

Ordinance Governing Master of Pharmacy M. Pharm. Degree Course

Syllabus / Curriculum
2017 - 18



Accredited 'A' Grade by NAAC
Placed in Category 'A' by MHRD(GOI)

KLE UNIVERSITY

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Edition Year : 2017

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VISION

To be an outstanding University of excellence ever in pursuit of newer horizons to build self reliant global citizens through assured quality educational programs.

MISSION

- To promote sustainable development of higher education consistent with statutory and regulatory requirements.
- To plan continuously provide necessary infrastructure, learning resources required for quality education and innovations.
- To stimulate to extend the frontiers of knowledge, through faculty development and continuing education programs.
- To make research a significant activity involving staff, students and society.
- To promote industry / organization, interaction/collaborations with regional/national / international bodies.
- To establish healthy systems for communication among all stakeholders for vision oriented growth.
- To fulfill the national obligation through rural health missions.

OBJECTIVES

The objectives are to realize the following at university and its constituent institutions:

- To implement effectively the programs through creativity and innovation in teaching, learning and evaluation.
- To make existing programs more careers oriented through effective system of review and redesign of curriculum.
- To impart spirit of enquiry and scientific temperament among students through research oriented activities.
- To enhance reading and learning capabilities among faculty and students and inculcate sense of life long learning.
- To promulgate process for effective, continuous, objective oriented student performance evaluation.
- To ordinate periodic performance evaluation of the faculty.
- To incorporate themes to build values. Civic responsibilities & sense of national integrity.
- To ensure that the academic, career and personal counseling are in-built into the system of curriculum delivery.
- To strengthen, develop and implement staff and student welfare programs.
- To adopt and implement principles of participation, transparency and accountability in governance of academic and administrative activities.
- To constantly display sensitivity and respond to changing educational, social, and community demands.
- To promote public-private partnership.

INSIGNIA



The Emblem of the University is a Philosophical statement in Symbolic.

The Emblem...

A close look at the emblem unveils a pillar, a symbol of the “University of Excellence” built on strong values & principles.

The Palm and the Seven Stars...

The Palm is the palm of the teacher- the hand that acts, promises & guides the students to reach for the Seven Stars...

The Seven Stars signify the ‘Saptarishi Dnyanamandal’, the Great Bear-a constellation made of Seven Stars in the sky, each signifying a particular Domain. Our culture says: The true objective of human birth is to master these Knowledge Domains.

The Seven Stars also represent the Saptarishis, the founders of KLE Society whose selfless service and intense desire for “Dnyana Dasoha” laid the foundation for creating the knowledge called KLE Society.

Hence another significance of the raised palm is our tribute to these great Souls for making this University a possibility.

Empowering Professionals...

‘Empowering Professionals’, inscription at the base of the Emblem conveys that our Organization with its strength, maturity and wisdom forever strive to empower the student community to become globally competent professionals. It has been a guiding force for many student generations in the past, and will continue to inspire many forthcoming generations.



KLE UNIVERSITY

(Formerly known as KLE Academy of Higher Education & Research)

[Established under Section 3 of the UGC Act, 1956 vide Government of India Notification No. F. 9-19/2000-U.3(A)]

Accredited 'A' Grade by NAAC

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Ref. No. KLEU/AC/10-11/

3rd April 2010

NOTIFICATION

Sub : **Ordinance governing the syllabus/curriculum for
Master of Pharmacy Course**

Ref : Minutes of the meeting of the Academic Council of the University
held on 13th March 2010.

In exercise of the powers conferred under Rule A-04 (i) of the Memorandum of Association of the University, the Academic Council of the University is pleased to approve the Ordinance governing the syllabus / curriculum for the following **Master of Pharmacy Course** in its meeting held on 13th March 2010.

The Ordinance shall be effective for the students admitted to **Master of Pharmacy Course** under the Faculty of Pharmacy in the constituent college of the University viz. KLEs College of Pharmacy, Belgaum from the academic session 2009-10 onwards.

By Order

REGISTRAR

To

The Dean,
Faculty of Pharmacy
KLEs College of Pharmacy
BELGAUM.

CC to :

1. The Secretary, University Grants Commission, New Delhi.
2. The PA to Hon. Chancellor, KLE University, Belgaum.
3. The Special Officer to Hon. Vice-Chancellor, KLE University, Belgaum.
4. All Officers of the University - Academic Affairs / Examination Branch.

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CHAPTER – I:

REGULATIONS

1. Short Title and Commencement

These regulations shall be called as “The Revised Regulations for the Master of Pharmacy (M. Pharm.) Degree Program - Credit Based Semester System (CBSS) of the Pharmacy Council of India, New Delhi”. They shall come into effect from the Academic Year 2016-17. The regulations framed are subject to modifications from time to time by the authorities of the university.

2. Minimum qualification for admission

A Pass in the following examinations

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

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

3. Duration of the program

1. 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.

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 the month of December/January to May/June in every calendar year.

6. Attendance and progress

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

7. Program/Course credit structure

As per the philosophy of Credit Based Semester System, certain quantum of academic work viz. theory classes, practical classes, seminars, assignments, 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/per activity.

7.1. Credit assignment

7.1.1. Theory and Laboratory courses

Courses are broadly classified as Theory and Practical. Theory courses consist of lecture (L) and 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 by 1.

7.2. Minimum credit requirements

The minimum credit points required for the award of M. Pharm. degree is 95. However based on the credit points earned by the students under the head of co-curricular activities, a student shall earn a maximum of 100 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 14. 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.

S.No.	Specialization	Code
1.	Pharmaceutics	MPH
2.	Pharmaceutical Chemistry	MPC
3.	Pharmaceutical Quality Assurance	MQA
4.	Pharmacy Practice	MPP
5.	Pharmacology	MPL
6.	Pharmacognosy	MPG

The course of study for M.Pharm. specializations shall include Semester wise Theory & Practical as given in Table – 2 to 7. 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 7.

