekker Inc, New York, 1996.
11. Basic Pharmacokinetics,1 st edition, Sunil S Jambhekar and Philip J Breen, pharmaceutical press, RPS Publishing,2009.
12. Absorption and Drug Development- Solubility, Permeability, and Charge State, Alex Avdeef, John Wiley & Sons, Inc, 2003.

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CourseCode	Course Name	Credits
MPH203T	**Computer Aided Drug Delivery System**	**4**

- **Prerequisites:**
  - Basics of drug delivery systems, computer applications
  - Basics of pharmacokinetics and pharmacodynamics.
- **Course Outcomes: After completion of this course students should be able to:**

1. Recall & relate skills necessary for computer applications in pharmaceutical research and development who want to understand the application of computers across the entire drug research and development process.
2. Outline the principles of more integrated and coherent use of computerized information (informatics) in the drug development process.
3. Construct the simulated model of drug delivery systems based on ADME parameters, use of statistical techniques, clinical data collection and management.
4. Recommend applications of artificial intelligence and robotics in pharmaceutical automation, evaluate the current challenges and predict the future directions.

Sr. No.	Content	Hours
Unit1:	**Computers in Pharmaceutical Research and Development and Quality-by-Design In Pharmaceutical Development**	**12**
1.1	Computers in Pharmaceutical Research and Development:	
a.	A General Overview: History of Computers in Pharmaceutical Research and Development.	1
b.	Statistical modeling in Pharmaceutical research and development: Descriptive versus Mechanistic Modeling, Statistical Parameters, Estimation, ConfidenceRegions, Nonlinearity at the Optimum, Sensitivity Analysis, Optimal Design, PopulationModeling	5
1.2	Quality-by-Design In Pharmaceutical Development:	3
a.	Introduction, ICH Q8 guideline	1
b.	Regulatory and industry views on QbD, Scientifically based QbD -examples of application.	2
Unit2:	**Computational Modeling Of Drug Disposition**	**12**
2.1	Introduction, Modeling Techniques: Drug Absorption, Solubility,Intestinal Permeation, Drug Distribution ,Drug Excretion	6
2.2	Active Transport; P-gp, BCRP, Nucleoside Transporters, hPEPT1, ASBT, OCT, OATP,BBB-Choline Transporter.	6

Unit3:	**Computer-aided formulation development**	**12**
3.1	Concept of optimization, Optimization parameters, Optimization technology & Screening design. Experimental designs, Factorial design, composite designs, mixture designs, response surface methodology. Applications of systematic optimization techniques	7
3.2	Computers in Pharmaceutical Formulation: Development of pharmaceutical emulsions, microemulsion drug carriers	2
3.3	Legal Protection of Innovative Uses of Computers in R&D. The Ethicsof Computing in Pharmaceutical Research, Computers in Market Analysis	3
Unit4:	**Computer-aided biopharmaceutical characterization, ComputerSimulations in Pharmacokinetics and Pharmacodynamics; and Computers in Clinical Development**	**12**
4.1	Computer-aided biopharmaceutical characterization:	
a.	Gastrointestinal absorption simulation: Introduction, Theoretical background, Model construction, Parameter sensitivity analysis,Virtual trial, Fed vs. fasted state	5
b.	In vitro dissolution and in vitro- in vivo correlation, Biowaiverconsiderations	3
4.2	Computer Simulations in Pharmacokinetics and Pharmacodynamics:	
	Introduction, Computer Simulation: Whole Organism, IsolatedTissues, Organs, Cell, Proteins and Genes.	2
4.3	Computers in Clinical Development:	
	Clinical Data Collection and Management, Regulation of ComputerSystems	2
Unit5:	**Artificial Intelligence (AI), Robotics and Computational fluidDynamics**	**12**
5.1	**Artificial Intelligence:** General overview of Artificial intelligence,Machine learning & Deep learning, Concept of Artificial neural network, Pharmaceutical applications, Advantages and Disadvantages. Current Challenges and Future Directions. Overview of Robotics, Pharmaceutical application of robotics,Pharmaceutical Automation,	8
5.2	**Computational fluid dynamics**: General overview, Steps in computational fluid dynamics, methods ofdiscretization, Pharmaceutical applications of computational fluid dynamics	4
	Total Hours	**60**

Reference material:

. **Books:**

1. Pharmaceutical Product Development: Insights Into Pharmaceutical Processes, Management and Regulatory Affairs, by Vandana B. Patravale, John I. Disouza, Maharukh Rustomjee, CRC press

2. Computer Applications in Pharmaceutical Research and Development, Sean Ekins, 2006, John Wiley & Sons.
3. Computer-Aided Applications in Pharmaceutical Technology, 1st Edition, Jelena Djuris, Woodhead Publishing
4. Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James. G.Boylan, Marcel Dekker Inc, New York, 1996.

B. Articles:

1. Katiyar, R. S. and Jha, P. K. (2018). Molecular simulations in drug delivery: opportunities and challenges. WIREs Computational Molecular Science, 8(4). https://doi.org/10.1002/wcms.1358
2. Kotzabasaki, M., & Froudakis, G. E. (2018). Review of computer simulations on anti-cancer drug delivery in MOFs. Inorganic Chemistry Frontiers, 5, 1255-1272.
3. Wang, W., Ye, Z., Gao, H., & Ouyang, D. (2021). Computational pharmaceutics - A new paradigm of drug delivery. Journal of Controlled Release, 338, 119-136.
4. Lin, L., & Wong, H. (2017). Predicting Oral Drug Absorption: Mini Review on Physiologically-Based Pharmacokinetic Models. Pharmaceutics, 9(4), 41.
5. Tistaert, C., Heimbach, T., Xia, B., Parrott, N., Samant, T. S., & Kesisoglou, F. (2019). Food Effect Projections via Physiologically Based Pharmacokinetic Modeling: Predictive Case Studies. Journal of Pharmaceutical Sciences, 108(1), 592-602.

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CourseCode	Course Name	Credits
MPH 204T	**Cosmetics and Cosmeceuticals**	**4**

- **Prerequisites:**
  - Basic knowledge of cosmetics and formulation development processes.
- **Course Outcomes: After completion of this course students should be able to:**
  1. Define cosmetics and understand the regulatory requirements for labelling, import,manufacturing and sale of cosmetic products in India.
  2. Understand the biological concepts related to different problems of the skin, hair, oralcavity.
  3. Study and review COSMOS guidelines for different classes of ingredients.
  4. Classify the key ingredients, building blocks, their chemical classes and types, the herbal ingredients used in skin care, hair care required for making cosmetics and cosmeceuticals.
  5. Apply the key ingredients for design and formulation of cosmeceutical products like sunscreen, antiageing, anti-acne and formulations for oral cavity problems.

Sr. No.	Content	Hours
Unit1:	**Cosmetics – Regulatory:**	**12**
1.1	Definition of cosmetic products as per Indian regulation. Indian regulatory requirements for labeling of cosmetics Regulatory provisionsrelating to import of cosmetics., Misbranded and spurious cosmetics.	6
1.2	**Regulatory provisions relating to manufacture of cosmetics –** Conditions for obtaining license, prohibition of manufacture and sale ofcertain cosmetics, loan license, offences and penalties.	6
Unit2:	**Cosmetics - Biological aspects :**	**10**
2.1	Skin related problems like dry skin, acne, pigmentation, pricklyheat, wrinkles and body odor. **Self Study:** Structure of Skin	3
2.2	Hair growth cycle. **Self Study:** Structure of hair	1
2.3	Common problems associated with oral cavity.	3
2.4	Cleansing and care needs for face, eye lids, lips, hands, feet, nail,scalp, neck, body and under-arm.	3
Unit3:	**Formulation Building blocks:**	**12**
3.1	Building blocks for different product formulations ofcosmetics/cosmeceuticals.	2
3.2	Surfactants – Classification and application. Emollients, rheologicaladditives: classification and application	2
3.3	Antimicrobial used as preservatives, their merits and demerits. Factorsaffecting microbial preservative efficacy.	2
3.4	Building blocks for formulation of a moisturizing cream, vanishingcream, cold cream, shampoo and toothpaste.	2

3.5	Soaps and syndets bars.	1
3.6	Perfumes; Classification of perfumes. Perfume ingredients listed asallergens in EU regulation.	2
3.7	Controversial ingredients: Parabens, formaldehyde liberators, dioxane.	1
Unit4:	Design of cosmeceutical products	**12**
4.1	Sun protection, sunscreens classification and regulatory aspects.Addressing sun-protection through cosmeceutical formulations.	3
4.2	Addressing dry skin, acne, pigmentation, prickly heat, wrinkles, bodyodor through cosmeceutical formulations.	4
4.3	Addressing dandruff through cosmeceutical formulations.	1
4.4	Addressing dental cavities, bleeding gums, mouth odor and sensitiveteeth through cosmeceutical formulations.	4
Unit5:	**Herbal Cosmetics:**	**10**
5.1	Herbal ingredients used in Hair care, skin care and oral care.	3
5.2	Review of guidelines for herbal cosmetics by private bodies like cosmos with respect to preservatives, emollients, foaming agents,emulsifiers and rheology modifiers.	3
5.3	Challenges in formulating herbal cosmetics.	4
Unit6:	**Application of novel approaches in cosmetic formulations**	**4**
6.1	Concepts of microemulsions, liposomes, niosomes, nanoparticles,iontophoresis, to enhance functional attributes & delivery of cosmeceuticals	4
	Total Hours	**60**

Reference material:

Books:**

1. Harry"s Cosmeticology. 8th edition.
2. Poucher"sperfumecosmeticsandSoaps,10th edition.
3. Cosmetics - Formulation, Manufacture and quality control, PP.Sharma, 4th edition
4. Handbook of cosmetic science and Technology A. O. Barel, M. Paye and H.I. Maibach. 3rd edition
5. Cosmetic and Toiletries recent suppliers catalogue.
6. CTFA directory.

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CourseCode	Course Name	Credit s
MPH205P	Pharmaceutics Practical -II	4

- **Prerequisites:**
  - Have practical knowledge in preparation of novel pharmaceutical products, concepts in vitro and in vivo studies.
- **Course Outcomes: After completion of this course students should be able to:**
  1. Learner will gain knowledge in the area of advances in novel drug delivery systems.
  2. Learners will know methods used to determine and interpret the bioavailability and bioequivalence parameters along with statistical aspects of bioequivalence study.
  3. Learner will attain knowledge and skills necessary for computer applications in pharmaceutical research and development, preclinical and clinical development using statistical models/ software, including optimization of formulation and process of
  4. manufacturing, computational modeling of drug disposition.
  5. Learner will gain knowledge and skills necessary for developing synthetic and herbal cosmetic and cosmeceutical products.

Exp.No.	Title of the Experiment
1	To study the effect of salt addition in microcapsules preparation
2	Preparation and evaluation of alginate beads
3	Formulation and evaluation of gelatin /albumin microspheres
4	Formulation and evaluation of liposomes/niosomes
5	Formulation and evaluation of spherules
6	Improvement of dissolution characteristics of slightly soluble drug by solid dispersion technique.
7	Comparison of dissolution of two different marketed products /brands
8	Protein binding studies of a highly protein bound drug & poorly protein bound drug
9	Bioavailability studies of Paracetamol in animals.
10	Pharmacokinetic and IVIVC data analysis by WinnolineR software
11	*In vitro* cell studies for permeability and metabolism
12	DoE Using Design Expert® Software
13	Formulation data analysis Using Design Expert® Software
14	Quality-by-Design in Pharmaceutical Development
15	Computer Simulations in Pharmacokinetics and Pharmacodynamics
16	Computational Modelling Of Drug Disposition
17	To develop Clinical Data Collection manual
18	To carry out Sensitivity Analysis, and Population Modeling
19	Development and evaluation of Creams
20	Development and evaluation of Shampoo and Toothpaste base
21	To incorporate herbal and chemical actives to develop products
22	To address dry skin, acne, blemish, wrinkles, bleeding gums and dandruff

23	Design of Novel Drug Delivery System like Nanosuspension/ Nanoemulsion/SLN/ NLC

Reference material

1. S. P. Vyas and R. K. Khar, Controlled Drug Delivery - concepts and advances, Vallabh Prakashan, New Delhi, First edition 2002.
2. Clinical Pharmacokinetics, Concepts and Applications 3rd edition by Malcolm Rowland and Thom~ N. Tozer, Lea and Febiger, Philadelphia, 1995
3. Dissolution, Bioavailability and Bioequivalence, Abdou. H.M, Mack Publishing Company, Pennsylvania 1989
4. Computer-Aided Applications in Pharmaceutical Technology, 1st Edition, Jelena Djuris, Woodhead Publishing
5. Cosmetics - Formulation, Manufacture and quality control, PP Sharma, 4th edition

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Course code	Course Name	Credits
AEC_MX_102	Multidisciplinary Subject	**-**

Students will opt for one of the core subject of other department PG course of SEM II running by the college as an audit course.

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M. Pharm Pharmaceutical Chemistry Semester 1

Course Code	Course Name	Credits
MPC101T	**Modern Pharmaceutical Analytical Techniques**	**4**

- **Prerequisites:**
  - Knowledge of Liquid-liquid extraction- Partition coefficient, molecular diffusion, mass transfer
  - Knowledge of Adsorption, adsorption isotherms, quantum theory, difference between protons, neutrons, and electrons
  - Knowledge of Carbocation stability, fission and rearrangements.
  - Knowledge of the Difference between protons, neutrons, and electrons
- **Course Outcomes: After completion of this course students should be able to:**
  1. Recall with examples the terminologies associated with spectroscopy, chromatography, X-ray diffraction, electrophoresis, potentiometry, and thermal analysis
  2. Explain and illustrate the theory, instrumentation, and applications of various techniques involved in spectroscopy, chromatography, X-ray diffraction, electrophoresis, potentiometry and thermal analysis, and chromatographic parameters.
  3. Apply the knowledge gained to calculate concentration by UV-visible spectroscopy, predict the IR frequencies, number of signals in NMR, and fragmentation pattern in MS for simple organic compounds.
  4. Predict the spectroscopic behavior of molecules.

