

Ordinance Governing  
**Master of Pharmacy**  
M. Pharm. Degree Course

\*\*\*  
Syllabus / Curriculum

**2025-2026**



Accredited 'A+' Grade by NAAC (3rd Cycle)  
Placed in Category 'A' by MoE (GoI)

**KLE ACADEMY OF HIGHER EDUCATION AND RESEARCH**

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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 programmes.

## **MISSION**

- To promote sustainable development of Higher Education consistent with statutory and regulatory requirements.
- To plan and 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 Programmes.
- 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 Mission.

## **OBJECTIVES**

The objectives are to realize the following at KAHER and its Constituent Institutions :

- To implement effectively programmes through creativity and innovation in teaching, learning and evaluation.
- To make existing programmes more career oriented through effective system of review and redesign of curriculum.
- To impart spirit of inquiry 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 and 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 students welfare programmes.
- 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 KAHER is a Philosophical statement in Symbolic.*

## ***The Emblem...***

*A close look at the emblem unveils a pillar, a symbol of the 'KAHER of Excellence' built on strong Values & Principles.*

## ***The Palm & the Seven Stars...***

*The Palm is the palm of the teacher - the hand that acts, promises and 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 Knowledge 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 kingdom called KLE Society.*

*Hence another significance of the raised Palm is our tribute to these great Souls for making this KAHER a possibility.*

## ***Empowering Professionals...***

*'Empowering Professionals', the inscription at the base of the Emblem conveys that our Organization with its strength, maturity & wisdom will 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 Academy of Higher Education & Research

(Deemed-to-be-University)

[Declared as Deemed-to-be-University u/s 3 & 12B of the UGC Act, 1956 vide Government of India Notification No. F.9-19/2000-U.3 (A)]

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Ref. No. KAHER/2025-26/D-26062516

24<sup>th</sup> June, 2025

### NOTIFICATION

Sub: **Ordinance governing revision in the course curriculum of  
M. Pharma under the Faculty of Pharmacy.**

Ref : Minutes of the 58<sup>th</sup> Academic Council meeting held on 25<sup>th</sup> March, 2025.

In exercise of the powers conferred under Rule 6 (9) of the Memorandum of Association of the KLE Academy of Higher Education and Research in its **58<sup>th</sup> Academic Council** meeting held on **25<sup>th</sup> March, 2025** has approved revision in the curriculum of **M. Pharma** under the **Faculty of Pharmacy** from the academic year **2025-26** onwards.

By Order

**Dr. Mrs. Jyoti M. Nagamoti**  
Director, Academic Affairs

**Prof. Dr. M.S. Ganachari**  
Registrar

To

**The Dean,**  
Faculty of Pharmacy,  
KAHER, BELAGAVI.

CC to :

1. The Special Officer to Hon, Vice-Chancellor, KAHER, Belagavi.
2. The Principal, KLE College of Pharmacy, Belagavi/Hubballi/Bengaluru.
3. The Controller of Examinations, KAHER, Belagavi.
4. The Director, Academic Affairs, KAHER, Belagavi.
5. The Director, IQAC, KAHER, Belagavi.

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### **PHARMACEUTICS (DETAILED SYLLABUS)**

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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
7	Pharmaceutical Analysis	MPA

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
<b>Semester I</b>					
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
<b>Total</b>		<b>35</b>	<b>26</b>	<b>35</b>	<b>650</b>

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
<b>Total</b>		<b>35</b>	<b>26</b>	<b>35</b>	<b>650</b>

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

Course Code	Course	Credit Hours	Credit Points	Hrs./Wk	Marks
<b>Semester I</b>					
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
<b>Total</b>		<b>35</b>	<b>26</b>	<b>35</b>	<b>650</b>
<b>Semester II</b>					
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
<b>Total</b>		<b>35</b>	<b>26</b>	<b>35</b>	<b>650</b>