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

Course	Code	Course	Credit Hours	Credit Points	Hrs./Week	Marks
Semester I						
	MPH101T	Modern Pharmaceutical Analytical Techniques	4	4	4	100
	MPH102T	Drug Delivery System	4	4	4	100
	MPH103T	Modern Pharmaceutics	4	4	4	100
	MPH104T	Regulatory Affair	4	4	4	100
	MPH105P	Pharmaceutics Practical I	12	6	12	150
	-	Seminar/Assignment	7	4	7	100
Total			35	26	35	650

Semester II					
MPH201T	Molecular Pharmaceutics (Nano Tech and Targeted DDS)	4	4	4	100
MPH202T	Advanced Biopharmaceutics & Pharmacokinetics	4	4	4	100
MPH203T	Computer Aided Drug Delivery System	4	4	4	100
MPH204T	Cosmetic and Cosmeceuticals	4	4	4	100
MPH205P	Pharmaceutics Practical II	12	6	12	150
-	Seminar/Assignment	7	4	7	100
Total		35	26	35	650

Table – 3: Course of study for M. Pharm.

(Pharmaceutical Chemistry)

Course Code	Course	Credit Hours	Credit Points	Hrs./Wk	Marks
Semester I					
MPC101T	Modern Pharmaceutical Analytical Techniques	4	4	4	100
MPC102T	Advanced Organic Chemistry-I	4	4	4	100
MPC103T	Advanced Medicinal Chemistry	4	4	4	100
MPC104T	Chemistry of Natural Products	4	4	4	100
MPC105P	Pharmaceutical Chemistry Practical I	12	6	12	150
-	Seminar/Assignment	7	4	7	100
Total		35	26	35	650
Semester II					
MPC201T	Advanced Spectral Analysis	4	4	4	100
MPC202T	Advanced Organic Chemistry -II	4	4	4	100
MPC203T	Computer Aided Drug Design	4	4	4	100
MPC204T	Pharmaceutical Process Chemistry	4	4	4	100
MPC205P	Pharmaceutical Chemistry Practical II	12	6	12	150
-	Seminar/Assignment	7	4	7	100
Total		35	26	35	650

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

Course Code	Course	Credit Hours	Credit Points	Hrs./Wk	Marks
Semester I					
MQA101T	Modern Pharmaceutical Analytical Techniques	4	4	4	100
MQA102T	Quality Management System	4	4	4	100
MQA103T	Quality Control and Quality Assurance	4	4	4	100
MQA104T	Product Development and Technology Transfer	4	4	4	100
MQA105P	Pharmaceutical Quality Assurance Practical I	12	6	12	150
-	Seminar/Assignment	7	4	7	100
Total		35	26	35	650
Semester II					
MQA201T	Hazards and Safety Management	4	4	4	100
MQA202T	Pharmaceutical Validation	4	4	4	100
MQA203T	Audits and Regulatory Compliance	4	4	4	100
MQA204T	Pharmaceutical Manufacturing Technology	4	4	4	100
MQA205P	Pharmaceutical Quality Assurance Practical II	12	6	12	150
-	Seminar/Assignment	7	4	7	100
Total		35	26	35	650

Table – 5: Course of study for M. Pharm.
(Pharmacy Practice)

Course Code	Course	Credit Hours	Credit Points	Hrs./Wk	Marks
Semester I					
MPP101T	Clinical Pharmacy Practice	4	4	4	100
MPP102T	Pharmacotherapeutics-I	4	4	4	100
MPP103T	Hospital & Community Pharmacy	4	4	4	100
MPP104T	Clinical Research	4	4	4	100
MPP105P	Pharmacy Practice Practical I	12	6	12	150
-	Seminar/Assignment	7	4	7	100
Total		35	26	35	650
Semester II					
MPP201T	Principles of Quality Use of Medicines	4	4	4	100
MPP202T	Pharmacotherapeutics II	4	4	4	100
MPP203T	Clinical Pharmacokinetics and Therapeutic Drug Monitoring	4	4	4	100
MPP204T	Pharmacoepidemiology & Pharmacoeconomics	4	4	4	100
MPP205P	Pharmacy Practice Practical II	12	6	12	150
-	Seminar/Assignment	7	4	7	100
Total		35	26	35	650

Table – 6: Course of study for M. Pharm. (Pharmacology)

Course Code	Course	Credit Hours	Credit Points	Hrs./Wk	Marks
Semester I					
MPL101T	Modern Pharmaceutical Analytical Techniques	4	4	4	100
MPL102T	Advanced Pharmacology-I	4	4	4	100
MPL103T	Pharmacological and Toxicological Screening Methods-I	4	4	4	100
MPL104T	Cellular and Molecular Pharmacology	4	4	4	100
MPL105P	Pharmacology Practical I	12	6	12	150
-	Seminar/Assignment	7	4	7	100
Total		35	26	35	650
Semester II					
MPL201T	Advanced Pharmacology II	4	4	4	100
MPL202T	Pharmacological and Toxicological Screening Methods-II	4	4	4	100
MPL203T	Principles of Drug Discovery	4	4	4	100
MPL204T	Clinical Research and Pharmacovigilance	4	4	4	100
MPL205P	Pharmacology Practical II	12	6	12	150
-	Seminar/Assignment	7	4	7	100
Total		35	26	35	650

**Table – 7: Course of study for M. Pharm.
(Pharmacognosy)**

Course Code	Course	Credit Hours	Credit Points	Hrs./Wk	Marks
Semester I					
MPG101T	Modern Pharmaceutical Analytical Techniques	4	4	4	100
MPG102T	Advanced Pharmacognosy-1	4	4	4	100
MPG103T	Phytochemistry	4	4	4	100
MPG104T	Industrial Pharmacognostical Technology	4	4	4	100
MPG105P	Pharmacognosy Practical I	12	6	12	150
-	Seminar/Assignment	7	4	7	100
Total		35	26	35	650
Semester II					
MPG201T	Medicinal Plant biotechnology	4	4	4	100
MPG202T	Advanced Pharmacognosy-II	4	4	4	100
MPG203T	Indian system of medicine	4	4	4	100
MPG204T	Herbal cosmetics	4	4	4	100
MPG205P	Pharmacognosy Practical II	12	6	12	150
-	Seminar/Assignment	7	4	7	100
Total		35	26	35	650