Sr. No.	Content	Hours
Unit 1:		**8**
1.1	**UV-Visible spectroscopy**: • *Principle*, Instrumentation of UV-Visible Spectroscopy **(Self-study: 1 hr)** • Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and **(Self-study)** • Applications of UV-Visible spectroscopy: Case study-based applications for single component and multicomponent analysis • Interpretation of UV-visible spectra of a simple organic compound • Difference/Derivative spectroscopy	2
1.2	**IR spectroscopy**: • Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier -Transform IR Spectrometer, Factors affecting vibrational frequencies **(Self-study)** • Applications of IR spectroscopy: Including case-study for use of Near IR as a PAT tool, Data interpretation of IR spectra of a simple organic compound	2
1.3	**Spectroflourimetry**: • Theory of Fluorescence, Factors affecting fluorescence, Quenchers **(Self-study)** • Instrumentation and Applications of fluorescence spectrophotometer	2

1.4	**Flame emission spectroscopy and Atomic absorption spectroscopy**: • Principle, Instrumentation, Interferences and Applications **(Self-study)** • Use of AAS for analysis of elemental impurities	2
Unit 2:		**9**
2.1	**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	7
2.2	Interpretation of ^{1}H NMR spectrum of simple organic compounds	2
Unit 3:		**9**
3.1	**Mass Spectrometry:** Principle, Theory, Instrumentation of Mass Spectroscopy. Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI. Analyzers - Quadrupole and Time of Flight. Mass fragmentation and its rules, Metastable ions, Isotopic peaks. Applications of Mass spectroscopy	7
3.2	Interpretation of mass spectrum of simple organic compounds	2
Unit 4:		**10**
4.1	Introduction to chromatography and classification of chromatographic methods based on the mechanism of separation **(Self-study)**	1
4.2	Numericals based on calculation of chromatographic parameters	2
4.3	**Chromatography:** Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution and applications of the following: a. Thin Layer chromatography b. High Performance Thin Layer chromatography c. Paper chromatography d. Ion exchange chromatography e. Column chromatography f. Gas chromatography g. High Performance Liquid chromatography h. Affinity chromatography i. Gel chromatography j. Ultra-High Performance Liquid chromatography	7
Unit 5:		**10**
5.1	**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	4

	f. Iso electric focusing	
5.2	**X-ray Crystallography** - Production of X rays, Different X ray diffraction methods, Bragg 's law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X- ray diffraction.	3
5.3	**Immunological assays**: RIA (Radioimmunoassay), ELISA, RT-PCR, Bioluminescence assays	3
Unit 6:		**14**
6.1	**ICP-MS:** Principle and Instrumentation, Sample preparation techniques and method development strategies, Pharmaceutical Applications	2
6.2	**Hyphenated techniques:** Principle, interfaces used and applications of: LC-MS, GC-MS and HPTLC-MS	4
6.3	**Advanced Microscopic techniques:** Principle, Instrumentation and Applications of: SEM & TEM	3
6.4	**Potentiometry:** Principle, working, Ion selective Electrodes and Application of potentiometry **(Self-study)**	1
6.5	**Thermal Techniques:** • **Differential Scanning Calorimetry (DSC):** Principle, thermal transitions and Instrumentation (Heat flux and power-compensation and designs), Modulated DSC, Hyper DSC, experimental parameters (sample preparation, experimental conditions, calibration, heating and cooling rates, resolution, source of errors) and their influence, advantage and disadvantages, pharmaceutical applications. • **Differential Thermal Analysis (DTA):** Principle, instrumentation and advantage and disadvantages, pharmaceutical applications, derivative differential thermal analysis (DDTA) • **Thermogravimetric Analysis TGA:** Principle, instrumentation, factors affecting results, advantage and disadvantages, pharmaceutical applications	4
	Total Hours	**60**

Reference material:

1. D. A. Skoog, F. J. Holler and S. R. Crouch, Principles of Instrumental Analysis, Saunders College Publishing, USA.
2. K. A. Connors, A Textbook of Pharmaceutical Analysis, John Wiley and Sons, Canada.
3. A. H. Beckett and J. B. Stenlake, Practical Pharmaceutical Chemistry, ,Vol. 6, Part I and II, CBS Publishers and Distributors, India.
4. D. A. Skoog, D. M. West, F. J. Holler and S. R. Crouch, Fundamentals of Analytical Chemistry, Saunders College Publishing, USA.
5. G. D. Christian, Analytical Chemistry, John Wiley & Sons, Singapore, reprint by Wiley India Pvt. Ltd.
6. H.H. Willard, L. L. Merrit and J. A. Dean, Instrumental Method of Analysis, CBS Publishers & Distributors, New Delhi.

7. Ashutosh. Kar, Pharmaceutical Drug Analysis, New Age International (P) Ltd. Publishers, India.
8. S. S. Mahajan, Instrumental Methods of Analysis, Popular Prakashan Pvt Ltd., India.
9. G. R. Chatwal and S. K. Anand, Instrumental methods of chemical analysis, Himalaya Publishing House Pvt. Ltd.
10. Indian Pharmacopoeia, The Indian Pharmacopoeia Commission, Ghaziabad, Government of India. Latest Edition
11. J. Mendham, R. C. Denney, J. D. Barnes, M. J. K. Thomas, Vogel's Textbook of Quantitative Chemical Analysis, Pearson Education Ltd.
12. D. G. Watson, Pharmaceutical Analysis –A textbook for pharmacy students and pharmaceutical chemists. Churchill Livingstone Elsevier.
13. J. W. Robinson, E. M. S. Frame and G. M. Frame II, Undergraduate Instrumental Analysis, Marcel Dekker, New York, USA.
14. R. Kellnar, J. M. Mermet, M. Otto, M. Valcarceland, H. M. Widmer, Analytical Chemistry: A modern approach to analytical science, Wiley-VCH, USA.
15. J. W. Munson, Pharmaceutical Analysis: Modern methods (in two parts), Marcel Dekker Inc., USA.
16. W. Kemp, Organic Spectroscopy, Palgrave Publishers Ltd., New York, USA.
17. R. M. Silverstein, F. X. Webster and D. J. Kiemle, Spectrometric identification of organic compounds, John Wiley & Sons, Inc. (Indian edition), New Delhi.
18. D. B. Troy and P. Beringer, Remington-The Science and Practice of Pharmacy, Vol-I & II, Wolters Kluwer/ Lippincott Williams & Wilkins (Indian edition), New Delhi.
19. J. W. Robinson, E. M. S. Frame and G. M. Frame II, Undergraduate Instrumental Analysis, Marcel Dekker, New York, USA.
20. J. R. Dyer, Applications Of Absorption Spectroscopy Of Organic Compounds, Prentice- Hall of India Pvt Ltd, New Delhi, India.
21. D. L. Pavia, G. M. Lampman, G. S. Kriz and J. R. Vyvyan, Introduction to Spectroscopy, Brooks/Cole Cengage Learning, Australia.
22. Y. R. Sharma, Elementary organic spectroscopy-Principles and Chemical Applications, S. Chand & Company Ltd, New Delhi, India

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Course Code	Course Name	Credits
MPC102T	Advanced Organic Chemistry I	4

- **Prerequisites:**
  - Basic understanding of general chemistry principles, including atomic structure, chemical bonding, and reaction stoichiometry.
  - Proficiency in organic chemistry fundamentals, including nomenclature, structure, and properties of organic compounds
- **Course Outcomes: After completion of this course students should be able to:**
  1. Apply knowledge of organic intermediates and reaction mechanisms to predict the outcomes of specific organic reactions.
  2. Explain the significance of named reactions in organic synthesis and their applications in the construction of complex organic molecules.
  3. Evaluate the roles of synthetic reagents in organic synthesis, including protection strategies, and their impact on overall synthetic strategies.
  4. Understand the synthetic pathways and applications of heterocyclic compounds in synthesizing pharmaceuticals and natural products.
  5. Analyze synthetic targets and propose efficient synthetic routes using the synthon approach, contributing to developing synthetic methodologies.

Sr. No.	Content	Hours
Unit 1:	**Basic Aspects of Organic Chemistry**	**12**
1.1	Organic intermediates: Carbocations, carbanions, free radicals, carbenes and nitrenes. Their method of formation, stability, and synthetic applications.	4
1.2	Types of reaction mechanisms and methods of determining them	1
1.3	Detailed knowledge regarding the reactions, mechanisms, and their relative reactivity and orientations. a. Addition reactions (Electrophilic addition of alkenes, Nucleophilic addition of carbonyl compounds) b. Nucleophilic uni- and bimolecular reactions (S_N1 and S_N2), Electrophilic Aromatic Substitution and Nucleophilic Aromatic Substitution. c. Elimination reactions (E_1 & E_2; Hoffman & Saytzeff's rule) d. Rearrangement reaction (Concerted, Cationic, Anionic)	7
Unit 2:	**Study of mechanism and synthetic applications of the following named Reactions**	**12**
2.1	Ugi reaction, Brook rearrangement, Ullmann coupling reactions, Dieckmann Reaction, Doebner-Miller Reaction, Sandmeyer Reaction, Mitsunobu reaction, Mannich reaction, Vilsmeyer-Haack Reaction, Sharpless asymmetric epoxidation, Baeyer-Villiger oxidation, Shapiro & Suzuki reaction, Ozonolysis and Michael addition reaction	12
Unit 3:	**Photochemical and Pericyclic Reactions**	**12**
3.1	Aluminiumisopropoxide, N-bromosuccinimide, diazomethane, dicyclohexylcarbodimide, Wilkinson reagent, Witting reagent. Osmium tetroxide, titanium chloride, diazopropane, diethyl azodicarboxylate, Triphenylphosphine, Benzotriazol-1-	8

	yloxytris(dimethylamino) phosphonium hexafluoro-phosphate (BOP).	
3.2	Protecting groups • Role of protection in organic synthesis • Protection for the hydroxyl group, including 1,2-and1,3-diols: ethers, esters, carbonates, cyclic acetals & ketals • Protection for the Carbonyl Group: Acetals and Ketals • Protection for the Carboxyl Group: amides and hydrazides, esters • Protection for the Amino Group and Amino acids: carbamates and amides	4
Unit 4:		**12**
4.1	Organic Name reactions with their respective mechanism and applications involved in the synthesis of drugs containing five, six-membered and fused heterocycles such as Debus-Radziszewski imidazole synthesis, Knorr Pyrazole Synthesis Pinner Pyrimidine Synthesis, Combes Quinoline Synthesis, Bernthsen Acridine Synthesis, Smiles rearrangement and Traube purine synthesis.	6
4.2	Synthesis of a few representative drugs containing these heterocyclic nuclei such as Ketoconazole, Metronidazole, Miconazole, celecoxib, antipyrine, Metamizole sodium, Terconazole, Alprazolam, Triamterene, Sulfamerazine, Trimethoprim, Hydroxychloroquine, Quinine, Chloroquine, Quinacrine, Amsacrine, Prochlorperazine, Promazine, Chlorpromazine, Theophylline, Mercaptopurine and Thioguanine.	6
Unit 5:		**12**
5.1	Basic principles, terminologies, and advantages of retrosynthesis; guidelines for dissection of molecules. Functional group interconversion and addition (FGI and FGA)	5
5.2	C-X disconnections; C-C disconnections – alcohols and carbonyl compounds; 1,2-, 1,3-,1,4-, 1,5-, 1,6-difunctionalized compounds	5
5.3	Strategies for synthesis of three, four, five, and six-membered rings.	2
	Total Hours	60

Reference material:

A. Books:

1. **"**Advanced Organic chemistry, Reaction, Mechanisms and Structure", J March, John Wiley and Sons, New York.
2. "Mechanism and Structure in Organic Chemistry", ES Gould, Hold Rinchart and Winston, New York.
3. "Organic Chemistry" Clayden, Greeves, Warren and Woihers., Oxford University Press 2001.
4. "Organic Chemistry" Vol I and II. I.L. Finar. ELBS, Pearson Education Lts, Dorling Kindersley 9India) Pvt. Ltd.
5. A guide to mechanisms in Organic Chemistry, Peter Skyes (Orient Longman, New Delhi).
6. Reactive Intermediates in Organic Chemistry, Tandom and Gowel, Oxford & IBH Publishers.
7. Combinational Chemistry – Synthesis and applications – Stephen R Wilson & Anthony W Czarnik, Wiley – Blackwell.
8. Carey, Organic Chemistry, 5th Edition (Viva Books Pvt. Ltd.)

9. Organic Synthesis - The Disconnection Approach, S. Warren, Wiley India
10. Principles of Organic Synthesis, ROC Norman and JM Coxan, Nelson Thorns.
11. Organic Synthesis - Special Techniques. VK Ahluwalia and R Agarwal, Narosa Publishers.
12. Organic Reaction Mechanisms IVth Edtn, VK Ahluwalia and RK Parashar, Narosa Publishers**.**

B. Websites:

1. https://www.chemtube3d.com/category/organic-reactions/electrophilic-addition-to-alkenes/
2. https://www.chemtube3d.com/category/organic-reactions/nucleophilic-substitution/
3. https://www.chemtube3d.com/category/organic-reactions/electrophilic-aromatic-substitution/
4. https://www.chemtube3d.com/category/organic-reactions/elimination/
5. https://www.chemtube3d.com/category/organic-reactions/rearrangements/

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Course Code	Course Name	Credits
MPC103T	Advanced Medicinal Chemistry	4

- **Prerequisites:**
  - Basics of medicinal chemistry which includes the structures, scaffolds, stereochemistry, rational development, mechanism of action at the molecular level, metabolism, and SAR of various classes of drugs.
  - Principles of biochemistry like enzyme kinetics, proteins, peptides etc.
  - Stereochemical aspects in ADME
- **Course Outcomes: After completion of this course students should be able to:**
  1. Understand different stages of drug discovery and drug-receptor interactions
  2. Apply the principles of medicinal chemistry in drug research
  3. Analyze different techniques for drug discovery and medicinal chemistry
  4. Create appropriate enzyme inhibitor or peptidomimetic if given the case

Sr. No.	Content	Hours
Unit 1:	**Drug Discovery**	**12**
1.1	Stages of drug discovery, lead discovery; identification, validation and diversity of drug targets Drug discovery via metabolism and metabolomics	4
1.2	Biological drug targets: Receptors, types, binding and activation, theories of drug-receptor interaction, drug-receptor interactions, agonists vs antagonists	8
1.3	Artificial enzymes. **(Self-study)**	1
Unit 2:	Prodrug Design and Analog design	**12**
2.1	Prodrug design: Basic concept, Carrier linked prodrugs including GDEPT, ADEPT, VDEPT, PDEPT, CDEPT, Bioprecursors, Prodrugs of functional group, Prodrugs to improve patient acceptability, Drug solubility, Drug absorption and distribution, site-specific drug delivery and sustained drug action. Rationale of prodrug design and practical consideration of prodrug design.	4
2.2	Combating drug resistance: Causes for drug resistance, strategies to combat drug resistance in antibiotics and anticancer therapy, Genetic principles of drug resistance.	4
2.3	Analog Design: Introduction, Classical & Nonclassical, Bioisosteric replacement strategies, rigid analogs, alteration of chain branching, changes in ring size, ring position isomers, design of stereoisomers and geometric isomers, fragments of a lead molecule, variation in interatomic distance.	4
Unit 3:	**Medicinal chemistry aspects of the following class of drugs**	**12**
3.1	The systematic study, SAR, Mechanism of action and synthesis of new generation molecules of the following class of drugs: a. Anti-hypertensive drugs: endothelin receptor antagonist sulfonamides b. Psychoactive drugs : synthetic cathinones c. Anticonvulsant drugs (Imidazobenzodiazepin) d. H1 antagonits (Second-generation) e. H2 receptor antagonists, Famotidine, Ranitidine) f. COX1 (Mofezolac)& COX2 inhibitors (2 coxib derivatives) ,	5

	g. Adrenergic agents (Silodosin analogs) h. Cholinergic agents(Revefenacin) i. Antineoplastic (CDK4/6) j. Antiviral agents. (Remdesivir, Nirmatrelvir)	
3.2	Stereochemistry and Drug action: Realization that stereoselectivity is a prerequisite for evolution. Role of chirality in selective and specific therapeutic agents. Case studies, Enantio selectivity in drug adsorption, metabolism, distribution, , elimination and Toxicity.	8
Unit 4:	**Rational Design of Enzyme Inhibitors**	12
4.1	Enzyme Kinetics (Self-study) & Principles of Enzyme Inhibitors	2
4.2	Enzyme inhibitors in medicine, Enzyme inhibitors in basic research	2
4.3	Rational design of non-covalently and covalently binding enzyme inhibitors Slow-tight binder, transition state analog, multi-substrate, and mechanism based inhibitors	8
Unit 5:	**Peptidomimetics**	**12**
5.1	Therapeutic values of Peptidomimetics	2
5.2	Design of peptidomimetics by manipulation of the amino acids, modification of the peptide backbone, and incorporating conformational constraints locally or globally.	8
5.3	Chemistry of prostaglandins, leukotrienes and thromboxanes. (Self Study) examples of Peptidomimetics and strategies adopted thereof.	1
	Total Hours	**60**