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

Course Code	Course	Credit Hours	Credit Points	Hrs./Week	Marks
<b>Semester I</b>					
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
<b>Total</b>		<b>35</b>	<b>26</b>	<b>35</b>	<b>650</b>
<b>Semester II</b>					
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
<b>Total</b>		<b>35</b>	<b>26</b>	<b>35</b>	<b>650</b>

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

Course Code	Course	Credit Hours	Credit Points	Hrs./Wk	Marks
<b>Semester I</b>					
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
<b>Total</b>		<b>35</b>	<b>26</b>	<b>35</b>	<b>650</b>
<b>Semester II</b>					
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 & Pharmacoconomics	4	4	4	100
MPP205P	Pharmacy Practice Practical II	12	6	12	150
-	Seminar/Assignment	7	4	7	100
<b>Total</b>		<b>35</b>	<b>26</b>	<b>35</b>	<b>650</b>

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

Course Code	Course	Credit Hours	Credit Points	Hrs./Wk	Marks
<b>Semester I</b>					
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
<b>Total</b>		<b>35</b>	<b>26</b>	<b>35</b>	<b>650</b>
<b>Semester II</b>					
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
<b>Total</b>		<b>35</b>	<b>26</b>	<b>35</b>	<b>650</b>

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

Course Code	Course	Credit Hours	Credit Points	Hrs./Wk	Marks
<b>Semester I</b>					
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
<b>Total</b>		<b>35</b>	<b>26</b>	<b>35</b>	<b>650</b>
<b>Semester II</b>					
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
<b>Total</b>		<b>35</b>	<b>26</b>	<b>35</b>	<b>650</b>

**Table -8 : Course of study for M. Pharm.  
(Pharmaceutical Analysis)**

Course Code	Course	Credit Hours	Credit Points	Hrs./wk	Marks
<b>Semester I</b>					
MPA101T	Modern Pharmaceutical Analytical Techniques	4	4	4	100
MPA102T	Advanced Pharmaceutical Analysis	4	4	4	100
MPA103T	Pharmaceutical Validation	4	4	4	100
MPA104T	Food Analysis	4	4	4	100
MPA105P	Pharmaceutical Analysis Practical I	12	6	12	150
-	Seminar/Assignment	7	4	7	100
<b>Total</b>		<b>35</b>	<b>26</b>	<b>35</b>	<b>650</b>
<b>Semester II</b>					
MPA201T	Advanced Instrumental Analysis	4	4	4	100
MPA202T	Modern Bio-Analytical Techniques	4	4	4	100
MPA203T	Quality Control and Quality Assurance	4	4	4	100
MPA204T	Herbal and Cosmetic Analysis	4	4	4	100
MPA205P	Pharmaceutical Analysis Practical II	12	6	12	150
-	Seminar/Assignment	7	4	7	100
<b>Total</b>		<b>35</b>	<b>26</b>	<b>35</b>	<b>650</b>

**Table - 9: 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
	<b>Total</b>	<b>35</b>	<b>21</b>

\* Non University Exam

**Table - 10: 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
	<b>Total</b>	<b>35</b>	<b>20</b>

**Table - 11: 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*
<b>Total Credit Points</b>	<b>Minimum = 95 Maximum = 100*</b>