**Table – 8: Course of study for M. Pharm. III Semester
(Common for All Specializations)**

Course Code	Course	Credit Hours	Credit Points
MRM 301T	Research Methodology and Biostatistics*	4	4
-	Journal club	1	1
-	Discussion / Presentation (Proposal Presentation)	2	2
-	Research Work	28	14
Total		35	21

* Non University Exam

Table – 9: Course of study for M. Pharm. IV Semester
(Common for All Specializations)

Course Code	Course	Credit Hours	Credit Points
-	Journal Club	1	1
-	Research Work	31	16
-	Discussion/Final Presentation	3	3
	Total	35	20

Table – 10: Semester wise credits distribution

Semester	Credit Points
I	26
II	26
III	21
IV	20
Co-curricular Activities(Attending Conference, Scientific Presentations and Other Scholarly Activities)	Minimum = 02 Maximum = 07*
Total Credit Points	Minimum = 95 Maximum = 100*

*Credit Points for Co-curricular Activities

Table – 11: Guidelines for Awarding Credit Points for Co-curricular Activities

Name of the Activity	Maximum Credit Points Eligible / Activity
Participation in National Level Seminar/Conference/Workshop/Symposium/ Training Programs (related to the specialization of the student)	01
Participation in international Level Seminar/Conference/Workshop/Symposium/ Training Programs (related to the specialization of the student)	02
Academic Award/Research Award from State Level/National Agencies	01
Academic Award/Research Award from International Agencies	02
Research / Review Publication in National Journals (Indexed in Scopus / Web of Science)	01
Research / Review Publication in International Journals (Indexed in Scopus / Web of Science)	02

Note: International Conference: Held Outside India

International Journal: The Editorial Board outside India

*The credit points assigned for extracurricular and or co-curricular activities shall be given by the Principals of the colleges and the same shall be submitted to the

University. The criteria to acquire this credit point shall be defined by the colleges from time to time.

10. Program Committee

1. The M. Pharm. programme shall have a Programme Committee constituted by the Head of the institution in consultation with all the Heads of the departments.

2. The composition of the Programme 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 Head of the institution.

3. Duties of the Programme 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 Programme Committee shall meet at least twice in a semester preferably at the end of each sessionalexam and before the end semester exam.

11. Examinations/Assessments

The schemes for internal assessment and end semester examinations are given in Table – 12.

11.1. End semester examinations

The End Semester Examinations for each theory and practical coursethrough semesters I to IVshall beconducted by the respective university except for the subject with asterix symbol (*) in table I and II for which examinations shall be conducted by the subject experts at college level and the marks/grades shall be submitted to the university.

**Table – 12: Schemes for internal assessments and end semester examinations
(Pharmaceutics- MPH)**

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total			
			Marks	Duration				
Semester I								
MPH101T	Modern Pharmaceutical Analytical Techniques	10	15	1Hr	25	75	3Hrs	100
MPH102T	Drug Delivery System	10	15	1Hr	25	75	3Hrs	100
MPH103T	Modren Pharmaceutics	10	15	1Hr	25	75	3Hrs	100
MPH104T	Regulatory Affair	10	15	1Hr	25	75	3Hrs	100
MPH105P	Pharmaceutics Practical I	20	30	6Hrs	50	100	6Hrs	150
-	Seminar/Assignment	-	-	-	-	-	-	100
Total							650	
Semester II								
MPH201T	Molecular Pharmaceutics (Nano Tech and Targeted DDS)	10	15	1Hr	25	75	3Hrs	100
MPH202T	Advanced Biopharmaceutics & Pharmacokinetics	10	15	1Hr	25	75	3Hrs	100
MPH203T	Computer Aided Drug Delivery System	10	15	1Hr	25	75	3Hrs	100
MPH204T	Cosmetic and Cosmeceuticals	10	15	1Hr	25	75	3Hrs	100
MPH205P	Pharmaceutics Practical II	20	30	6Hrs	50	100	6Hrs	150
-	Seminar/Assignment	-	-	-	-	-	-	100
Total							650	

**Table – 13: Schemes for internal assessments and end semester examinations
(Pharmaceutical Chemistry-MPC)**

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Mar ks		
			Marks	Durati on		Mar ks	Durati on	
Semester I								
MPC101T	Modern Pharmaceutical Analytical Techniques	10	15	1Hr	25	75	3Hrs	100
MPC1012T	Advanced Organic Chemistry-I	10	15	1Hr	25	75	3Hrs	100
MPC103T	Advanced Medicinal Chemistry	10	15	1Hr	25	75	3Hrs	100
MPC104T	Chemistry of Natural Products	10	15	1Hr	25	75	3Hrs	100
MPC105P	Pharmaceutical Chemistry Practical I	20	30	6Hrs	50	100	6Hrs	150
-	Seminar/Assignment	-	-	-	-	-	-	100
Total							650	
Semester II								
MPC201T	Advanced Spectral Analysis	10	15	1Hr	25	75	3Hrs	100
MPC202T	Advanced Organic Chemistry -II	10	15	1Hr	25	75	3Hrs	100
MPC203T	Computer Aided Drug Design	10	15	1Hr	25	75	3Hrs	100
MPC204T	Pharmaceutical Process Chemistry	10	15	1Hr	25	75	3Hrs	100
MPC205P	Pharmaceutical Chemistry Practical II	20	30	6Hrs	50	100	6Hrs	150
-	Seminar/Assignment	-	-	-	-	-	-	100
Total							650	