Reference material:

Books:

1. Medicinal Chemistry by Burger, Vol I –VI.
2.Wilson and Gisvold's Textbook of Organic Medicinal and Pharmaceutical Chemistry, 12 th Edition, Lppincott Williams & Wilkins, Woltess Kluwer (India) Pvt.Ltd, New Delhi.
3. Comprehensive Medicinal Chemistry – Corwin and Hansch.
4. Computational and structural approaches to drug design edited by Robert M Stroud and Janet. F Moore 80
5. Introduction to Quantitative Drug Design by Y.C. Martin.
6. Principles of Medicinal Chemistry by William Foye, 7 th Edition, Ippincott Williams & Wilkins, Woltess Kluwer (India) Pvt.Ltd, New Delhi.
7. Drug Design Volumes by Arienes, Academic Press, Elsevier Publishers, Noida, Uttar Pradesh..
8. Principles of Drug Design by Smith.
9. The Organic Chemistry of the Drug Design and Drug action by Richard B.Silverman, II Edition, Elsevier Publishers, New Delhi.
10. An Introduction to Medicinal Chemistry, Graham L.Patrick, III Edition, Oxford University Press, USA.
11. Biopharmaceutics and pharmacokinetics, DM.Brahmankar, Sunil B. Jaiswal II Edition, 2014, Vallabh Prakashan, New Delhi.
12. Peptidomimetics in Organic and Medicinal Chemistry by Antonio Guarna and Andrea Trabocchi, First edition, Wiley publishers.

Articles:

1. https://www.frontiersin.org/articles/10.3389/fddsv.2023.1201419/full
2. https://pubs.rsc.org/en/content/articlelanding/2024/cs/d2cs00957a/unauth
3. https://www.frontiersin.org/articles/10.3389/fchem.2021.802120/full

4. https://www.researchgate.net/publication/372797630_The_Use_of_Enzyme_Inhibitors_in_Drug_Discovery_Current_Strategies_and_Future_Prospects
5. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8877306/

Course Code	Course Name	Credits
MPC104T	**Chemistry of Natural Products**	**4**

- **Prerequisites:**
  - The learner should have basic knowledge of Phytochemistry and Biochemistry and spectroscopic analysis
- **Course Outcomes: After completion of this course students should be able to:**
  1. Recognize the different types of natural compounds, and their chemistry and medicinal importance
  2. Explain the phytochemical importance of alkaloids, flavonoids, steroids, terpenoids and vitamins in drug discovery
  3. Use rDNA technology in new drug discovery
  4. Justify the structure elucidation of natural compounds based on its various spectroscopic parameters

Sr. No.	Content	Hours
Unit 1:	**Study of Natural products as leads for new pharmaceuticals for the following class of drugs**	**12**
a.	Drugs Affecting the Central Nervous System: Morphine Alkaloids	2
b.	Anticancer Drugs: Paclitaxel and Docetaxel, Etoposide, and Teniposide	2
c.	Cardiovascular Drugs: Lovastatin, Teprotide and Dicoumarol	2
d.	Neuromuscular Blocking Drugs: Curare alkaloids	2
e.	Anti-malarial drugs and Analogues	2
f.	Chemistry of macrolid antibiotics (Erythromycin, Azithromycin, Roxithromycin, and Clarithromycin) and β - Lactam antibiotics (Cephalosporins and Carbapenem)	2
Unit 2:		**12**
a.	**Alkaloids** General introduction, classification, isolation, purification, molecular modification and biological activity of alkaloids, general methods of structural determination of alkaloids, structural elucidation and stereochemistry of ephedrine, morphine, ergot, emetine and reserpine.	**4**
b.	**Flavonoids** Introduction, isolation and purification of flavonoids, General methods of structural determination of flavonoids; Structural elucidation of quercetin.	**4**
c.	**Steroids** General introduction, chemistry of sterols, sapogenin and cardiac glycosides. Stereochemistry and nomenclature of steroids, chemistry of contraceptive agents male & female sex hormones (Testosterone, Estradiol, Progesterone), adrenocorticoids (Cortisone), contraceptive agents and steroids (Vit – D).	**4**
Unit 3:		**12**

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a.	**Terpenoids** Classification, isolation, isoprene rule and general methods of structural elucidation of Terpenoids; Structural elucidation of drugs belonging to mono (citral, menthol, camphor), di(retinol, Phytol, taxol) and tri terpenoids (Squalene,Ginsenoside) carotinoids (β carotene)	6
b.	Vitamins Chemistry and Physiological significance of Vitamin A, B1, B2, B12, C, E, Folic acid and Niacin	6
Unit 4:		**12**
a.	**Recombinant DNA technology and drug discovery** rDNA technology, hybridoma technology, New pharmaceuticals derived from biotechnology; Oligonucleotide therapy. Gene therapy: Introduction, Clinical application and recent advances in gene therapy, principles of RNA & DNA estimation	6
b.	**Active constituent of certain crude drugs used in Indigenous system** Diabetic therapy – Gymnema sylvestre, Salacia reticulate, Pterocarpus marsupiam, Swertia chirata, Trigonella foenum graccum; Liver dysfunction – Phyllanthus niruri; Antitumor – Curcuma longa Linn. 1. Study herbal formulations/Neutraceutical of the above herbs and make a report 2. Semisynthetic Phytoconstituents of any one of the above herbs to be taken as a case study.	6
Unit 5:	**Structural Characterization of natural compounds**	**12**
	Structural characterization of natural compounds using IR, 1HNMR, 13CNMR and MS Spectroscopy of specific drugs e.g., Penicillin Morphine Camphor Vit-D Quercetin Digitalis glycosides	12
	Total Hours	60

Reference material:

A. **Books**:**

1. Modern Methods of Plant Analysis, Peech and M.V.Tracey, Springer – Verlag, Berlin, Heidelberg.
2. Phytochemistry Vol. I and II by Miller, Jan Nostrant Rein Hld.
3. Recent advances in Phytochemistry Vol. I to IV – Scikel Runeckles, Springer Science & Business Media.
4. Chemistry of natural products Vol I onwards IWPAC.
5. Natural Product Chemistry Nakanishi Gggolo, University Science Books, California.
6. Natural Product Chemistry "A laboratory guide" – Rapheal Khan.
7. The Alkaloid Chemistry and Physiology by RHF Manske, Academic Press.
8. Introduction to molecular Phytochemistry – CHJ Wells, Chapmannstall.
9. Organic Chemistry of Natural Products Vol I and II by Gurdeep and Chatwall, Himalaya Publishing House.

10. Organic Chemistry of Natural Products Vol I and II by O.P. Agarwal, Krishan Prakashan.
11. Organic Chemistry Vol I and II by I.L. Finar, Pearson Education.
12. Elements of Biotechnology by P.K. Gupta, Rastogi Publishers.
13. Pharmaceutical Biotechnology by S.P.Vyas and V.K.Dixit, CBS Publishers.
14. Biotechnology by Purohit and Mathur, Agro-Bios, 13th edition.
15. Phytochemical methods of Harborne, Springer, Netherlands.
16. Burger's Medicinal Chemistry.

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Course Code	Course Name	Credits
MPC105P	Pharmaceutical Chemistry Practical I	4

- **Prerequisites:**
  - Skills learned during the Analytical, organic, inorganic and medicinal chemistry labs at UG level
  - Use of safety techniques and instruments
  - Interpretation of analytical and spectral data
- **Course Outcomes: After completion of this course students should be able to:**
  1. Perform quantitative analysis of organic compounds using analytical techniques
  2. Implementing the various reactions of synthetic importance
  3. Purify the synthesized compounds
  4. Perform calculations relevant to synthetic experiments

Unit 1:	**Analytical experiments**	**Hours: 18 hours**
1.1	1. Analysis of Pharmacopoeial compounds and their formulations by UV Vis spectrophotometer. 2. Simultaneous estimation of multi-component containing formulations by UV spectrophotometry	
1.2	3. Experiments based on Column chromatography 4. Experiments based on HPLC 5. Experiments based on Gas Chromatography	
1.3	6. Estimation of riboflavin/quinine sulfate by fluorimetry 7. Estimation of sodium/potassium by flame photometry	
Unit 2:	**Synthesis, Purification and characterization experiments**	**Hours: 42 hours**
2.1	8. Claisen-schmidt reaction (Condensation). 9. Benzilic acid rearrangement. 10. Beckmann rearrangement. 11. Hofmann rearrangement 12. Mannich reaction	
2.2	13. Synthesis of medicinally important compounds involving more than one step along with purification and Characterization using TLC, melting point, and IR spectroscopy (2 experiments) 1. Benzocaine from PNBA 2. Phenytoin from benzoin 14. Estimation of elements and functional groups in organic natural compounds 15. Isolation, characterization like melting point, mixed melting point, molecular weight determination, functional group analysis, a co-chromatographic technique for identification of isolated compounds, and interpretation of UV and IR data. 16. Some typical degradation reactions to be carried on selected plant constituents (oxidative, pH degradation, photolytic, and heat degradatio of Quercetin) 17. Purification of organic solvents	
	Total Hours	**60**

Reference material:

1. Vogel‟s A Text-book of Practical Organic Chemistry: Including Qualitative Organic Analysis, Fifth Edition, A.I. Vogel, A.R. Tatchell, B.S. Furnis, A.J. Hannaford P.W.G. Smith

2. Practical Organic Chemistry by Mann FC & Saunders BC, Longman Group Limited, London.

3. Laboratory Techniques in Organic Chemistry, Ahluwalia V.K. I.K. Publishers.

4. Practical Organic Synthesis: A Student's Guide - Reinhart Keese, Martin Brändle, Trevor Toube.

5. A.H. Beckett and J.B. Stenlake, Practical Pharmaceutical Chemistry, 4th Edn., Part I and II, CBS Publishers and Distributors, India.

6. Indian Pharmacopoeia, The Indian Pharmacopeia Commission, Ghaziabad, Government of India.

7. J. Mendham, R. C. Denney, J. D. Barnes, M.J. K. Thomas, Vogel‟s Textbook of Quantitative Chemical Analysis, Pearson Education Ltd.

8. L. R. Snyder, J. J. Kirkland, J. L. Glajch, Practical HPLC Method Development, 2nd

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Course code	Course Name	Credits
IKS_MP_101	Yoga: A key to healthy life	-

- **Prerequisites**
  - Basic knowledge of Yoga and human health
- **Course Outcomes: After the completion of course, learner will be able to:**
  3. Improvement in mental and physical health
  4. Provide improved attention in studies and better interpersonal relationships

Sr. No.	Content	Hours
1	**UNIT 1: INTRODUCTION**	**10**
1.1	Yoga-Meaning and definition, yoga misconceptions and comparison between yoga and exercise, Introduction to Ashtanga yoga (eight limbs of yoga), Pranav sadhana, Mudra and Bandh	6
1.2	Yoga therapy	2
1.3	Yoga and diet	2
2	**UNIT 2: AASANA (Introduction, contraindications, benefits and demonstration of following asanas**	**12**
2.1	**Sitting postures**: Swastikasana, padmasana, Marjarasana, Bhadrasana, Vajrasana, Ustrasana, Sasakasana, Vakrasana, Paschimatanasana, Parvatasana	3
2.2	**Standing postures**: Tadasana, Vrksasana, Pada-hastasana, Ardha chakrasana, Trikonasana	3
2.3	**SUPINE POSTURES**: Setubandhasana, Uttana padasana, Ardha halasana, Pavana muktasana, Savasana, Viparit karni, tadagi mudra	3
2.4	**Prone postures**: Makarasana, Bhujangasana, Salabhasana, Naukasana, Matsyasana	2
2.5	Suryanamaskar	1
3	**UNIT 3: PRANAYAMA (Introduction, contraindications, benefits and demonstration of following pranayama)**	**02**
3.1	Kapalabhati, Anulom vilom, Sitali, Sitakari, Bhramari, Ujiayi, Bhastrika, Uddiyana bandha	2
4	**UNIT 4: STRESS MANAGEMENT**	**06**
4.1	Meditation, Yog nidra, Shavasana, Mindfulness, Prayers	4
4.2	Yogic lifestyle	2
	TOTAL	**30**

Recommended Books (Latest Editions)

1. Websites: https://ayush.gov.in/ Ministry of Ayurveda, Yoga & Naturopathy, Unani, Siddha and Homoeopathy (AYUSH)

Books: Know yoga Live Yoga, By ShriKrishna Mhaskar

M. Pharm Pharmaceutical Chemistry Semester 2

Course Code	Course Name	Credits
MPC201T	Advanced Spectra Analysis	4

- **Prerequisites:**
  - Before undertaking the course, students should have knowledge of the following:
  - Basics of UV-vis spectroscopy, IR spectroscopy, NMR & MS
  - Basics of organic chemistry
- **Course Outcomes: After completion of this course students should be able to:**
  1. Recall with examples the terminologies of advanced chromatographic & hyphenated techniques, thermal analysis & radio immunoassays
  2. Explain and illustrate the theory and applications of 1-D & 2-D NMR, advanced chromatographic & hyphenated techniques, thermal analysis & radio immunoassays
  3. Apply the knowledge gained and perform mathematical calculations to obtain: chemical shift values and relative intensities of peaks in 1H NMR; λmax, and DBE of organic compounds; mass to charge ratio of fragments in MS
  4. Interpret the spectral data and predict the structure of organic compounds.