\*Credit Points for Co-curricular Activities

**Table - 12: Guidelines for Awarding Credit Points for Co-curricular Activities**

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

**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 course through semesters I to IV shall be conducted 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 - 13: 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	
			Marks	Duration				
<b>Semester I</b>								
<b>MPH101T</b>	Modern Pharmaceutical Analytical Techniques	10	15	1Hr	25	75	3Hrs	100
<b>MPH102T</b>	Drug Delivery System	10	15	1Hr	25	75	3Hrs	100
<b>MPH103T</b>	Modern Pharmaceutics	10	15	1Hr	25	75	3Hrs	100
<b>MPH104T</b>	Regulatory Affairs	10	15	1Hr	25	75	3Hrs	100
<b>MPH105P</b>	Pharmaceutics Practical I	20	30	6Hrs	50	100	6Hrs	150
-	Seminar/Assignment	-	-	-	-	-	-	100
<b>Total</b>								<b>650</b>
<b>Semester II</b>								
<b>MPH201T</b>	Molecular Pharmaceutics (Nano Tech and Targeted DDS)	10	15	1Hr	25	75	3Hrs	100
<b>MPH202T</b>	Advanced Biopharmaceutics & Pharmacokinetics	10	15	1Hr	25	75	3Hrs	100
<b>MPH203T</b>	Computer Aided Drug Delivery System	10	15	1Hr	25	75	3Hrs	100
<b>MPH204T</b>	Cosmetic and Cosmeceuticals	10	15	1Hr	25	75	3Hrs	100
<b>MPH205P</b>	Pharmaceutics Practical II	20	30	6Hrs	50	100	6Hrs	150
-	Seminar/Assignment	-	-	-	-	-	-	100
<b>Total</b>								<b>650</b>

**Table - 14: 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	Durati on	
			Marks	Durati on				
<b>Semester I</b>								
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
<b>Total</b>								<b>650</b>
<b>Semester II</b>								
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
<b>Total</b>								<b>650</b>

**Table - 15: 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					
<b>Semester I</b>									
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	
<b>Total</b>									<b>650</b>
<b>Semester II</b>									
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	
<b>Total</b>									<b>650</b>

**Table - 16: 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	Duration	
			Marks	Duration				
<b>Semester I</b>								
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
<b>Total</b>								<b>650</b>
<b>Semester II</b>								
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
<b>Total</b>								<b>650</b>

**Table - 17: 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				
<b>Semester I</b>								
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
<b>Total</b>								<b>650</b>
<b>Semester II</b>								
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
<b>Total</b>								<b>650</b>

**Table - 18: 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		
			Marks	Duration					
<b>Semester I</b>									
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	
<b>Total</b>									<b>650</b>
<b>Semester II</b>									
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	
<b>Total</b>									<b>650</b>

**Table -19 : Schemes for internal assessments and end semester examinations  
(Pharmaceutical Analysis-MPA)**

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
<b>SEMESTER I</b>								
MPA101T	Modern Pharmaceutical Analysis	10	15	1Hr	25	75	3 Hrs	100
MPA102T	Advanced Pharmaceutical Analysis	10	15	1Hr	25	75	3 Hrs	100
MPA103T	Pharmaceutical Validation	10	15	1Hr	25	75	3 Hrs	100
MPA104T	Food Analysis	10	15	1Hr	25	75	3 Hrs	100
MPA105P	Pharmaceutical Analysis Practical-I	20	30	6Hrs	50	100	6 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
<b>Total</b>								<b>650</b>
<b>SEMESTER II</b>								
MPA201T	Advanced Instrumental Analysis	10	15	1Hr	25	75	3 Hrs	100
MPA202T	Modern Bio-Analytical Techniques	10	15	1Hr	25	75	3 Hrs	100
MPA203T	Quality Control and Quality Assurance	10	15	1Hr	25	75	3 Hrs	100
MPA204T	Herbal and Cosmetic analysis	10	15	1 Hr	25	75	3 Hrs	100
MPA205P	Pharmaceutical Analysis Practical -II	20	30	6 Hrs	50	100	6 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
<b>Total</b>								<b>650</b>

**Table - 20: 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					
<b>Semester III</b>									
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	
<b>Total</b>									<b>525</b>
<b>Semester IV</b>									
-	Journal club	-	-	-	25	-	-	25	
-	Discussion / Presentation (Proposal Presentation)	-	-	-	75	-	-	75	
-	Research work and Colloquium	-	-	-	-	400	1Hr	400	
<b>Total</b>									<b>500</b>

**\*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 - 21: Scheme for awarding internal assessment: Continuous mode**

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

**Table - 22: Guidelines for the allotment of marks for attendance**

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

#### 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 - 23: 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 - 24: 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.

## PHARMACEUTICS (MPH)

### MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES (MPH 101T)

#### Scope

This subject deals with various advanced analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are NMR, Mass spectrometer, IR, HPLC, GC etc.