**Table – 14: Schemes for internal assessments and end semester examinations
(Pharmaceutical Quality Assurance-MQA)**

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
Semester I								
MQA101T	Modern Pharmaceutical Analytical Techniques	10	15	1Hr	25	75	3Hrs	100
MQA102T	Quality Management System	10	15	1Hr	25	75	3Hrs	100
MQA103T	Quality Control and Quality Assurance	10	15	1Hr	25	75	3Hrs	100
MQA104T	Product Development and Technology Transfer	10	15	1Hr	25	75	3Hrs	100
MQA105P	Pharmaceutical Quality Assurance Practical I	20	30	6Hrs	50	100	6Hrs	150
-	Seminar/Assignment	-	-	-	-	-	-	100
Total							650	
Semester II								
MQA201T	Hazards and Safety Management	10	15	1Hr	25	75	3Hrs	100
MQA202T	Pharmaceutical Validation	10	15	1Hr	25	75	3Hrs	100
MQA203T	Audits and Regulatory Compliance	10	15	1Hr	25	75	3Hrs	100
MQA204T	Pharmaceutical Manufacturing Technology	10	15	1Hr	25	75	3Hrs	100
MQA205P	Pharmaceutical Quality Assurance Practical II	20	30	6Hrs	50	100	6Hrs	10
-	Seminar/Assignment	-	-	-	-	-	-	100
Total							650	

**Table – 15: Schemes for internal assessments and end semester examinations
(Pharmacy Practice)**

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks		
			Marks	Durati on		Marks	Durati on	
Semester I								
MPP101T	Clinical Pharmacy Practice	10	15	1Hr	25	75	3Hrs	100
MPP102T	Pharmacotherapeutics-I	10	15	1Hr	25	75	3Hrs	100
MPP103T	Hospital & Community Pharmacy	10	15	1Hr	25	75	3Hrs	100
MPP104T	Clinical Research	10	15	1Hr	25	75	3Hrs	100
MPP105P	Pharmacy Practice Practical I	20	30	6Hrs	50	100	6Hrs	150
-	Seminar/Assignment	-	-	-	-	-	-	100
Total							650	
Semester II								
MPP201T	Principles of Quality Use of Medicines	10	15	1Hr	25	75	3Hrs	100
MPP202T	Pharmacotherapeutics II	10	15	1Hr	25	75	3Hrs	100
MPP203T	Clinical Pharmacokinetics and Therapeutic Drug Monitoring	10	15	1Hr	25	75	3Hrs	100
MPP204T	Pharmacoepidemiology & Pharmacoeconomics	10	15	1Hr	25	75	3Hrs	100
MPP205P	Pharmacy Practice Practical II	20	30	6Hrs	50	100	6Hrs	150
-	Seminar/Assignment	-	-	-	-	-	-	100
Total							650	

Table – 16: Schemes for internal assessments and end semester examinations (Pharmacology)

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total			
			Marks	Duration		Marks	Duration	
Semester I								
MPL101T	Modern Pharmaceutical Analytical Techniques	10	15	1Hr	25	75	3Hrs	100
MPL102T	Advanced Pharmacology-I	10	15	1Hr	25	75	3Hrs	100
MPL103T	Pharmacological and Toxicological Screening Methods-I	10	15	1Hr	25	75	3Hrs	100
MPL104T	Cellular and Molecular Pharmacology	10	15	1Hr	25	75	3Hrs	100
MPL105P	Pharmacology Practical I	20	30	6Hrs	50	100	6Hrs	150
-	Seminar/Assignment	-	-	-	-	-	-	100
Total							650	
Semester II								
MPL201T	Advanced Pharmacology II	10	15	1Hr	25	75	3Hrs	100
MPL202T	Pharmacological and Toxicological Screening Methods-II	10	15	1Hr	25	75	3Hrs	100
MPL203T	Principles of Drug Discovery	10	15	1Hr	25	75	3Hrs	100
MPL204T	Clinical Research and Pharmacovigilance	10	15	1Hr	25	75	3Hrs	100
MPL205P	Pharmacology Practical- II	20	30	6Hrs	50	100	6Hrs	150
-	Seminar/Assignment	-	-	-	-	-	-	100
Total							650	

**Table – 17: Schemes for internal assessments and end semester examinations
(Pharmacognosy)**

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total			
			Marks	Duration				
Semester I								
MPG101T	Modern Pharmaceutical Analytical Techniques	10	15	1Hr	25	75	3Hrs	100
MPG102T	Advanced Pharmacognosy-1	10	15	1Hr	25	75	3Hrs	100
MPG103T	Phytochemistry	10	15	1Hr	25	75	3Hrs	100
MPG104T	Industrial Pharmacognostical Technology	10	15	1Hr	25	75	3Hrs	100
MPG105P	Pharmacognosy Practical I	20	30	6Hrs	50	100	6Hrs	150
-	Seminar/Assignment	-	-	-	-	-	-	100
Total							650	
Semester II								
MPG201T	Medicinal Plant biotechnology	10	15	1Hr	25	75	3Hrs	100
MPG202T	Advanced Pharmacognosy-II	10	15	1Hr	25	75	3Hrs	100
MPG203T	Indian system of medicine	10	15	1Hr	25	75	3Hrs	100
MPG204T	Herbal cosmetics	10	15	1Hr	25	75	3Hrs	100
MPG205P	Pharmacognosy Practical II	20	30	6Hrs	50	100	6Hrs	150
-	Seminar/Assignment	-	-	-	-	-	-	100
Total							650	

**Table – 18: Schemes for internal assessments and end semester examinations
(Semester III& IV)**

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total			
			Marks	Duration		Marks	Duration	
Semester III								
MRM301T	Research Methodology and Biostatistics*	10	15	1Hr	25	75	3Hrs	100
	Journal club	-	-	-	25	-	-	25
	Discussion / Presentation (Proposal Presentation)	-	-	-	50	-	-	50
	Research work*	-	-	-	-	350	1Hr	350
Total							525	
Semester IV								
-	Journal club	-	-	-	25	-	-	25
-	Discussion / Presentation (Proposal Presentation)	-	-	-	75	-	-	75
-	Research work and Colloquium	-	-	-	-	400	1Hr	400
Total							500	

***Non University Examination**

11.2. Internal assessment: Continuous mode

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

Table – 19: Scheme for awarding internal assessment: Continuous mode

Theory	
Criteria	Maximum Marks
Attendance (Refer Table – 28)	8
Student – Teacher interaction	2
Total	10
Practical	
Attendance (Refer Table – 28)	10
Based on Practical Records, Regular viva voce, etc.	10
Total	20

Table – 20: Guidelines for the allotment of marks for attendance

Percentage of Attendance	Theory	Practical
95 – 100	8	10
90 – 94	6	7.5
85 – 89	4	5
80 – 84	2	2.5
Less than 80	0	0

11.2.1. Sessional Exams

Two sessional exams shall be conducted for each theory / practical course as per the schedule fixed by the college(s). The scheme of question paper for theory and practical sessional examinations is given in the table. The average marks of two sessional exams shall be computed for internal assessment as per the requirements given in tables.