Sr. No.	Content	Hours
Unit 1:	**UV and IR spectroscopy**	**8**
1.1	Woodward–Fieser rulefor1,3-butadienes, cyclicdienes and α, β-carbonyl compounds and interpretation compounds of enones	4
1.2	ATR-IR: Concept,Principle and Applications	2
1.3	IR Interpretation of organic compounds using chemical structures	2
Unit 2:	**NMR**	**12**
2.1	1-D and 2-D NMR, NOESY and COSY, HECTOR, INADEQUATE techniques	5
2.2	Interpretation of organic compounds: Structural elucidation problems based on ^{1}H NMR and ^{13}C NMR	7
Unit 3:	**Mass Spectroscopy**	**12**
3.1	Mass fragmentation and its rules, Fragmentation of important functional groups like alcohols, amines, carbonyl groups and alkanes, Metastable ions, McLafferty rearrangement, Ring rule, Isotopic peaks	6
3.2	Interpretation of organic compounds	6
Unit 4:	**Chromatography**	**10**
4	Principle, Instrumentation and Applications of the following: a) GC-MS **(Self-study)** b) GC-AAS c) LC-MS **(Self-study)** d) LC-FTIR e) LC-NMR f) CE-MS g) High Performance Thin Layer chromatography **(Self-study)** h) Supercritical fluid chromatography i) Ion Chromatography **(Self-study)** j) I-EC (Ion-Exclusion Chromatography) k) Flash chromatography	10

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Unit 5:		**12**
5.1	Thermal methods of analysis: Introduction, principle, instrumentation and application of DSC, DTA and TGA (Self-study)	4
5.2	Raman Spectroscopy: Introduction, Principle, Instrumentation and Applications.	4
5.3	• Radio immunoassay: Biological standardization, bioassay, ELISA, • Radioimmunoassay of digitalis and insulin **(Self-study)**	5
Unit 6:	**Circular Dichroism**	**6**
6.	• Principle, Instrumentation and Applications of Circular Dichroism • Interpretation of CD spectra of a simple protein	6
	Total Hours	**60**

Reference material:

1. D. A. Skoog, F. J. Holler and S. R. Crouch, Principles of Instrumental Analysis, Saunders College Publishing, USA.
2. K. A. Connors, A Textbook of Pharmaceutical Analysis, John Wiley and Sons, Canada.
3. A. H. Beckett and J. B. Stenlake, Practical Pharmaceutical Chemistry, ,Vol. 6, Part I and II, CBS Publishers and Distributors, India.
4. D. A. Skoog, D. M. West, F. J. Holler and S. R. Crouch, Fundamentals of Analytical Chemistry, Saunders College Publishing, USA.
5. G. D. Christian, Analytical Chemistry, John Wiley & Sons, Singapore, reprint by Wiley India Pvt. Ltd.
6. H.H. Willard, L. L. Merrit and J. A. Dean, Instrumental Method of Analysis, CBS Publishers & Distributors, New Delhi.
7. Ashutosh. Kar, Pharmaceutical Drug Analysis, New Age International (P) Ltd. Publishers, India.
8. S. S. Mahajan, Instrumental Methods of Analysis, Popular Prakashan Pvt Ltd., India.
9. G. R. Chatwal and S. K. Anand, Instrumental methods of chemical analysis, Himalaya Publishing House Pvt. Ltd.
10. Indian Pharmacopoeia, The Indian Pharmacopoeia Commission, Ghaziabad, Government of India. Latest Edition
11. J. Mendham, R. C. Denney, J. D. Barnes, M. J. K. Thomas, Vogel's Textbook of Quantitative Chemical Analysis, Pearson Education Ltd.
12. D. G. Watson, Pharmaceutical Analysis –A textbook for pharmacy students and pharmaceutical chemists. Churchill Livingstone Elsevier.
13. J. W. Robinson, E. M. S. Frame and G. M. Frame II, Undergraduate Instrumental Analysis, Marcel Dekker, New York, USA.
14. R. Kellnar, J. M. Mermet, M. Otto, M. Valcarceland, H. M. Widmer, Analytical Chemistry: A modern approach to analytical science, Wiley-VCH, USA.
15. J. W. Munson, Pharmaceutical Analysis: Modern methods (in two parts), Marcel Dekker Inc., USA.
16. W. Kemp, Organic Spectroscopy, Palgrave Publishers Ltd., New York, USA.
17. R. M. Silverstein, F. X. Webster and D. J. Kiemle, Spectrometric identification of organic compounds, John Wiley & Sons, Inc. (Indian edition), New Delhi.
18. D. B. Troy and P. Beringer, Remington-The Science and Practice of Pharmacy, Vol-I & II, Wolters Kluwer/ Lippincott Williams & Wilkins (Indian edition), New Delhi.
19. J. W. Robinson, E. M. S. Frame and G. M. Frame II, Undergraduate Instrumental Analysis, Marcel Dekker, New York, USA.

20. J. R. Dyer, Applications Of Absorption Spectroscopy Of Organic Compounds, Prentice- Hall of India Pvt Ltd, New Delhi, India.
21. D. L. Pavia, G. M. Lampman, G. S. Kriz and J. R. Vyvyan, Introduction to Spectroscopy, Brooks/Cole Cengage Learning, Australia.
22. Y. R. Sharma, Elementary organic spectroscopy-Principles and Chemical Applications, S. Chand & Company Ltd, New Delhi, India

Course Code	Course Name	Credits
MPC202T	Advanced Organic Chemistry II	4

- **Prerequisites:**
  - Knowledge of basic laboratory techniques commonly used in organic chemistry experiments.
  - Strong problem-solving skills and critical thinking abilities to analyze and apply theoretical concepts to practical scenarios.
- **Course Outcomes: After completion of this course students should be able to:**
  1. Recall with examples the terminologies of advanced chromatographic & hyphenated techniques, thermal analysis & radio immunoassays
  2. Explain and illustrate the theory and applications of 1-D & 2-D NMR, advanced chromatographic & hyphenated techniques, thermal analysis & radio immunoassays
  3. Apply the knowledge gained and perform mathematical calculations to obtain: chemical shift values and relative intensities of peaks in 1H NMR; λmax, and DBE of organic compounds; mass to charge ratio of fragments in MS
  4. Interpret the spectral data and predict the structure of organic compounds

Sr. No.	Content	Hours
Unit 1:	**Green Chemistry**	**12**
1.1	Introduction, principles of green chemistry	**4**
1.2	Microwave-assisted reactions: Merit and demerits of its use, increased reaction rates, mechanism, superheating effects of microwave, effects of solvents in microwave-assisted synthesis, microwave technology in process optimization, its applications in various organic reactions and heterocycles synthesis	**3**
1.3	Ultrasound-assisted reactions: Types of sonochemical reactions, homogenous, heterogeneous liquid-liquid and liquid-solid reactions, synthetic applications	**2**
1.4	Continuous flow reactors: Working principle, advantages, and synthetic applications	**1**
1.5	Click Chemistry: Characteristics, Classification- Cycloaddition (Huisgen 1,3-dipolar Cycloaddition), Nucleophilic ring-openings, non-aldol carbonyl chemistry, carbon-carbon multiple bonds addition,	**1**
1.6	Mechanochemistry: Principle, Equipment, Applications	**1**
Unit 2:	**Chemistry of peptides**	**12**
2.1	Coupling reactions in peptide synthesis	2
2.2	Principles of solid phase peptide synthesis, t-BOC, and FMOC protocols, various solid supports and linkers: Activation procedures, peptide bond formation, deprotection and cleavage from resin, low and high HF cleavage protocols, formation of free peptides and peptide amides, purification and case studies, site-specific chemical modifications of peptides	4
2.3	Segment and sequential strategies for solution phase peptide synthesis with any two case studies	2

2.4	Side reactions in peptide synthesis: Deletion peptides, side reactions initiated by proton abstraction, protonation, over-activation, and side reactions of individual amino acids.	4
Unit 3:	**Photochemical and Pericyclic Reactions**	**12**
3.1	Basic principles of photochemical reactions. Photo-oxidation, photo-addition and photo-fragmentation.	7
3.2	Pericyclic reactions: Mechanism, Types of pericyclic reactions such as cycloaddition, electrocyclic reaction, and sigmatropic rearrangement reactions with examples	5
Unit 4:	**Catalysis**	**12**
4.1	Types of catalysis, heterogeneous and homogeneous catalysis, advantages and disadvantages	1
4.2	Heterogeneous catalysis – preparation, characterization, kinetics, supported catalysts, catalyst deactivation, and regeneration, some examples of heterogeneous catalysis used in the synthesis of drugs.	2
4.3	Homogenous catalysis, hydrogenation, hydroformylation, hydrocyanation, Wilkinson catalysts, chiral ligands, chiral induction, and Ziegler-Natta catalysts, some examples of homogenous catalysis used in the synthesis of drugs	2
4.4	Transition-metal and Organo-catalysis in organic synthesis: Metal-catalyzed reactions Hapticity of ligand, 18 electron rule, Palladium complexes, Crosscoupling reactions: Shapiro, Heck, and Suzuki reaction	5
4.5	Biocatalysis: Use of enzymes in organic synthesis, immobilized enzymes/cells in organic reaction.	1
4.6	Phase transfer catalysis - theory and applications	1
Unit 5:	**Stereochemistry and asymmetric synthesis**	**12**
5.1	Basic concepts in stereochemistry – optical activity, specific rotation, racemates and resolution of racemates, the Cahn, Ingold, Prelog (CIP) sequence rule, meso compounds, pseudo asymmetric centers, axes of symmetry, Fischer's D and L notation, cis-trans isomerism, E and Z notation.	6
5.2	Methods of asymmetric synthesis using the chiral pool, chiral auxiliaries and catalytic asymmetric synthesis, enantiopure separation, and Stereoselective synthesis with examples.	6
	Total Hours	**60**

Reference material:

A. **Books**:**

1. "Advanced Organic chemistry, Reaction, mechanisms and structure", J March, John Wiley and Sons, New York.
2. "Mechanism and structure in organic chemistry", ES Gould, Hold Rinchart and Winston, NewYork.
3. "Organic Chemistry" Clayden, Greeves, Warren and Woihers., Oxford University Press 2001.
4. "Organic Chemistry" Vol I and II. I.L. Finar. ELBS, Sixth ed., 1995.
5. Carey, Organic chemistry, 5th edition (Viva Books Pvt. Ltd.)
6. Organic synthesis-the disconnection approach, S. Warren, Wily India
7. Principles of organic synthesis, ROCNorman and JMCoxan, Nelson thorns
8. Organic synthesis- Special techniques VK Ahluwalia and R Aggarwal, Narosa Publishers.

9. Organic reaction mechanisms IV Ed, VK Ahluwalia and RK Parashar, Narosa Publishers**.**

B. Weblinks:

a. https://www.chemtube3d.com/category/organic-reactions/pericyclic-reactions/
b. https://www.stereoelectronics.org/webSC/SC306.html
c. https://www.chemtube3d.com/claydenbinap/
d. https://www.chemtube3d.com/claydenepoxides/
e. https://www.chemtube3d.com/asymauxdaevans/
f. https://www.chemtube3d.com/asymauxboronenolate1/
g. https://www.chemtube3d.com/asymorgano_cbs_carbonyl_reduction/
h. https://www.chemtube3d.com/asymcathydrogenation_ru/
i. https://www.chemtube3d.com/asymcat-tartrate/

C. Articles:

1. Rehman et al., Side Reactions in peptide synthesis Side Reactions in peptide synthesis Side Reactions in peptide synthesis, International Journal of Pharmaceutical Research & Technology, Volume 10, 2018, 1-12.
2. Lidström et al., Microwave assisted organic synthesis—a review, Tetrahedron, Volume 57, Issue 45,2001, 9225-9283.
3. Puri et al., Applications of Ultrasound in Organic Synthesis - A Green Approach, Current Organic Chemistry, Volume 17, Issue 16, 2013, 1790-1828.
4. Hein CD et al., Click chemistry, a powerful tool for pharmaceutical sciences. Pharm Res. Volume 25, Issue 10, 2008, 2216-2230.

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Course Code	Course Name	Credits
MPC203T	Computer-Aided Drug Design	4

- **Prerequisites:**
  - Basics of Protein 3D structure, computer applications
  - Basics of organic chemistry related to bond characteristics interaction and reactivity
  - Advanced Medicinal Chemistry, Chemistry of Natural Products, Modern Pharmaceutical Analytical Techniques.
- **Course Outcomes: After completion of this course students should be able to:**
  1. Recall and relate the different geometries of protein along with the structure-activity relationship of existing studied drugs and their interactions with the protein residues
  2. Classify and explain the different techniques to calculate the potential and kinetic energies of the system using Quantum and Molecular Mechanics, energy minimization, and molecular conformational space search in the binding cavity of protein
  3. Relate the use of the minimization and conformational search of protein and ligand to construct and develop a model based on desired techniques like molecular docking, 3D-QSAR, pharmacophore modeling, homology modeling, molecular dynamics, etc.
  4. Evaluate the results obtained based on the characteristics of different interactions (docking), equation (QSAR), binding energy (dynamics) and interpret the molecular mechanism of how a drug acts in a particular manner to be either inhibiting or stimulating the enzyme/receptor

Sr. No.	Content	Hours
Unit 1:		**12**
1.1	History, different techniques, and applications, Sources of structure, and file formats	3
1.2	Molecular and Quantum Mechanics in drug design. forcefield, optimization and simulation Energy Minimization Methods: comparison between global minimum conformation and bioactive conformation. (systemic search, MD and monte carlo, Genetic algorithm)	7
1.3	Software hardware and languages used in molecular modeling and visualization	2
Unit 2:	**Molecular Properties and Drug Design**	**12**
2.1	Physicochemical parameters and methods to calculate physicochemical parameters: Hammett equation and electronic parameters (sigma), lipophilicity effects and parameters (log P, pi-substituent constant), steric effects (Taft steric and MR parameters)	4
2.2	Experimental and theoretical approaches for the determination of log P, Pi , sigma, taft constant and MR	3
2.3	Prediction and analysis of ADMET properties of new molecules and its importance in drug design. Introduction of Chemoinformatics Introduction of metabolomics	5
Unit 3:	**Quantitative Structure-Activity Relationships: Applications**	**12**
3.1	Quantitative Structure-Activity Relationships: Basics.	2

3.2	Hansch analysis, Free Wilson analysis and the relationship between them, Advantages and disadvantages; Deriving 2D-QSAR equations.	4
3.3	3D-QSAR approaches and contour map analysis.	4
3.4	Statistical methods used in QSAR analysis and importance of statistical parameters.	2
Unit 4:	**Molecular Modeling and Docking**	**12**
4.1	A. Molecular docking and drug-receptor interactions: Rigid docking, flexible docking and extra-precision docking. B. Various docking methods and scoring functions. C. Agents acting on enzymes such as DHFR, HMG-CoA reductase and HIV protease, choline esterase (AchE & BchE).	6
4.2	De novo drug design: Receptor/enzyme-interaction and its analysis, Receptor/enzyme cavity size prediction, predicting the functional components of cavities, Fragment-based drug design.	3
4.3	A. Introduction of Bioinformatics B. Homology modeling and generation of 3D-structure of protein. C. Steps involved and application of homology model,	3
Unit 5:	**Pharmacophore Mapping and Virtual Screening**	**12**
5.1	Concept of pharmacophore, pharmacophore mapping, identification of Pharmacophore features and Pharmacophore modeling; Conformational search used in pharmacophore mapping.	5
5.2	In Silico Drug Design and Virtual Screening Techniques Similarity-based methods and Pharmacophore-based screening, structure-based In-silico virtual screening protocols.	2
5.3	Advanced Methods in CADD 1. Molecular dynamics and free energy of binding 2. Application of AI and Machine learning	5
	Total Hours	**60**

Reference material:

1. The Organic Chemistry of Drug Design and Drug action by Richard B. Silverman, Elsevier Publishers.
2. Medicinal Chemistry by Burger, Wiley Publishing Co.
3. Wilson and Gisvold's Textbook of Organic Medicinal and Pharmaceutical Chemistry, Ippincott Williams & Wilkins.
4. Principles of Drug Design by Smith and Williams, CRC Press, Taylor & Francis.
5. Andrew R Leach - Molecular Modelling - Principles and Applications

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Course Code	Course Name	Credits
MPC204T	**Pharmaceutical Process Chemistry**	**4**

- **Prerequisites:**
  - Principles of Organic chemistry, environmental sciences, Jurisprudence, and pharmaceutical engineering.
- **Course Outcomes: After completion of this course students should be able to:**
  1. Describe the strategies of the scale-up process of APIs and intermediates.
  2. Elaborate various unit operations and various reactions in process chemistry.