#### Objectives

After completion of course student is able to know,

- Chemicals and Excipients
- The analysis of various drugs in single and combination dosage forms
- Theoretical and practical skills of the instruments

#### THEORY

60 Hrs

1. **a. UV-Visible spectroscopy:** Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV-Visible spectroscopy.
  - b. **IR spectroscopy:** Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier - Transform IR Spectrometer, Factors affecting vibrational frequencies and Applications of IR spectroscopy
  - c. **Spectrofluorimetry:** Theory of Fluorescence, Factors affecting fluorescence, Quenchers, Instrumentation and Applications of fluorescence spectrophotometer.
  - d. **Flame emission spectroscopy and Atomic absorption spectroscopy:** Principle, Instrumentation, Interferences and Applications. **10Hrs**
2. **NMR spectroscopy:** Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and <sup>13</sup>C NMR. Applications of NMR spectroscopy. **10 Hrs**
3. **Mass Spectroscopy:** Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules, Meta stable ions, Isotopic peaks and Applications of Mass spectroscopy **10Hrs**

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

a) Paper chromatography b) Thin Layer chromatography c) Ion exchange chromatography d) Column chromatography e) Gas chromatography f) High Performance Liquid chromatography g) Affinity chromatography **10Hrs**

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

**b. 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 **10Hrs**

6. **Thermal Techniques:** 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). **TGA:** Principle, instrumentation, factors affecting results, advantage and disadvantages, pharmaceutical applications. **10 Hrs**

## REFERENCES

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

## DRUG DELIVERY SYSTEMS

(MPH102T)

### SCOPE

This course is designed to impart knowledge on the area of advances in novel drug delivery systems.

### OBJECTIVES

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

- The various approaches for development of novel drug delivery systems.
- The criteria for selection of drugs and polymers for the development of delivering system
- The formulation and evaluation of Novel drug delivery systems.

### THEORY 60 Hrs

1. **Sustained Release (SR) and Controlled Release (CR) formulations:** Introduction & basic concepts, advantages/ disadvantages, factors influencing, Physicochemical & biological approaches for SR/CR formulation, Mechanism of Drug Delivery from SR/CR formulation. Polymers: introduction, definition, classification, properties and application 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. **10Hrs**
2. **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 Feedback regulated Drug Delivery Systems; Principles & Fundamentals, Chronomodulated Drug delivery systems and bio informatics in drug delivery systems. **10 Hrs**
3. **Gastro-Retentive Drug Delivery Systems:** Principle, concepts, advantages and disadvantages, Modulation of GI transit time, approaches to extend GI transit. Buccal Drug Delivery Systems: Principle of muco adhesion, advantages and disadvantages, Mechanism of drug permeation, Methods of formulation and its evaluations. **10 Hrs**

4. **Ocular Drug Delivery Systems:** Barriers of drug permeation, Methods to overcome barriers. Key concepts of formulation and evaluation of ophthalmic dosage forms. **06 Hrs**
5. **Transdermal Drug Delivery Systems:** Structure of skin and barriers, Penetration enhancers, Transdermal Drug Delivery Systems, Formulation and evaluation. **10 Hrs**
6. **Protein and Peptide Delivery:** Barriers for protein delivery. Formulation and Evaluation of delivery systems of proteins and other macromolecules. **08 Hrs**
7. **Vaccine delivery systems:** Vaccines, uptake of antigens, single shot vaccines, mucosal and transdermal delivery of vaccines. **06 Hrs**

#### REFERENCES

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
4. N.K. Jain, Controlled and Novel Drug Delivery, CBS Publishers & Distributors, New Delhi, First edition 1997 (reprint in 2001).
5. S.P.Vyas and R.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) desirable

## MODERN PHARMACEUTICS

(MPH 103T)

### Scope

Course designed to impart advanced knowledge and skills required to learn various aspects and concepts at pharmaceutical industries

### Objectives

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

- The elements of preformulation studies.
- The Active Pharmaceutical Ingredients and Generic drug Product development
- Industrial Management and GMP Considerations.
- Optimization Techniques & Pilot Plant Scale Up Techniques
- Stability Testing, sterilization process & packaging of dosage forms.