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 as specified in 12, 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.

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

Reexamination of end semester examination shall be conducted as per the schedule given in table 29. The exact dates of examinations shall be notified from time to time.

Table – 21: Tentative schedule of end semester examinations

Semester	For Regular Candidates	For Failed Candidates
I and III	November / December	May / June
II and IV	May / June	November / December

16. Allowed to keep terms (ATKT):

No student shall be admitted to any examination unless he/she fulfills the norms given in 6. ATKT rules are applicable as follows:

A student shall be eligible to carry forward all the courses of I and II semesters till the III semester examinations. However, he/she shall not be eligible to attend the courses of IV semester until all the courses of I, II and III semesters are successfully completed.

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

17.1. 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 – 22.

Table – 22: 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 C_1, C_2, C_3 and C_4 and the student's grade points in these courses are G_1, G_2, G_3 and G_4 , 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:

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

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, \dots is the total number of credits for semester I, II, III, and S_1, S_2, S_3, \dots is the SGPA of semester I, II, III,

20. Declaration of class

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

First Class with Distinction = CGPA of 7.50 and above

First Class = CGPA of 6.00 to 7.49

Second Class = CGPA of 5.00 to 5.99

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. 4 copies of the project report shall be submitted (typed & bound copy not less than 75 pages).

The internal and external examiner appointed by the University shall evaluate the project at the time of the Practical examinations of other semester(s). The projects shall be evaluated as per the criteria given below.

Evaluation of Dissertation Book:

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

Evaluation of Presentation:

Presentation of work	100 Marks
Communication skills	50 Marks
Question and answer skills	100 Marks
<hr/>	
Total	250 Marks

22. Award of Ranks

Ranks and Medals shall be awarded on the basis of final CGPA. However, candidates who fail in one or more courses during the M.Pharm program shall not be eligible for award of ranks. Moreover, the candidates should have completed the M. Pharm program in minimum prescribed number of years, (two years) for the award of Ranks.

23. Award of degree

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

24. Duration for completion of the program of study

The duration for the completion of the program shall be fixed as double the actual duration of the program and the students have to pass within the said period, otherwise they have to get fresh Registration.

25. Revaluation / Retotaling of answer papers

There is no provision for revaluation of the answer papers in any examination. However, the candidates can apply for retotaling by paying prescribed fee.

26. Re-admission after break of study

Candidate who seeks re-admission to the program after break of study has to get the approval from the university by paying a condonation fee.

ADVANCED ORGANIC CHEMISTRY - I (MPC 102T)

Scope

The subject is designed to provide in-depth knowledge about advances in organic chemistry, different techniques of organic synthesis and their applications to process chemistry as well as drug discovery.

Objectives

Upon completion of course, the student shall be to understand

- The principles and applications of retrosynthesis
- The mechanism & applications of various named reactions
- The concept of disconnection to develop synthetic routes for small target molecule.
- The various catalysts used in organic reactions
- The chemistry of heterocyclic compounds

THEORY	60 Hrs
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1. Basic Aspects of Organic Chemistry:	12 Hrs
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1. Organic intermediates: Carbocations, carbanions, free radicals, carbenes and nitrenes. Their method of formation, stability and synthetic applications.
2. Types of reaction mechanisms and methods of determining them,
3. Detailed knowledge regarding the reactions, mechanisms and their relative reactivity and orientations.

Addition reactions

- a) Nucleophilic uni- and bimolecular reactions (SN1 and SN2)
- b) Elimination reactions (E1 & E2; Hoffman & Saytzeff's rule)
- c) Rearrangement reaction

2. Study of mechanism and synthetic applications of following named Reactions:	12Hrs
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Ugi reaction, Brook rearrangement, Ullmann coupling reactions, Dieckmann

Reaction, Doebner-Miller Reaction, Sandmeyer Reaction, Mitsunobu reaction, Mannich reaction, Vilsmeier-Haack Reaction, Sharpless asymmetric epoxidation, Baeyer-Villiger oxidation, Shapiro & Suzuki reaction, Ozonolysis and Michael addition reaction.

3. Synthetic Reagents & Applications: 12 Hrs

Aluminiumisopropoxide, N-bromosuccinamide, diazomethane, dicyclohexylcarbodiimide, Wilkinson reagent, Wittig reagent. Osmium tetroxide, titanium chloride, diazopropane, diethyl azodicarboxylate, Triphenylphosphine, Benzotriazol-1-yloxy) tris (dimethylamino) phosphonium hexafluoro-phosphate (BOP).

Protecting groups

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

4. Heterocyclic Chemistry: 12 Hrs

Organic Name reactions with their respective mechanism and application involved in synthesis of drugs containing five, six membered and fused heterocyclics such as Debus-Radziszewski imidazole synthesis, Knorr Pyrazole Synthesis, Pinner Pyrimidine Synthesis, Combes Quinoline Synthesis, Berntsen Acridine Synthesis, Smiles rearrangement and Traube purine synthesis.

Synthesis of few representative drugs containing these heterocyclic nucleus such as Ketoconazole, Metronidazole, Miconazole, celecoxib, antipyrin, Metamizole sodium, Terconazole, Alprazolam, Triamterene, Sulfamerazine, Trimethoprim, Hydroxychloroquine, Quinine, Chloroquine, Quinacrine, Amsacrine, Prochlorperazine, Promazine, Chlorpromazine, Theophylline, Mercaptopurine and Thioguanine.