Sr. No.	Content	Hours
Unit 1:	**Process chemistry**	**12**
1.1	Introduction, Synthetic strategy Stages of the scale-up process: Bench, pilot, and large-scale process.	5
1.2	Factors and Calculation Costing for the manufacture of API	1
1.3	In-process control and validation of large-scale processes. Case studies of some scale-up processes of APIs.	4
1.4	Impurities in API, types, and their sources including genotoxic impurities	2
Unit 2:	**Unit Processes-I**	**12**
2.1	Extraction: Liquid equilibria, extraction with reflux, extraction with agitation, counter-current extraction.	2
2.2	Filtration: Theory of filtration, pressure and vacuum filtration, centrifugal filtration,	3
2.3	Distillation: azeotropic and steam distillation	2
2.4	Evaporation: Types of evaporators, factors affecting evaporation.	2
2.5	Crystallization: Crystallization from aqueous, nonaqueous solutions factors affecting crystallization, and nucleation. Principle and general methods of Preparation of polymorphs, hydrates, solvates and amorphous APIs.	3
Unit 3:	**Unit Processes-II**	**12**
3.1	Nitration: Nitrating agents, Aromatic nitration, kinetics and mechanism of aromatic nitration, process equipment for technical nitration, mixed acid for nitration,	4
3.2	Halogenation: Kinetics of halogenations, types of halogenations, catalytic halogenations. Case study on industrial halogenation process.	4
3.3	Oxidation: Introduction, types of oxidative reactions, Liquid phase oxidation with oxidizing agents. Nonmetallic Oxidizing agents such as H2O2, sodium hypochlorite, Oxygen gas, and ozonolysis.	4
Unit 4:	**Unit Processes-III**	**12**
4.1	Reduction:	4

	Catalytic hydrogenation, Heterogeneous and homogeneous catalyst; Hydrogen transfer reactions, Metal hydrides. Case study on industrial reduction process.	
4.2	Fermentation: Aerobic and anaerobic fermentation. Production of i. Antibiotics; Penicillin and Streptomycin, ii. Vitamins: B2 and B12 iii. Statins: Lovastatin, Simvastatin	4
4.3	Reaction progress kinetic analysis i. Streamlining reaction steps, route selection, ii. Characteristics of expedient routes, characteristics of cost-effective routes, reagent selection, families of reagents useful for scale-up.	4
Unit 5:	**Industrial Safety**	**12**
5.1	MSDS (Material Safety Data Sheet), hazard labels of chemicals, and Personal Protection Equipment (PPE)	4
5.2	Fire hazards, types of fire & fire extinguishers	2
5.3	Occupational Health & Safety Assessment Series 1800 (OHSAS-1800) ISO 45001 Guideline and ISO-14001(Environmental Management System),	4
5.4	Effluents and its management	2
	Total Hours	60

Reference material:

1. Process Chemistry in the Pharmaceutical Industry: Challenges in an Ever-Changing Climate-An Overview; K. Gadamasetti, CRC Press.
2. Pharmaceutical Manufacturing Encyclopedia, 3rd edition, Volume 2.
3. Medicinal Chemistry by Burger, 6th edition, Volume 1-8.
4. W.L. McCabe, J.C Smith, Peter Harriott. Unit operations of chemical engineering, 7th edition, McGraw Hill
5. Polymorphism in Pharmaceutical Solids.Dekker Series Volume 95 Ed: H G Brittain (1999)
6. Regina M. Murphy: Introduction to Chemical Processes: Principles, Analysis, Synthesis
7. Peter J. Harrington: Pharmaceutical Process Chemistry for Synthesis:Rethinking the Routes to Scale-Up
8. P.H.Groggins: Unit processes in organic synthesis (MGH)
9. F.A.Henglein: Chemical Technology (Pergamon)
10. M.Gopal: Dryden's Outlines of Chemical Technology, WEP East-West Press
11. Clausen,Mattson: Principle of Industrial Chemistry, Wiley Publishing Co.,
12. Lowenheim & M.K. Moran: Industrial Chemicals
13. S.D. Shukla & G.N. Pandey: A text book of Chemical Technology Vol. II, Vikas Publishing House
14. J.K. Stille: Industrial Organic Chemistry (PH)
15. Shreve: Chemical Process, Mc Grawhill.
16. B.K.Sharma: Industrial Chemistry, Goel Publishing House
17. ICH Guidelines
18. United States Food and Drug Administration official website www.fda.gov

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Course Code	Course Name	Credits
MPC205P	**Pharmaceutical Chemistry II Practical**	**4**

- **Prerequisites:**
  Before undertaking the course, students should:
  - Possess the skills acquired during the Analytical, organic, inorganic and medicinal chemistry labs at UG level
  - Possess the skills acquired during Pharmaceutical Chemistry Practical – I
  - Use of safety techniques and instruments
  - Possess the uderstanding of analytical and spectral data
  - Possess the understanding of working of computers and software
- **Course Outcomes: After completion of this course students should be able to:**
  1. Perform the various reactions of synthetic importance.
  2. Isolate products and interpret the experimental data.
  3. Experiment with computer-aided techniques, validate the models and interpret and predict the results.

Exp. No.	Title of the Experiment
1.	Synthesis of organic compounds by adapting different approaches involving: Oxidation: Benzoic Acid
2.	Reduction/hydrogenation: PABA
3.	Nitration :meta-dinitrobenzene
4.	Comparative study of synthesis of APIs/intermediates by different synthetic Routes (2 Experiments) Benzimidazole:
5.	Assignments on regulatory requirements in API (2 assignments)
6.	Determination of purity by DSC in pharmaceuticals
7.	Identification of organic compounds using FT-IR, NMR, CNMR, and Mass spectra Comparison of absorption spectra by UV and Wood ward – Fieser rule
8.	Preparation of 4-chlorobenzhydrylpiperazine. (an intermediate for cetirizine HCl).
9.	Preparation of 4-iodotolene from p-toluidine.
10.	Preparation of umbelliferone by Pechhman reaction
11.	Preparation of triphenyl imidazole
12.	To perform the Microwave irradiated reactions of synthetic importance: Knovenengel reaction
13.	To perform the Microwave-irradiated reactions of synthetic importance (Phenytoin)
14.	Determination of log P, MR, hydrogen bond donors, and acceptors of selected drugs using software
15.	Calculation of ADMET properties of drug molecules and its analysis using Software
16.	2D-QSAR based experiments
17.	3D-QSAR based experiments
18.	Docking study-based experiment
19.	Virtual screening-based experiment
20.	Homology modeling of a protein

Reference material:

A. Books:**

1. Vogel's A Text-book of Practical Organic Chemistry: Including Qualitative Organic Analysis, Fifth Edition, A.I. Vogel, A.R. Tatchell, B.S. Furnis, A.J. Hannaford P.W.G. Smith
2. Practical Organic Chemistry by Mann FC & Saunders BC, Longman Group Limited, London.
3. R. M. Silverstein, F. X. Webster and D. J. Kiemle, Spectrometric identification of organic compounds, John Wiley & Sons, Inc. (Indian edition), New Delhi.
4. D. L. Pavia, G. M. Lampman, G. S. Kriz and J. R. Vyvyan, Introduction to Spectroscopy, Brooks/Cole Cengage Learning, Australia
5. Molecular Modeling: Basic Principles and Applications 3rd Edition, Hans-Dieter Höltje, Wolfgang Sippl, Didier Rognan, Gerd Folkers
6. Molecular Modelling: Principles and Applications Andrew R. Leach

B. Websites:

1. www.organic-chemistry.org
2. https://rxn.res.ibm.com/
3. www.bindingdb.org
4. https://biosig.lab.uq.edu.au/pkcsm/prediction
5. https://www.chemcomp.com/moe/help/latest/index_tut.html

C. Articles:

1. https://books.rsc.org/books/edited-volume/1850/chapter/2279633/Microwave-Assisted-Green-Organic-Synthesis
2. https://chem.libretexts.org/Bookshelves/Organic_Chemistry/Organic_Chemistry_Lab_Techniques_(Nichols)

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Course code	Course Name	Credits
AEC_MX_102	Multidisciplinary Subject	**-**

Students will opt for one of the core subject of other department PG course of SEM II running by the college as an audit course.

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M. Pharm
Quality Assurance
Semester 1

Course Code	Course Name	Credits
MQA101T	**Modern Pharmaceutical Analytical Techniques**	**4**

- **Prerequisites:**
  - Liquid-liquid extraction- Partition coefficient, molecular diffusion, mass transfer, Adsorption, adsorption isotherms, quantum theory, difference between protons, neutrons and electrons
  - Carbocation stability, fission and rearrangements
  - Difference between protons, neutrons and electrons
  - Concepts such as spin quantum number, magnetic dipole and magnetic moment, magnetic field strength
  - Structure of atoms, atomic orbitals and energy associated, structure of molecules, molecular orbitals and their energy, different types of molecular bonds, molecular orbital theory
  - Electromagnetic radiation, origin, nature of EMR, energy of EMR and propagation of EMR, photoelectric effect
  - EMF, Electrode potential, representation of electrolytic/ galvanic cell, types of electrodes
  - Concept of latent heats, exothermic and endothermic reactions

- **Course Outcomes: After completion of this course students should be able to:**
  1. Recall with examples the terminologies associated with spectroscopy, chromatography, X-ray diffraction, electrophoresis, potentiometry, and thermal analysis
  2. Explain and illustrate the theory, instrumentation, and applications of various techniques involved in spectroscopy, chromatography, X-ray diffraction, electrophoresis, potentiometry and thermal analysis, and chromatographic parameters
  3. Apply the knowledge gained to calculate concentration by UV-visible spectroscopy, predict the IR frequencies, number of signals in NMR, and fragmentation pattern in MS for simple organic compounds
  4. Read and interpret simple UV, IR, NMR, and Mass spectra to predict the presence or absence of structural features and elucidate molecular structures, as well as interpret simple chromatograms to determine various chromatographic parameters
  5. Predict the spectroscopic behaviour of molecules

Sr. No.	Content	Hours
Unit 1		**08**
1.1	**UV-Visible spectroscopy**: • *Principle,* Instrumentation of UV-Visible Spectroscopy **(Self-study)** • Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect **(Self-study)** • Applications of UV-Visible spectroscopy: Case study-based applications for single component and multicomponent analysis • Interpretation of UV-visible spectra of a simple organic compound • Difference/Derivative spectroscopy	02
1.2	**IR spectroscopy**:	02

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	• Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier -Transform IR Spectrometer, Factors affecting vibrational frequencies **(Self-study)** • Applications of IR spectroscopy: Including case-study for use of Near IR as a PAT tool, Data interpretation of IR spectra of a simple organic compound	
1.3	**Spectroflourimetry**: • Theory of Fluorescence, Factors affecting fluorescence, Quenchers **(Self-study)** • Instrumentation and Applications of fluorescence spectrophotometer	02
1.4	**Flame emission spectroscopy and Atomic absorption spectroscopy**: • Principle, Instrumentation, Interferences and Applications **(Self-study)** • Use of AAS for analysis of elemental impurities	02
Unit 2		**09**
2.1	**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	07
2.2	Interpretation of ^{1}H NMR spectrum of simple organic compounds	02
Unit 3		**09**
3.1	**Mass Spectrometry:** Principle, Theory, Instrumentation of Mass Spectroscopy. Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI. Analyzers - Quadrupole and Time of Flight. Mass fragmentation and its rules, Metastable ions, Isotopic peaks. Applications of Mass spectroscopy	07
3.2	Interpretation of mass spectrum of simple organic compounds	02
Unit 4		**10**
4.1	Introduction to chromatography and classification of chromatographic methods based on the mechanism of separation **(Self-study)**	01
4.2	Numericals based on calculation of chromatographic parameters	02
4.3	**Chromatography:** Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution and applications of the following: a. Thin Layer chromatography **(Self - study)** b. High Performance Thin Layer chromatography **c.** Paper chromatography **(Self-study)** d. Ion exchange chromatography e. Column chromatography **f.** Gas chromatography **(Self-study)**	07

	g. High Performance Liquid chromatography **(Self-study)** h. Affinity chromatography i. Gel chromatography j. Ultra-High Performance Liquid chromatography	
Unit 5		**10**
5.1	**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	04
5.2	**X-ray Crystallography** - Production of X rays, Different X ray diffraction methods, Bragg 's law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X- ray diffraction.	03
5.3	**Immunological assays**: RIA (Radioimmunoassay), ELISA, RT-PCR, Bioluminescence assays	03
Unit 6		**14**
6.1	**ICP-MS:** Principle and Instrumentation, Sample preparation techniques and method development strategies, Pharmaceutical Applications	02
6.2	**Hyphenated techniques:** Principle, interfaces used and applications of: LC-MS, GC-MS and HPTLC-MS	04
6.3	**Advanced Microscopic techniques:** Principle, Instrumentation and Applications of: SEM & TEM	03
6.4	**Potentiometry:** Principle, working, Ion selective Electrodes and Application of potentiometry **(Self-study)**	01
6.5	**Thermal Techniques:** • **Differential Scanning Calorimetry (DSC):** Principle, thermal transitions and Instrumentation (Heat flux and power-compensation and designs), Modulated DSC, Hyper DSC, experimental parameters (sample preparation, experimental conditions, calibration, heating and cooling rates, resolution, source of errors) and their influence, advantage and disadvantages, pharmaceutical applications. • **Differential Thermal Analysis (DTA):** Principle, instrumentation and advantage and disadvantages, pharmaceutical applications, derivative differential thermal analysis (DDTA) • **Thermogravimetric Analysis TGA:** Principle, instrumentation, factors affecting results, advantage and disadvantages, pharmaceutical applications	04
	Total Hours	**60**

Reference material:

1. D. A. Skoog, F. J. Holler and S. R. Crouch, Principles of Instrumental Analysis, Saunders College Publishing, USA.
2. K. A. Connors, A Textbook of Pharmaceutical Analysis, John Wiley and Sons, Canada.
3. A. H. Beckett and J. B. Stenlake, Practical Pharmaceutical Chemistry, ,Vol. 6, Part I and II, CBS Publishers and Distributors, India.
4. D. A. Skoog, D. M. West, F. J. Holler and S. R. Crouch, Fundamentals of Analytical Chemistry, Saunders College Publishing, USA.
5. G. D. Christian, Analytical Chemistry, John Wiley & Sons, Singapore, reprint by Wiley India Pvt. Ltd.
6. H.H. Willard, L. L. Merrit and J. A. Dean, Instrumental Method of Analysis, CBS Publishers & Distributors, New Delhi.
7. Ashutosh. Kar, Pharmaceutical Drug Analysis, New Age International (P) Ltd. Publishers, India.
8. S. S. Mahajan, Instrumental Methods of Analysis, Popular Prakashan Pvt Ltd., India.
9. G. R. Chatwal and S. K. Anand, Instrumental methods of chemical analysis, Himalaya Publishing House Pvt. Ltd.
10. Indian Pharmacopoeia, The Indian Pharmacopoeia Commission, Ghaziabad, Government of India. Latest Edition
11. J. Mendham, R. C. Denney, J. D. Barnes, M. J. K. Thomas, Vogel's Textbook of Quantitative Chemical Analysis, Pearson Education Ltd.
12. D. G. Watson, Pharmaceutical Analysis –A textbook for pharmacy students and pharmaceutical chemists. Churchill Livingstone Elsevier.
13. J. W. Robinson, E. M. S. Frame and G. M. Frame II, Undergraduate Instrumental Analysis, Marcel Dekker, New York, USA.
14. R. Kellnar, J. M. Mermet, M. Otto, M. Valcarceland, H. M. Widmer, Analytical Chemistry: A modern approach to analytical science, Wiley-VCH, USA.
15. J. W. Munson, Pharmaceutical Analysis: Modern methods (in two parts), Marcel Dekker Inc., USA.
16. W. Kemp, Organic Spectroscopy, Palgrave Publishers Ltd., New York, USA.
17. R. M. Silverstein, F. X. Webster and D. J. Kiemle, Spectrometric identification of organic compounds, John Wiley & Sons, Inc. (Indian edition), New Delhi.
18. D. B. Troy and P. Beringer, Remington-The Science and Practice of Pharmacy, Vol-I & II, Wolters Kluwer/ Lippincott Williams & Wilkins (Indian edition), New Delhi.
19. J. W. Robinson, E. M. S. Frame and G. M. Frame II, Undergraduate Instrumental Analysis, Marcel Dekker, New York, USA.
20. J. R. Dyer, Applications Of Absorption Spectroscopy Of Organic Compounds, Prentice- Hall of India Pvt Ltd, New Delhi, India.
21. D. L. Pavia, G. M. Lampman, G. S. Kriz and J. R. Vyvyan, Introduction to Spectroscopy, Brooks/Cole Cengage Learning, Australia.
22. Y. R. Sharma, Elementary organic spectroscopy-Principles and Chemical Applications, S. Chand & Company Ltd, New Delhi, India

Course Code	Course Name	Credits
MQA102T	**Quality Management System**	**4**

- **Prerequisites:**
  - Fundamental concepts of Quality Assurance

- **Course Outcomes: After completion of this course students should be able to:**
  1. Understand the concept of quality, strategic quality management and define different terms involved in quality management systems
  2. Understand the concept of statistical process control (SPC) and explain the principles involved in SPC like process capability, control chart analysis and process control
  3. Recognize the importance of customer, different concepts required to achieve customer satisfaction and desired quality the development of quality culture and define and comprehend the different terms, types and process involved in benchmarking
  4. Comprehend principles involved in pharmaceutical quality management like six sigma, ISO, WHO-GMP and CFR-21
  5. Apply ICH guidelines for drug stability, risk management and quality by design

Sr. No.	Content	Hours
Unit 1	**Introduction to Quality**	**11**
1.1	Evolution of Quality, Definition of Quality, Dimensions of Quality	01
1.2	**Quality as a Strategic Decision:** Meaning of strategy and strategic quality management, mission and vision statements, quality policy, Quality objectives, strategic planning and implementation, McKinsey 7s model, Competitive analysis. Management commitment to quality	03
1.3	• **Customer Focus:** Meaning of customer and customer focus, Classification of customers, Customer focus, Customer perception of quality, Factors affecting customer perception, Customer requirements, Meeting customer needs and expectations, Customer satisfaction and Customer delight, Handling customer complaints, Understanding customer behaviour, concept of internal and external customers • Case studies: On practical aspects for Pharma CRO and CMO expectations **(Self-study)**	04
1.4	**Cost of Quality:** Cost of quality, Categories of cost of Quality, Models of cost of quality, optimising costs, Preventing cost of quality	03
Unit 2	**Pharmaceutical Quality Management**	**11**
2.1	• Basics of Quality Management • 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	06
2.2	• OSHA guidelines, CFR-21 part 11 • WHO-GMP requirements, NABL certification and accreditation	04
2.3	Total Quality Management (TQM) **{Self-study}**	01

Unit 3	**Six system inspection model and quality system**	**10**
3.1	Quality Management system, Production system, Facility and Equipment system, Laboratory control system, Materials system, Packaging, and labelling system. Concept of self-inspection	03
3.2	Quality systems: Change Management/ Change control	02
3.3	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, Batch Review and Batch Release, area clearance/ Line clearance	04
3.4	Concept of IPQC **(Self-study)**	01
Unit 4	**Drug stability and quality risk management**	**10**
4.1	ICH guidelines for stability testing of drug substances and drug products	03
4.2	Study of ICH Q8, Quality by Design and Process development report	03
4.3	Quality risk management: Introduction, risk assessment, risk control, risk review, risk management tools, HACCP, risk ranking and filtering according to ICH Q9 guidelines	04
Unit 5	**Statistical Process Control**	**08**
5.1	Definition and Importance of SPC, Quality measurement in manufacturing	02
5.2	Statistical control charts - concepts and general aspects, Advantages of statistical control	03
5.3	Process capability, Estimating Inherent or potential capability from a control chart analysis, Measuring process control and quality improvement, Pursuit of decreased process variability	03
Unit 6	**Regulatory Compliance through Quality Management and development of Quality Culture**	**03**
	Benchmarking: Definition of benchmarking, Reasons for benchmarking, Types of Benchmarking, Benchmarking process, Advantages of benchmarking, Limitations of benchmarking	03
Unit 7	**Jurisdiction**	**03**
	Basics of Environmental Protection Act 1986 and Factories Act 1948	03
Unit 8	**Site and Plant Security**	**04**
	Security personnel, Entry procedures to site & plant, Internal security, Vehicle parking, Canteen & cooking, Garden & horticulture	04
	Total Hours	**60**

Reference material:

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. Fairfield- Sonn, 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
8. Root Cause Analysis, The Core of Problem Solving and Corrective Action, Duke Okes, 2009, ASQ Publications.
9. A Guide to Total Quality Management by Kaushik Maitra and Sedhan K. Ghosh
10. Good Manufacturing Practices for Pharmaceuticals-A Plan for Total Quality Control by Sidney H. Willing & James R Stoker. (Drugs & Pharm. Sciences) Vol. 78; Marcel Dekker Inc.
11. Regulatory guidelines related to GMP by
    a. 21 Code of Federal Regulation, Parts 210, 211&58 (USFDA guidelines)
    b. EU, MHRA, UK Guidelines on GMP
    c. Schedule M of Drug & Cosmetics Act.
12. Quality Planning & Analysis by J. M. Juran and F. M. Gryna, Tata Mcgraw Hill, India.
13. Quality Assurance Guide by Organization of Pharmaceutical Producers of India.
14. Environmental protection act 1986 and Factories act 1948

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Course Code	Course Name	Credits
MQA103T	**Quality Control and Quality Assurance**	**4**

- **Prerequisites:**
  - Prior knowledge of pharmaceutical manufacturing and pharmaceutical jurisprudence

- **Course Outcomes: After completion of this course students should be able to:**
  1. Understand the roles and responsibilities of Quality Control and Quality Assurance departments in pharmaceutical industry
  2. Understand the significance of cGMP and ICH Guidelines in pharmaceutical industry
  3. Describe the analysis of raw materials, packaging materials, in process quality control (IPQC) and finished products for different pharmaceutical dosage forms
  4. Apply knowledge of regulatory requirements for preparing, maintaining, retaining and retrieving the data and documents in pharmaceutical industry
  5. Understand the scope and importance of Intellectual Property Rights (IPR) and quality certifications applicable to pharmaceutical industries

Sr. No.	Content	Hours
Unit 1	**Introduction**	**11**
1.1	Concept and evolution and scopes of Quality Control and Quality Assurance, Good Laboratory Practice, GMP Overview of ICH **(Self-study)**	03
1.2	Guidelines - QSEM, with special emphasis on Q- series guidelines	03
1.3	Good Laboratory Practices: Scope of GLP, Definitions Quality assurance unit **(Self-study)**	02
1.4	Protocol for conduct of non-clinical testing, control on animal house, report preparation and documentation. CPCSEA guidelines	03
Unit 2	**Good Manufacturing Practises**	**12**
2	cGMP guidelines according to schedule M, USFDA (inclusive of CDER and CBER) 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 Practice	12
Unit 3	**Raw material analysis, In process quality control and Finished product testing**	**11**
3.1	• Analysis of raw materials, finished products, packaging materials • In process quality control (IPQC) **(Self-study)** • Developing specification (ICH Q6 and Q3), purchase specifications and maintenance of stores for raw materials	05
3.2	• In process quality control and finished products quality control for following dosage forms in Pharma industry according to Indian, US and British pharmacopeia: tablets, capsules, ointments, suppositories, creams, parenteral, ophthalmic and surgical products	04

	• How to refer pharmacopeia) **(Self-study)**	
3.3	Field based exposure to QC department of pharmaceutical industry	02
Unit 4	**Documentation in Pharmaceutical Industry**	**Hours: 16**
4.1	Documentation in pharmaceutical industry: Three tier documentation, Policy, Procedures and Work instructions, and records (Formats), Basic principles- How to maintain, retention and retrieval etc. Standard operating procedures (How to write), Master Batch Record, Batch Manufacturing Record, Quality audit plan and reports. Specification and test procedures, Protocols and reports. Distribution records. Electronic data handling.	04
4.2	Concepts of controlled and uncontrolled documents. Submission documents for regulators DMFs, as Common Technical Document and Electronic Common Technical Documentation (CTD, eCTD).	04
4.3	Concept of regulated and non-regulated markets	02
4.4	Data integrity and compliance with CGMP (USFDA/EMA)	04
4.5	Field based exposure to QA department of pharmaceutical industry	02
5	**Case studies**	**Hours: 10**
	Simulation of common QC & QA problems encountered in the pharmaceutical industry	
	Total Hours	**60**

Reference material:

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 compendium of Guidelines 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

Course Code	Course Name	Credits
MQA104T	**Product Development and Technology Transfer**	**4**

- **Prerequisites:**
  - Have foundational knowledge in pharmaceutical development and manufacturing

- **Course Outcomes: After completion of this course students should be able to:**

1. Understand the new product development process, pilot plant scale up and packaging requirements
2. Understand the necessary information to transfer technology from R&D to actual manufacturing by sorting out various information obtained during R&D
3. Understand the requirements in the manufacturing settings and regulatory activities
4. Correlate the theoretical knowledge with professional and practical need of pharmaceutical industry

Sr. No.	Content	Hours
Unit 1	**Principle of drug discovery and development**	**09**
1.1	• 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 – CDSCO, USFDA & EU	08
1.2	Role of Development QA in R&D/Clinical studies	01
Unit 2	**Preformulation studies**	**08**
2.1	Introduction/concept, organoleptic properties, purity, impurity profiles, particle size, shape and surface area.	02
2.2	Solubility, Methods to improve solubility of Drugs: Surfactants & its importance, co-solvency	02
2.3	Techniques for the study of Crystal properties and polymorphism	02
2.4	Pre-formulation protocol, Stability testing during product development	02
Unit 3	**Pilot Plant Scale up**	**09**
3.1	Concept, Significance, design, layout of pilot plant scale up study, operations, large scale manufacturing techniques (formula, equipment, process, stability and quality control) of solids, liquids, semisolid and parenteral dosage forms	06
3.2	New era of drug products: opportunities and challenges (including biologicals; RNA based products and cell/gene products)	03
Unit 4	**Pharmaceutical packaging**	**08**
4.1	Pharmaceutical dosage form and their packaging requirements. Pharmaceutical packaging materials	03
4.2	Medical device packaging, Enteral Packaging, Aseptic packaging systems, Container closure systems, Issues facing modern drug packaging, Selection, and evaluation of pharmaceutical	03

	packaging materials	
4.3	Quality control test: Containers, closures, and secondary packing materials	02
Unit 5	**Technology Transfer**	**09**
5.1	Development of technology by R & D, Technology transfer from R & D to production, Optimization and Production, Qualitative and quantitative technology models	05
5.2	Documentation in technology transfer: Development report, technology transfer plan and Exhibit	04
Unit 6	**Manufacturing operations and controls**	**12**
6.1	Sanitation of manufacturing premises, mix-ups and cross contamination, processing of intermediates and bulk products, packaging operations, IPQC, release of finished product, process deviations, charge-in of components, 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	09
6.2	Introduction, scope, and importance of intellectual property rights. Concept of trade mark, copyright, and patents	02
6.3	Product recalls and type of recalls – CDSCO/US	01
Unit 7	**Quality by design in product development**	**05**
	Quality by design tools and methodologies including risk assessment, control strategy, Case studies	
	Total Hours	**60**

Reference material:

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. eon 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. Patrevale. 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.
10. Pharmaceutical Packaging technology by D.A. Dean. E.R. Evans, I.H. Hall. 1st Edition (Reprint 2006). Taylor and Francis. London and New York.