5. Synthon approach and retrosynthesis applications: 12 Hrs

- i. Basic principles, terminologies and advantages of retrosynthesis; guidelines for dissection of molecules. Functional group interconversion and addition (FGI and FGA)

- ii. C X disconnections; C C disconnections – alcohols and carbonyl compounds; 1,2 , 1,3 ,1,4 , 1,5 , 1,6 difunctionalized compounds
- iii. Strategies for synthesis of three, four, five and six membered ring.

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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

ADVANCED MEDICINAL CHEMISTRY (MPC 103T)

Scope

The subject is designed to impart knowledge about recent advances in the field of medicinal chemistry at the molecular level including different techniques for the rational drug design.

Objectives

At completion of this course it is expected that students will be able to understand

- Different stages of drug discovery
- Role of medicinal chemistry in drug research
- Different techniques for drug discovery
- Various strategies to design and develop new drug like molecules for biological targets
- Peptidomimetics

THEORY

60 Hrs

1. **Drug discovery:** Stages of drug discovery, lead discovery; identification, validation and diversity of drug targets. **12 Hrs**

Biological drug targets: Receptors, types, binding and activation, theories of drug receptor interaction, drug receptor interactions, agonists vs antagonists, artificial enzymes.

2. **Prodrug Design and Analog design:** **12 Hrs**

a. Prodrug design: Basic concept, Carrier linked prodrugs/ 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.

- b) Combating drug resistance:** Causes for drug resistance, strategies to combat drug resistance in antibiotics and anticancer therapy, Genetic principles of drug resistance.
- c) Analog Design:** Introduction, Classical & Non classical, Bioisosteric replacement strategies, rigid analogs, alteration of chain branching, changes

in ring size, ring position isomers, design of stereo isomers and geometric isomers, fragments of a lead molecule, variation in inter atomic distance.

3. a) **Medicinal chemistry aspects** of the following class of drugs Systematic study, SAR, Mechanism of action and synthesis of new generation molecules of following class of drugs: **12 Hrs**

a) Anti-hypertensive drugs, Psychoactive drugs, Anticonvulsant drugs, H1 & H2 receptor antagonist, COX1 & COX2 inhibitors, Adrenergic & Cholinergic agents, Antineoplastic and Antiviral agents.

b) Stereochemistry and Drug action: Realization that stereo selectivity is a pre-requisite for evolution. Role of chirality in selective and specific therapeutic agents. Case studies, Enantio selectivity in drug adsorption, metabolism, distribution and elimination.

4. **Rational Design of Enzyme Inhibitors** Enzyme kinetics & Principles of Enzyme inhibitors, Enzyme inhibitors in medicine, Enzyme inhibitors in basic research, rational design of non-covalently and covalently binding enzyme inhibitors. **12 Hrs**

5. **Peptidomimetics** Therapeutic values of Peptidomimetics, design of peptidomimetics by manipulation of the amino acids, modification of the peptide backbone, incorporating conformational constraints locally or globally. Chemistry of prostaglandins, leukotrienes and thromboxones. **12 Hrs**

REFERENCES

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10. An Introduction to Medicinal Chemistry, Graham L.Patrick, III Edition, Oxford University Press, USA.
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12. Peptidomimetics in Organic and Medicinal Chemistry by Antonio Guarna and Andrea Trabocchi, First edition, Wiley publishers.

CHEMISTRY OF NATURAL PRODUCTS (MPC 104T)

Scope

The subject is designed to provide detail knowledge about chemistry of medicinal compounds from natural origin and general methods of structural elucidation of such compounds. It also emphasizes on isolation, purification and characterization of medicinal compounds from natural origin.

Objectives

At completion of this course it is expected that students will be able to understand-

- Different types of natural compounds and their chemistry and medicinal importance
- The importance of natural compounds as lead molecules for new drug discovery
- The concept of rDNA technology tool for new drug discovery

General methods of structural elucidation of compounds of natural origin
Isolation, purification and characterization of simple chemical constituents from natural source

THEORY

60 Hrs

1. Study of Natural products as leads for new pharmaceuticals for the following class of drugs

- a) Drugs Affecting the Central Nervous System: Morphine Alkaloids
- b) Anticancer Drugs: Paclitaxel and Docetaxel, Etoposide, and Teniposide
- c) Cardiovascular Drugs: Lovastatin, Teprotide and Dicoumarol
- d) Neuromuscular Blocking Drugs: Curare alkaloids
- e) Anti-malarial drugs and Analogues
- f) Chemistry of macrolid antibiotics (Erythromycin, Azithromycin, Roxithromycin, and Clarithromycin) and β - Lactam antibiotics (Cephalosporins and Carbapenem)

12 Hrs

2. 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. **12 Hrs**

b) Flavonoids

Introduction, isolation and purification of flavonoids, General methods of structural determination of flavonoids; Structural elucidation of quercetin.

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).

3 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 (â carotene).

b) Vitamins Chemistry and Physiological significance of Vitamin A, B1, B2, B12, C, E, Folic acid and Niacin. **12 Hrs**

4 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

b). Active constituent of certain crude drugs used in Indigenous system
Diabetic therapy – *Gymnema sylvestre*, *Salacia reticulate*, *Pterocarpus marsupium*, *Swertia chirata*, *Trigonella foenum graecum*; **Liver dysfunction** – *Phyllanthus niruri*; **Antitumor** – *Curcuma longa* Linn. **12 Hrs**

5. Structural Characterization of natural compounds Structural characterization of natural compounds using IR, ¹HNMR, ¹³CNMR and MS Spectroscopy of specific drugs e.g., Penicillin, Morphine, Camphor, Vit-D, Quercetin and Digitalis glycosides. **12 Hrs**

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9. Organic Chemistry of Natural Products Vol I and II by Gurdeep and Chatwall, Himalaya Publishing House.
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15. Phytochemical methods of Harborne, Springer, Netherlands.
16. Burger’s Medicinal Chemistry.

PHARMACEUTICAL CHEMISTRY PRACTICAL - I **(MPC 105P)**

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

To perform the following reactions of synthetic importance

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

ADVANCED SPECTRAL ANALYSIS (MPC 201T)

Scope

This subject deals with various hyphenated analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are LC-MS, GC-MS, ATR-IR, DSC etc.