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Course Code	Course Name	Credits
MQA105P	**Pharmaceutical Quality Assurance Practical-I**	**4**

- **Prerequisites:**
  - Basics of principle of instrumental methods of analysis
  - Stability studies
  - In process quality control tests for different types of dosage forms

Course Outcomes: After completion of this course students should be able to:

1. Apply the principles of uv-vis spectroscopy, fluorescence spectroscopy and flame photometry to perform, analyse, determine, and report the content of drugs in formulation/sample solution
2. Relate the concept of in process quality control & stability studies to design and develop the protocol for testing of pharmaceuticals
3. Plan, execute and conclude the experiment using qualitative or quantitative techniques

Exp. No.	Title of the Experiment
1	Analysis of Pharmacopeial 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	Self- study: Case studies on • Total Quality Management • Six Sigma • Change Management/ Change control. Deviations, • Out of Specifications (OOS) • Out of Trend (OOT) • Root cause analysis • 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, parenteral 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 preformulation study for tablets, parenteral (2experiment).
14	To study the effect of pH on the solubility of drugs, (1experiment)
15	Quality control tests for Primary and secondary packaging materials
16	Accelerated stability studies (1experiment)
17	Improved solubility of drugs using surfactant systems(1experiment)
18	Improved solubility of drugs using co-solvency method(1experiment)

19	Determination of pk_a and Log P of drugs.
20.	Ability enhancement: Construction of quality control charts using MS Excel

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Course code	Course Name	Credits
IKS_MP_101	Yoga: A key to healthy life	-

- **Prerequisites**
  - Basic knowledge of Yoga and human health
- **Course Outcomes: After the completion of course, learner will be able to:**
  5. Improvement in mental and physical health
  6. Provide improved attention in studies and better interpersonal relationships

Sr. No.	Content	Hours
1	**UNIT 1: INTRODUCTION**	**10**
1.1	Yoga-Meaning and definition, yoga misconceptions and comparison between yoga and exercise, Introduction to Ashtanga yoga (eight limbs of yoga), Pranav sadhana, Mudra and Bandh	6
1.2	Yoga therapy	2
1.3	Yoga and diet	2
2	**UNIT 2: AASANA (Introduction, contraindications, benefits and demonstration of following asanas**	**12**
2.1	**Sitting postures**: Swastikasana, padmasana, Marjarasana, Bhadrasana, Vajrasana, Ustrasana, Sasakasana, Vakrasana, Paschimatanasana, Parvatasana	3
2.2	**Standing postures**: Tadasana, Vrksasana, Pada-hastasana, Ardha chakrasana, Trikonasana	3
2.3	**SUPINE POSTURES**: Setubandhasana, Uttana padasana, Ardha halasana, Pavana muktasana, Savasana, Viparit karni, tadagi mudra	3
2.4	**Prone postures**: Makarasana, Bhujangasana, Salabhasana, Naukasana, Matsyasana	2
2.5	Suryanamaskar	1
3	**UNIT 3: PRANAYAMA (Introduction, contraindications, benefits and demonstration of following pranayama)**	**02**
3.1	Kapalabhati, Anulom vilom, Sitali, Sitakari, Bhramari, Ujiayi, Bhastrika, Uddiyana bandha	2
4	**UNIT 4: STRESS MANAGEMENT**	**06**
4.1	Meditation, Yog nidra, Shavasana, Mindfulness, Prayers	4
4.2	Yogic lifestyle	2
	TOTAL	**30**

Recommended Books (Latest Editions)

1. Websites: https://ayush.gov.in/ Ministry of Ayurveda, Yoga & Naturopathy, Unani, Siddha and Homoeopathy (AYUSH)

Books: Know yoga Live Yoga, By ShriKrishna Mhaskar

M. Pharm
Quality Assurance
Semester 2

Course Code	Course Name	Credits
MQA201T	Hazards And Safety Management	4

- **Prerequisites:**
  - Knowledge of Environmental Sciences
  - Knowledge of Air Handling Units used in Pharma industry.
  - Knowledge of the Types of reactions carried out in Chemical/API industries

- **Course Outcomes: After completion of this course students should be able to:**
  1. Recall the environmental problems and develop an attitude of concern for the industry environment
  2. Make use of the knowledge gained to ensure safety standards in pharmaceutical industry
  3. Analyse and simplify the mechanism and management in different kinds of hazard management system
  4. Propose the method of Hazard assessment, procedure, and methodology for safe industrial atmosphere

Sr. No.	Content	Hours
Unit 1	**Multidisciplinary nature of environmental studies**	**12**
1.1	• 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. (biotic, abiotic) • Environmental hazards: Hazards based on Air, Water, Soil and Radioisotopes.	06
1.2	• Sustainability in the pharmaceutical industry – Initiatives like energy efficiency, sustainable manufacturing, water conservation, waste management, sustainable packaging • UN-PRME and SDGs – What are SDGs, How and why is it important for industries to set up sustainable goals in their business. • Government of India and sustainability - Ministry of Environment, Forest and Climate Change and other such initiatives • Case studies on global zero carbon emissions and renewable energy initiatives	06
Unit 2	**Air based hazards**	**12**
2.1	• Sources, Types of Hazards with examples • Air Quality Index (AQI) – Definition, importance, and significance • Asphyxiant gases – examples and sources • Air circulation maintenance industry for sterile area and non-sterile area	06

	• Clean Room Concept • Clean Room Classification with examples in pharmaceutical industry • Air Handling Unit for industry – HVAC – Components, design, significance	
2.2	• Preliminary Hazard Analysis (PHA) – Steps involved, components of PHA • Pressure cascade and air flow maintenance in pharmaceutical industry	06
Unit 3	**Chemical based hazards**	**12**
3.1	• 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	07
3.2	Regulations for chemical hazard	02
3.3	Management of over-Exposure to chemicals and TLV concept along with STEL, TWA	03
Unit 4	**Fire and Explosion**	**12**
4.1	• Introduction, Industrial processes, and hazards potential - mechanical, electrical, thermal and process hazards. • Safety and hazards regulations • Fire Triangle and Types of Fire	03
4.2	Fire protection system: Fire prevention, types of fire extinguishers and critical Hazard management system mechanical and chemical explosion, multiphase reactions, transport effects and global rates, Fire & Explosion hazard management (FEHM)	03
4.3	Preventive and protective management from fires and explosion electricity passivation, ventilation, and sprinkling, proofing, relief systems -relief valves, flares, scrubbers	04
4.4	Pharmaceutical Dust explosion	02
Unit 5	**Hazard and Risk Management**	**12**
5.1	• 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 (FMEA, FTA, HACCP)	05
5.2	Factory act and rules (CHAPTER IVA), fundamentals of accident prevention, elements of safety programme and safety management	01
5.3	Physicochemical measurements of effluents, BOD, COD, Determination of some contaminants, Effluent treatment procedure, Role of emergency services	03
5.4	Employee training in workplace – Handling of fire extinguishers, cardio-pulmonary resuscitation, knowledge of local emergency services, first aid training, emergency exit plan	03
	Total Hours	**60**

Reference material:

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, Map in Publishing Pvt. Ltd., Ahmedabad – 380013, India
4. Hazardous Chemicals: Safety Management and Global Regulations, T.S.S. Dikshith, CRC press

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Course Code	Course Name	Credits
MQA202T	**Audits and Regulatory Compliance**	**4**

- **Prerequisites:**
  - Understanding of Regulatory Frameworks
  - Basic Knowledge of Quality Management Systems

- **Course Outcomes: After completion of this course students should be able to:**

1. Understand the concept of Quality Management System, Quality audits& its role, importance in pharmaceutical manufacturing environment.
2. Apply the conceptual knowledge gained to design & conducting Audits of various areas in the pharmaceutical manufacturing, packaging, storage, distribution, Quality control and ancillary areas (utilities) to assess compliance to the applicable Regulatory requirements.
3. Create Audit check lists to conduct audits in the above specified areas in pharmaceutical industries including vendors and suppliers of API Raw & packaging materials.
4. Evaluate Audit observations into categories such as Critical, Major & Minor based on the severity of non-compliance to cGMP aspects and Regulatory requirements. Suggest CAPAs for compliance to CGMP aspects & Regulatory requirements.

Sr. No.	Content	Hours
Unit 1	**Introduction**	**09**
1.1	Objectives, Management of audit, Responsibilities, Planning process, administration, Classifications of deficiencies	08
1.2	Information gathering **(Self-study)**	01
Unit 2	**Role of quality systems and audits in pharmaceutical manufacturing environment**	**12**
2.1	cGMP Regulations, Quality assurance functions (Self-study)	02
2.2	Quality systems approach, Management responsibilities, Resource, Manufacturing operations, Evaluation activities, Transitioning to quality system approach, Audit checklist for drug industries	10
Unit 3	**Auditing of vendors and production department**	**12**
3.1	Bulk Pharmaceutical Chemicals and packaging material Vendor audit	06
3.2	Warehouse and weighing, Dry Production: Granulation, tableting, coating, capsules, sterile production and packaging	06
Unit 4	**Auditing of Microbiological laboratory**	**08**
4.1	Auditing the manufacturing process, Product and process information	06
4.2	General areas of interest in the building raw materials, Water, Packaging materials	06
Unit 5	**Auditing of Quality Assurance and engineering department**	**10**
5.1	Quality Assurance Maintenance	06
5.2	Critical systems: HVAC, Water, Water for Injection systems, ETP	04
Unit 6	**Other audits & Auditing agencies**	**05**
6.1	Auditing of Medical devices	02

6.2	Audits by notified bodies: EU, FDA, CDSCO	02
6.3	Introduction to ISO 13485 and ISO 14644	01
Unit 7	**Audit Case studies**	**04**
	Case studies with emphasis on remarks given for passed and failed audits	
	Total Hours	**60**

Reference material:

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).
5. 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.
6. Handbook of microbiological Quality control. Rosamund M. Baird, Norman A. Hodges, Stephen
7. FDA regulatory affairs: a guide for prescription drugs, medical devices, and biologics", edited By Douglas J. Pisano, David Mantus
8. Clinical Trials and Human Research: A Practical Guide to Regulatory" Compliance By Fay A.Rozovsky and Rodney K. Adams.
9. International medical device regulators forum. Guidelines for Regulatory Auditing of Quality Systems of Medical Device Manufacturers – Part 1: General Requirements.

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Course Code	Course Name	Credits
MQA203T	Pharmaceutical Validation	4

- **Prerequisites:**
  - Basic understanding of validation and how it can be applied to industry and thus improve the quality of the products

- **Course Outcomes: After completion of this course students should be able to:**
  1. Understand the concept of validation, qualification, and calibration
  2. Recall and describe procedure for qualification of instruments and equipment
  3. Summarize and illustrate the concept of process validation, cleaning validation of equipments employed in manufacture of pharmaceuticals and analytical method validation
  4. Correlate the knowledge of IPR with respect to pharmaceutical products

Sr. No.	Content	Hours
Unit 1	**Introduction to validation, calibration, and qualification**	**10**
1.1	Introduction to calibration and validation: Definition of Calibration, Qualification and Validation	02
1.2	Scope, frequency, and importance. Difference between calibration and validation. Calibration of weights and measures. Advantages of Validation, scope of Validation, Organization for Validation	03
1.3	Validation Master plan, Types of Validation, Streamlining of qualification & Validation process and Validation Master Plan	02
1.4	Test (FAT)/Site Acceptance Test (SAT), Installation qualification, Operational qualification, Performance qualification, Re-Qualification (Maintaining status, Calibration Preventive Maintenance, Change management)	03
Unit 2	**Qualification of equipment and instruments**	**10**
2.1	Qualification of manufacturing equipment: Dry Powder Mixers, Fluid Bed and Tray dryers, Tablet Compression (Machine), Dry heat sterilization/Tunnels, Autoclaves, Membrane filtration, Capsule filling machine	05
2.2	Qualification of analytical instruments: UV-Visible spectrophotometer, FTIR, DSC, GC, HPLC, HPTLC, LC-MS	05
Unit 3	**Qualification of laboratory equipment**	**10**
3.1	Hardness tester, Friability test apparatus, tap density tester, Disintegration tester, Dissolution test Apparatus	05
3.2	Validation of Utility systems: Pharmaceutical water system & pure steam, HVAC system, Compressed air and nitrogen	05
Unit 4	**Process validation**	**10**
4.1	Concept, Process, and documentation of Process Validation. Prospective, Concurrent & Retrospective Validation, Re validation criteria, Process Validation of various formulations (Coated tablets, Capsules, Ointment/Creams, Liquid Orals and aerosols.), Aseptic filling: Media fill	05

	validation, USFDA guidelines on Process Validation-A life cycle approach	
4.2	Analytical method validation: General principles, Validation of analytical method as per ICH guidelines and USP	05
Unit 5	**Cleaning validation**	**10**
5.1	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	06
5.2	Computerized system validation: Electronic records and digital signature - 21 CFR Part 11 and GAMP	04
Unit 6	**General principles of IPR**	**10**
6.1	Concepts of Intellectual Property (IP), Intellectual Property Protection (IPP), Intellectual Property Rights (IPR); Economic importance, mechanism for protection of Intellectual Property – patents, Copyright, Trademark; Factors affecting choice of IP protection; Penalties for violation; Role of IP in pharmaceutical industry; Global ramification and financial implications. Filing a patent application; patent application forms and guidelines. Types patent applications provisional and non-provisional, PCT and convention patent applications; International patenting requirement procedures and costs; Rights and responsibilities of a patentee; Practical aspects regarding maintaining of a Patent file; Patent infringement meaning and scope	07
6.2	Significance of transfer technology (TOT), IP and ethics-positive and negative aspects of IPP; Societal responsibility, avoiding unethical practices	03
	Total Hours	**60**

Reference material:

1. Sinko PJ. Martin's physical pharmacy and pharmaceutical sciences, 5th ed., B.I. Publications Pvt. Ltd, Noida, 2006.
2. Lieberman HA, Lachman L, Schwartz JB. Pharmaceutical dosage forms: tablets Vol. I-III, 2nd ed., CBS Publishers & distributors, New Delhi, 2005.
3. Banker GS, Rhodes CT. Modern Pharmaceutics, 4th ed., Marcel Dekker Inc, New York, 2005.
4. Sidney H Shalling, Murray M, Tuckerman. Shalliams Hitchings IV, Good manufacturing of pharmaceuticals (A Plan for total quality control) 3rd Edition. Bhalani publishing house Mumbai.
5. Indian Pharmacopoeia. Controller of Publication. Delhi, 1996.
6. British Pharmacopoeia. British Pharmacopoeia Commission Office, London, 2008.
7. United States Pharmacopoeia. United States Pharmacopeial Convention, Inc, USA, 2003.
8. Dean D A, Evans E R and Hall I H. Pharmaceutical Packaging Technology. London, Taylor & Francis, 1st Edition. UK.
9. Edward J Bauer. Pharmaceutical Packaging Handbook. 2009. Informa Health care USA Inc. New York.
10. Shaybe Cox Gad. Pharmaceutical Manufacturing Handbook. John Shalley and Sons, New Jersey, 2008.