Objectives

Upon completion of course, the student shall be to understand

- The principles and applications of retrosynthesis
- The mechanism & applications of various named reactions
- The concept of disconnection to develop synthetic routes for small target molecule.
- The various catalysts used in organic reactions
- The chemistry of heterocyclic compounds

THEORY

60hrs

1. **UV and IR spectroscopy:** Woodward – Fieser rule for 1,3-butadienes, cyclic dienes and α, β -carbonyl compounds and interpretation compounds of enones. ATR-IR, IR Interpretation of organic compounds. **12 Hrs**
2. **NMR spectroscopy:** 1-D and 2-D NMR, NOESY and COSY, HECTOR, INADEQUATE techniques, Interpretation of organic compounds. **12 Hrs**
3. **Mass Spectroscopy :** Mass fragmentation and its rules, Fragmentation of important functional groups like alcohols, amines, carbonyl groups and alkanes, Meta stable ions, McLafferty rearrangement, Ring rule, Isotopic peaks, Interpretation of organic compounds. **12 Hrs**
4. **Chromatography:** Principle, Instrumentation and Applications of the following : a) GC-MS b) GC-AAS c) LC-MS d) LC-FTIR e) LC-NMR f) CEMS g) High Performance Thin Layer chromatography h) Super critical fluid chromatography i) Ion Chromatography j) I-EC (IonExclusion Chromatography) k) Flash chromatography **12 Hrs**
5. **a). Thermal methods of analysis:** Introduction, principle, instrumentation and application of DSC, DTA and TGA.

b). Raman Spectroscopy: Introduction, Principle, Instrumentation and Applications.

c). Radio immuno assay: Biological standardization, bioassay, ELISA, Radioimmuno assay of digitalis and insulin. **12 Hrs**

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ADVANCED ORGANIC CHEMISTRY - II (MPC 202T)

Scope

The subject is designed to provide in-depth knowledge about advances in organic chemistry, different techniques of organic synthesis and their applications to process chemistry as well as drug discovery.

Objectives

Upon completion of course, the student shall be able to understand

- The principles and applications of Green chemistry
- The concept of peptide chemistry.
- The various catalysts used in organic reactions
- The concept of stereochemistry and asymmetric synthesis.

THEORY 60 Hrs

1. Green Chemistry:

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

12 Hrs

2. Chemistry of peptides

- a. Coupling reactions in peptide synthesis
- b. Principles of solid phase peptide synthesis, t-BOC and FMOC protocols, various solid supports and linkers: Activation procedures, peptide bond formation, deprotection and cleavage from resin, low and high HF

cleavage protocols, formation of free peptides and peptide amides, purification and case studies, site-specific chemical modifications of peptides

- c. Segment and sequential strategies for solution phase peptide synthesis with any two case studies
- d. Side reactions in peptide synthesis: Deletion peptides, side reactions initiated by proton abstraction, protonation, overactivation and side reactions of individual amino acids. **12Hrs**

3. Photochemical Reactions

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

Pericyclic reactions

Mechanism, Types of pericyclic reactions such as cyclo addition, electrocyclic reaction and sigmatropic rearrangement reactions with examples **12 Hrs**

4. Catalysis:

- a. Types of catalysis, heterogeneous and homogenous catalysis, advantages and disadvantages
- b. Heterogeneous catalysis – preparation, characterization, kinetics, supported catalysts, catalyst deactivation and regeneration, some examples of heterogeneous catalysis used in synthesis of drugs.
- c. Homogenous catalysis, hydrogenation, hydroformylation, hydrocyanation, Wilkinson catalysts, chiral ligands and chiral induction, Ziegler Natta catalysts, some examples of homogenous catalysis used in synthesis of drugs
- d. Transition-metal and Organo-catalysis in organic synthesis: Metal-catalyzed reactions
- e. Biocatalysis: Use of enzymes in organic synthesis, immobilized enzymes/cells in organic reaction.
- f. Phase transfer catalysis theory and applications **12 Hrs**

5. Stereochemistry & Asymmetric Synthesis

- a. Basic concepts in stereochemistry – optical activity, specific rotation,

racemates and resolution of racemates, the Cahn, Ingold, Prelog (CIP) sequence rule, meso compounds, pseudo asymmetric centres, axes of symmetry, Fischers D and L notation, cis-trans isomerism, E and Z notation.

- b. Methods of asymmetric synthesis using chiral pool, chiral auxiliaries and catalytic asymmetric synthesis, enantiopure separation and Stereo selective synthesis with examples. **12 Hrs**

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7. Principles of organic synthesis, R.C. Norman and J.M. Coxon, Nelson thorns
8. Organic synthesis- Special techniques VK Ahluwalia and R Aggarwal, Narosa Publishers.
9. Organic reaction mechanisms IV edtn, VK Ahluwalia and RK Parashar, Narosa Publishers.

COMPUTER AIDED DRUG DESIGN (MPC 203T)

Scope

The subject is designed to impart knowledge on the current state of the art techniques involved in computer assisted drug design.

Objectives

At completion of this course it is expected that students will be able to understand

- Role of CADD in drug discovery
- Different CADD techniques and their applications
- Various strategies to design and develop new drug like molecules.
- Working with molecular modeling softwares to design new drug molecules
- The in silico virtual screening protocols

Theory

60Hrs

1. Introduction to Computer Aided Drug Design (CADD)

12hrs

History, different techniques and applications.

Quantitative Structure Activity Relationships: Basics

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

2. Quantitative Structure Activity Relationships: Application

12 hrs

Hansch analysis, Free Wilson analysis and relationship between them, Advantages and disadvantages; Deriving 2D-QSAR equations. 3D-QSAR approaches and contour map analysis. Statistical methods used in QSAR analysis and importance of statistical parameters.

3. Molecular Modeling and Docking

12Hrs

a) Molecular and Quantum Mechanics in drug design.