11. Michael J. Akers, Sterile Drug Products Formulation, Packaging, Manufacturing, and Quality, Informa Healthcare, 2010.
12. Pharmaceutical Product Development: Insights Into Pharmaceutical Processes, Management and Regulatory Affairs, by Vandana B. Patravale, John I. Disouza, Maharukh Rustomjee,
13. B. T. Loftus & R. A. Nash, "Pharmaceutical Process Validation", Drugs and Pharm Sci. Series, Vol. 129, 3rd Ed., Marcel Dekker Inc., N.Y.
14. The Theory & Practice of Industrial Pharmacy, 3rd edition, Leon Lachman, Herbert A. Lieberman, Joseph. L. Karig, Varghese Publishing House, Bombay.
15. Validation Master plan by Terveeks or Deeks, Davis Harwood International publishing.
16. Validation of Aseptic Pharmaceutical Processes, 2nd Edition, by Carleton & Agalloco Marcel Dekker
17. Michael Levin, Pharmaceutical Process Scale-Up", Drugs and Pharm. Sci. Series, Vol. 157,2nd Ed., Marcel Dekker Inc., N.Y
18. Validation Standard Operating Procedures: A Step by Step Guide for Achieving Compliance in the Pharmaceutical, Medical Device, and Biotech Industries, Syed Imtiaz Haider
19. Pharmaceutical Equipment Validation: The Ultimate Qualification Handbook, Phillip A. Cloud, Interpharm Press
20. Validation of Pharmaceutical Processes: Sterile Products, Frederick J. Carlton (Ed.) and James Agalloco (Ed.), Marcel Dekker
21. Analytical Method validation and Instrument Performance Verification by Churg Chan, Heiman Lam, Y.C. Lee, Yue. Zhang, Wiley Interscience
22. Huber L. Validation and Qualification in Analytical Laboratories. Informa Healthcare
23. Wingate G. Validating Corporate Computer Systems: Good IT Practice for Pharmaceutical Manufacturers. Interpharm Press
24. LeBlanc DA. Validated Cleaning Technologies for Pharmaceutical Manufacturing. Interpharm Press

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Course Code	Course Name	Credits
MQA204T	Pharmaceutical Manufacturing Technology	4

- **Prerequisites:**
  - Basic understanding of pharmaceutical dosage forms and manufacturing process

- **Course Outcomes: After completion of this course students should be able to:**
  1. Understanding the legal requirements, licenses, plant layout, production planning for the pharmaceutical industry, process automation with respect to different dosage forms
  2. Explain the concept of quality by design (QbD) and process analytical technology (PAT) and understand the different terminologies and aspects involved in QbD and PAT
  3. Analyse the aseptic and non-sterile process technology including manufacturing requirements, new technologies and equipment required at each stage of manufacturing
  4. Evaluate packaging technology required for different types of dosage forms, evaluation of product package compatibility and stability aspects of packaging material

Sr. No.	Content	Hours
Unit 1	**Pharmaceutical Industry developments**	**12**
1.1	Legal requirements and Licenses for API and formulation industry	02
1.2	Plant location: Factors influencing Plant layout: Factors influencing, Special provisions, Storage space requirements, sterile and aseptic area layout	06
1.3	Production planning: General principles, production systems, calculation of standard cost, process planning, routing, loading, scheduling, dispatching of records, production control	04
Unit 2	**Aseptic process technology**	**12**
2.1	Manufacturing, manufacturing flowcharts, in process-quality control tests for following sterile dosage forms: Ointment, Suspension and Emulsion, Dry powder, Solution (Small Volume & large Volume)	03
2.2	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	03
2.3	Process Automation in Pharmaceutical Industry: With specific reference to manufacturing of sterile semisolids, Small Volume Parenterals & Large Volume Parenterals Monitoring of Parenteral manufacturing facility, Cleaning in Place (CIP), Sterilization in Place (SIP)	03
2.4	Prefilled Syringe, Powdered Jet, Needle Free Injections, and Form Fill Seal Technology (FFS)	02
2.5	Lyophilization technology: Principles, process, equipment	01
Unit 3	**Non sterile manufacturing process technology**	**12**

3.1	Manufacturing, manufacturing flowcharts, in process-quality control tests for following non-sterile solid dosage forms: Tablets (compressed & coated), Capsules (Hard gelatin capsule filling machines, Soft gelatin capsule manufacturing; Rotary die process)	04
3.2	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 and trouble shooting.	04
3.3	Coating technology: Process, equipment and process parameters, particle coating, fluidized bed coating, application techniques. Problems encountered and trouble shooting.	03
3.4	Advanced non-sterile solid product manufacturing technology: Process Automation in Pharmaceutical Industry with specific reference to manufacturing of tablets and coated products	01
Unit 4	**Containers and Closures for Pharmaceuticals**	**12**
4.1	• Types, performance, assuring quality of glass; Types of plastics used, Drug plastic interactions, biological tests, modification of plastics by drugs • Pharmacopoeial tests and specifications closure systems, • Extractables, and leachables	04
4.2	• 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. • Child resistant and Tamper-evident packaging	04
4.3	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.	04
Unit 5	**Quality by design (QbD) and process analytical technology (PAT)**	**12**
5.1	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.	06
5.2	Quality by Design, Formulations by Design, QbD for drug products, QbD for Drug Substances, QbD for Excipients, Analytical QbD.	04
5.3	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.	02
	Total Hours	**60**

Reference material:

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 Shalling, Murray M, Tuckerman. Shalliams 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 Pharmacopeial 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 Shalley and Sons, New Jersey, 2008.
12. Michael J. Akers, Sterile Drug Products Formulation, Packaging, Manufacturing, and Quality, Informa Healthcare, 2010.
13. Pharmaceutical Product Development: Insights Into Pharmaceutical Processes, Management and Regulatory Affairs, by Vandana B. Patravale, John I. Disouza, Maharukh Rustomjee, CRC press

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Course Code	Course Name	Credits
MQA205T	Pharmaceutical Quality Assurance Practical-II	4

- **Prerequisites:**
  - Quality management system
  - Quality Assurance system

- **Course Outcomes: After completion of this course students should be able to:**
  1. Understand the significance of control of hazardous substances and perform analysis to determine and report the content of hazardous substances in air/environment
  2. Relate the concept of quality assurance to design and develop the protocol f& checklists for testing of pharmaceuticals
  3. Plan, execute and conclude the experiment using qualitative or quantitative techniques

Exp. No.	Title of the Experiment
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 • Autoclave • Hot air oven • Powder Mixer (Dry) • 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: Role Play
14	Check list for tableting production: Role Play
15	Check list for sterile production area: Role Play
16	Check list for Water for injection: Role Play
17	Design of plant layout: Sterile and non-sterile
18	Case study on application of QbD: Hands on experience on software
19	Case study on application of PAT:
20.	Preparation of CTD for ‘X’ drug/raw material

Course code	Course Name	Credits
AEC_MX_102	Multidisciplinary Subject	**-**

Students will opt for one of the core subject of other department PG course of SEM II running by the college as an audit course.

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Semester 3

Course code	Course Name	Credits
MRM 301 T	Research Methodology and Biostatistics	04

- **Prerequisites**
  - Importance of research
  - Basic terminologies like hypothesis, aim, objectives, rationale in research
  - Basic arithmetic operations
- **Course Outcomes: After the completion of course, learner will be able to:**
  7. Recall and explain terms associated with research, research designs, methodology, biostatistics.
  8. Decide sample size, select sampling method, choose study design and data collection and data analysis methods.
  9. Perform simple calculations in descriptive and inferential statistics.
  10. Frame research questions, prepare a research protocol for arriving at answers to the research question
  11. Prepare and present an animal experimentation protocol for IAEC approval
  12. Understand, explain and discuss various facets of medical research.

Sr. No.	Content	Hours
1	**UNIT 1: General Research Methodology**	**08**
1.1	Research objectives, requirements, practical difficulties, review of literature, Common guidelines in drafting research articles and presentation.	2
1.2	Study design (Research design), types of studies	3
1.3	Strategies to eliminate errors/bias, controls, randomization, crossover design, placebo, blinding techniques	3
2	**UNIT 2: Biostatistics**	**12**
2.1	Definition, application, sample size, importance of sample size, factors influencing sample size, dropouts	2
2.2	Statistical tests of significance, 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), null hypothesis, P values, degree of freedom, interpretation of P values	10
3	**UNIT 3: Medical Research**	**12**
3.1	History, values in medical ethics, autonomy, beneficence, non-maleficence, double effect, conflicts between autonomy and beneficence/non-maleficence, euthanasia, informed consent	6
3.2	confidentiality, criticisms of orthodox medical ethics, the 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, and fatality.	6
4	**UNIT 4:**	**07**
4.1	**CCSEA guidelines for laboratory animal facility :** Goals, veterinary care, quarantine, surveillance, diagnosis, treatment and control of disease,	7

	personal hygiene, location of animal facilities to laboratories, anesthesia, euthanasia, physical facilities, environment, animal husbandry, record keeping, SOPs, personnel and training, and transport of lab animals. Protocol writing exercise Field-based exposure to Animal House	
5	**UNIT 5**	**06**
5.1	**Declaration of Helsinki:** History, introduction, basic principles for all medical research, and additional principles for medical research combined with medical care.	6
	TOTAL	**45**

Recommended Books (Latest Editions)

1. Fundamentals of Research Methodology and Statistics by Yogesh Kumar Singh
2. Practical Business Statistics by Andrew F Siegel
3. Research Methodology a step-by-step guide by Ranjit Kumar
4. Research Design by John M Creswell and J David Creswell
5. Research Methodology by CR Kothari
6. National Ethical Guidelines for Biomedical and Health Research Involving Human Participants
7. ICH GCP E6 (R2) Guidelines
8. CPCSEA Guidelines for Laboratory Animal Facility

Websites:

1. **https://www.youtube.com/watch?v=1Q6_LRZwZrc**
2. **https://www.youtube.com/watch?v=XISnc9PvxiE**

Articles:

1. Ganesh N. Dakhale, Sachin K. Hiware, Abhijit T. Shinde, and Mohini S. Mahatme, Basic biostatistics for post-graduate students,, Indian J Pharmacol. 2012 Jul-Aug; 44(4): 435–442.
2. Nanivadekar AS, Kannappan AR. Statistics for clinicians. Nominal data (I) *J Assoc Physicians India.* 1990;38:931–5.

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Course code	Course Name	Credits
AEC_MP_301	Scientific Writing	-

- **Prerequisites**
  - Proficiency in basic writing skills, including grammar, punctuation, and sentence structure.
- **Course Outcomes: After the completion of course, learner will be able to:**
  1. Develop the ability to effectively communicate scientific research related findings in a precise and systematic manner.
  2. Read relevant primary and secondary literature carefully and offer constructive criticism.
  3. Understand the iterative process of improving scientific writing skills with the help of the feedback received.
  4. Use the knowledge gained to also effectively write other academic documents like grant proposals and thesis.

Sr. No.	Content	Hours
1	**UNIT 1: Know the language (Basic English course)**	**07**
1.1	English in academic writing: Grammar and Sentence Structure, Vocabulary building, Paragraph Development	3
1.2	Argument matrix How to set the background of your article	1
1.3	Technical Writing Style, Common Writing Errors, Reading Comprehension	3
2	**UNIT 2: Understanding the Structure of Scientific Papers**	**09**
2.1	Title and Abstract, Introduction, How to set the background of your article and write rationale and objective(s), Methods, Results and discussion	4
2.2	References: Properly citing sources and following citation styles (e.g., APA, MLA) in the reference list. Referencing tools including AI tools	2
2.3	Designing effective tables, figures, graphical abstracts, graphs	3
3	**UNIT 3: Publication ethics and Plagiarism**	**02**
3.1	Introduction; Tools for the detection of plagiarism; Avoiding plagiarism	2
4	**UNIT 4: Scientific Publication Process**	**06**
4.1	Choosing the Right Journal, Authorship and Collaboration, Revision and Resubmission, Peer Review Process and Responding to peer review	3
4.2	Promoting Research Visibility: Techniques for increasing the visibility and impact of published research, including social media promotion, academic networking.	3
5	**UNIT 5: Drafting of other scientific documents**	**02**
5.1	Writing research **grant** proposal, Book review, thesis writing, career in scientific Writing	2
6	**UNIT 6: Experiential learning**	**04**
6.1	Case studies and presentations	4
	TOTAL	**30**

Recommended Books (Latest Editions)

1. Trisha Greenhalgh. How to read a paper. https://www.bmj.com/about-bmj/resources-readers/publications/how-read-paper
2. Guidance on Scientific Writing- Equator Network. https://www.equator-network.org/library/guidance-on-scientific-writing/
3. Kotz D, Cals J. Scientific writing and publishing in medicine and health sciences: A quick guide in English and German. Berlin, Boston: De Gruyter; 2021.

Websites:

1. https://www.elsevier.com/en-in/connect/11-steps-to-structuring-a-science-paper-editors-will-take-seriously
2. https://researcheracademy.elsevier.com/

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Course code	Course Name	Credits
VSC_MP_301	Practical Insights of HPLC Method Development	-

- **Prerequisites**
  - Basic understanding of chromatography principles
  - Familiarity with laboratory safety practices
  - Prior experience with HPLC instrumentation is beneficial but not mandatory
- **Course Outcomes: After the completion of course, learner will be able to:**
  1. Apply principles of HPLC method development to design and optimize chromatographic parameters, such as column temperature, flow rate, and gradient elution, for efficient separation of complex mixtures
  2. demonstrate the ability to analyze chromatographic data and interpret chromatograms to troubleshoot common issues encountered during HPLC method development, ensuring the reliability and robustness of analytical results
  3. Evaluate the performance of developed HPLC methods using method validation parameters, such as specificity, linearity, accuracy, precision, and robustness, to ensure the method meets regulatory requirements and analytical objectives.

Sr. No.	Content	Hours
1	**UNIT 1: Introduction to HPLC Method Development**	**06**
1.1	Overview of HPLC instrumentation and principles	2
1.2	Factors influencing HPLC method development: stationary phase selection, mobile phase composition, detection systems	2
1.3	Introduction to method optimization strategies	2
2	**UNIT 2: Stationary phase and Mobile phase selection**	**06**
2.1	Types of HPLC columns and their applications	1
2.2	Factors influencing stationary phase selection: polarity, particle size, surface chemistry	2
2.3	Mobile phase composition: solvent selection, pH considerations	1
2.4	Practical session: Preparation and optimization of mobile phases	2
3	**UNIT 3: Optimization of HPLC Parameters**	**04**
3.1	Column temperature optimization	0.5
3.2	Flow rate optimization	0.5
3.3	Gradient elution techniques	0.5
3.4	Detector wavelength selection and optimization	0.5
3.5	Practical session: Hands-on optimization of HPLC parameters using standard compounds	2
4	**UNIT 4: Troubleshooting and Method Validation**	**06**
4.1	Common issues in HPLC method development and troubleshooting strategies	2
4.2	Method validation parameters: specificity, linearity, accuracy, precision, robustness	2
4.3	Practical session: Method troubleshooting exercises and validation tests	2
5	**UNIT 5: Practical Applications and Case studies**	**08**
5.1	Analysis of real-world samples using developed HPLC methods	2
5.2	Interpretation of chromatograms and troubleshooting of method issues	2
5.3	Discussion of case studies highlighting successful method development strategies	2

5.4	Practical session: Analysis of unknown samples and presentation of results	2
	TOTAL	**30**

Recommended Books (Latest Editions)

1. High Performance Liquid Chromatography: Principles and Methods" by Salvador Sagrado and Marja-Liisa Riekkola
2. HPLC Method Development for Pharmaceuticals by Satinder Ahuja and Michael Dong
3. Practical High-Performance Liquid Chromatography by Veronika R. Meyer
4. HPLC: A Practical Guide by Melanie M. Johns and Joseph J. Pesek High-Performance Liquid Chromatography in Phytochemical Analysis by Monika Waksmundzka-Hajnos, Joseph Sherma, and Teresa Kowalska

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