- b) Energy Minimization Methods: comparison between global minimum conformation and bioactive conformation
- c) Molecular docking and drug receptor interactions: Rigid docking, flexible docking and extra-precision docking. Agents acting on enzymes such as DHFR, HMG-CoA reductase and HIV protease, choline esterase (AchE & BchE)

4. Molecular Properties and Drug Design

12Hrs

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

5. Pharmacophore Mapping and Virtual Screening

12 hrs

Concept of pharmacophore, pharmacophore mapping, identification of Pharmacophore features and Pharmacophore modeling; Conformational search used in pharmacophore mapping. In Silico Drug Design and Virtual Screening Techniques Similarity based methods and Pharmacophore based screening, structure based In-silico virtual screening protocols.

REFERENCES

1. Computational and structural approaches to drug discovery, Robert M Stroud and Janet. F Moore, RCS Publishers.
2. Introduction to Quantitative Drug Design by Y.C. Martin, CRC Press, Taylor & Francis group..
3. Drug Design by Ariens Volume 1 to 10, Academic Press, 1975, Elsevier Publishers.
4. Principles of Drug Design by Smith and Williams, CRC Press, Taylor & Francis.
5. The Organic Chemistry of the Drug Design and Drug action by Richard B. Silverman, Elsevier Publishers.
6. Medicinal Chemistry by Burger, Wiley Publishing Co.
7. An Introduction to Medicinal Chemistry –Graham L. Patrick, Oxford University Press.

8. Wilson and Gisvold's Text book of Organic Medicinal and Pharmaceutical Chemistry, Ippincott Williams & Wilkins.
9. Comprehensive Medicinal Chemistry – Corwin and Hansch, Pergamon Publishers.
10. Computational and structural approaches to drug design edited by Robert M Stroud and Janet. F Moore

PHARMACEUTICAL PROCESS CHEMISTRY

(MPC 204T)

Scope

Process chemistry is often described as scale up reactions, taking them from small quantities created in the research lab to the larger quantities that are needed for further testing and then to even larger quantities required for commercial production. The goal of a process chemist is to develop synthetic routes that are safe, cost-effective, environmentally friendly, and efficient. The subject is designed to impart knowledge on the development and optimization of a synthetic route/s and the pilot plant procedure for the manufacture of Active Pharmaceutical Ingredients (APIs) and new chemical entities (NCEs) for the drug development phase.

Objectives

At completion of this course it is expected that students will be able to understand

- The strategies of scale up process of APIs and intermediates
- The various unit operations and various reactions in process chemistry

THEORY

60 Hrs

1. Process chemistry

12 Hrs

Introduction, Synthetic strategy Stages of scale up process: Bench, pilot and large scale process. In-process control and validation of large scale process. Case studies of some scale up process of APIs. Impurities in API, types and their sources including genotoxic Impurities

2. Unit operations

12 Hrs

- Extraction: Liquid equilibria, extraction with reflux, extraction with agitation, counter current extraction.
- Filtration: Theory of filtration, pressure and vacuum filtration, centrifugal filtration,
- Distillation: azeotropic and steam distillation
- Evaporation: Types of evaporators, factors affecting evaporation.
- Crystallization: Crystallization from aqueous, non-aqueous solutions factors affecting crystallization, nucleation. Principle and general methods of Preparation of polymorphs, hydrates, solvates and amorphous APIs.

3. Unit Processes – I

12 Hrs

- a) Nitration: Nitrating agents, Aromatic nitration, kinetics and mechanism of aromatic nitration, process equipment for technical nitration, mixed acid for nitration,
- b) Halogenation: Kinetics of halogenations, types of halogenations, catalytic halogenations. Case study on industrial halogenation process.
- c) Oxidation: Introduction, types of oxidative reactions, Liquid phase oxidation with oxidizing agents. Nonmetallic Oxidizing agents such as H_2O_2 , sodium hypochlorite, Oxygen gas, ozonolysis.

4. Unit Processes – II

12 Hrs

- a) Reduction: Catalytic hydrogenation, Heterogeneous and homogeneous catalyst; Hydrogen transfer reactions, Metal hydrides. Case study on industrial reduction process.
- b) Fermentation: Aerobic and anaerobic fermentation. Production of Antibiotics; Penicillin and Streptomycin, Vitamins: B2 and B12. Statins: Lovastatin, Simvastatin
- c) Reaction progress kinetic analysis Streamlining reaction steps, route selection, Characteristics of expedient routes, characteristics of cost-effective routes, reagent selection, families of reagents useful for scale-up.

5. Industrial Safety

12 Hrs

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

REFERENCES

1. Process Chemistry in the Pharmaceutical Industry: Challenges in an Ever-Changing Climate-An Overview; K. Gadamasetti, 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

PHARMACEUTICAL CHEMISTRY PRACTICALS – II

(MPC 205P)

1. Synthesis of organic compounds by adapting different approaches involving (3 experiments) Oxidation Reduction/hydrogenation Nitration
2. Comparative study of synthesis of APIs/intermediates by different synthetic routes (2 experiments)
3. Assignments on regulatory requirements in API (2 experiments)
4. Comparison of absorption spectra by UV and Wood ward – Fieser rule
5. Interpretation of organic compounds by FT-IR
6. Interpretation of organic compounds by NMR
7. Interpretation of organic compounds by MS
8. Determination of purity by DSC in pharmaceuticals
9. Identification of organic compounds using FT-IR, NMR, CNMR and Mass spectra
10. To carry out the preparation of following organic compounds
11. Preparation of 4-chlorobenzhydrylpiperazine. (an intermediate for cetirizine HCl).
12. Preparation of 4-iodotoluene from p-toluidine.
13. NaBH₄ reduction of vanillin to vanillyl alcohol
14. Preparation of umbelliferone by Pechhman reaction
15. Preparation of triphenyl imidazole
16. To perform the Microwave irradiated reactions of synthetic importance (Any two)
17. Determination of log P, MR, hydrogen bond donors and acceptors of selected drugs using softwares
18. Calculation of ADMET properties of drug molecules and its analysis using softwares Pharmacophore modeling
19. 2D-QSAR based experiments

- 20. 3D-QSAR based experiments
- 21. Docking study based experiment
- 22. Virtual screening based experiment