### THEORY 60 Hrs

1. **a. Preformation Concepts** - Solubility, Drug Excipient interactions - different methods, kinetics of stability, Stability testing. Theories of dispersion and pharmaceutical Dispersion (Emulsion and Suspension, SMEDDS) preparation and stability Large and small volume parental - physiological and formulation consideration, Manufacturing and evaluation. **10 Hrs**  
**b. Optimization techniques in Pharmaceutical Formulation:** Concept and parameters of optimization, Optimization techniques in pharmaceutical formulation and processing. Statistical design, Response surface method, Contour designs, Factorial designs and application in formulation **10 Hrs**
2. **Validation:** Introduction to Pharmaceutical Validation, Scope & merits of Validation, Validation and calibration of Master plan, ICH & WHO guidelines for calibration and validation of equipments, Validation of specific dosage form, Types of validation. Government regulation, Manufacturing Process Model, URS, DQ, IQ, OQ & P.Q. of facilities. **10 Hrs**
3. **cGMP & Industrial Management:** Objectives and policies of current good manufacturing practices, layout of buildings, services, equipments and their maintenance 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. Concept of Total Quality Management. **10 Hrs**

4. **Compression and compaction:** Physics of tablet compression, compression, consolidation, effect of friction, distribution of forces, compaction profiles. **10Hrs**
5. **Study of consolidation parameters;** Diffusion parameters, Dissolution parameters and Pharmacokinetic parameters, Heckel plots, Similarity factors -  $f_2$  and  $f_1$ , Higuchi and Peppas plot, Linearity Concept of significance, Standard deviation, Chi square test, students T-test, ANOVA test. **10 Hrs**

## 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.
17. Encyclopaedia of Pharmaceutical technology, Vol I - III.

## REGULATORY AFFAIRS

(MPH 104T)

### Scope

Course designed to impart advanced knowledge and skills required to learn the concept of generic drug and their development, various regulatory filings in different countries, different phases of clinical trials and submitting regulatory documents : filing process of IND, NDA and ANDA

- To know the approval process of new drug, Investigational new drug and abbreviated new drug
- To know the chemistry, manufacturing controls and their regulatory importance
- To learn the documentation requirements for IND, NDA and ANDA

### Objectives:

Upon completion of the course, it is expected that the students will be able to understand

- The Concepts of innovator and generic drugs, drug development process
- The Regulatory guidance's and guidelines for filing and approval process
- Preparation of Dossiers and their submission to regulatory agencies in different countries
- Post approval regulatory requirements for actives and drug products
- Submission of global documents in CTD/ eCTD formats
- Clinical trials requirements for approvals for conducting clinical trials
- Pharmacovigilance and process of monitoring in clinical trials.

### THEORY 60 Hrs

1. a. **Documentation in Pharmaceutical industry:** Master formula record, DMF (Drug Master File), distribution records. Generic drugs product development Introduction , Hatch- Waxman act and amendments, CFR (CODE OF FEDERAL REGULATION) ,drug product performance, in-vitro, ANDA regulatory approval process, NDA approval process, BE and drug product assessment, in -vivo, scale up process approval changes, post marketing surveillance, outsourcing BA and BE to CRO. **12 Hrs**

- b. Regulatory requirement for product approval:** API, biologics, novel, therapies obtaining NDA, ANDA for generic drugs ways and means of US registration for foreign drugs. **12 Hrs**
2. **CMC, post approval regulatory affairs.** Regulation for combination products and medical devices. CTD and ECTD format, industry and FDA liaison. ICH - Guidelines of ICH-Q, S E, M. Regulatory requirements of EU, MHRA, TGA and ROW countries. **12 Hrs**
  3. **Non clinical drug development:** Global submission of IND, NDA, ANDA. Investigation of medicinal products dossier, dossier (IMPD) and investigator brochure (IB). **12 Hrs**
  4. **Clinical trials:** Developing clinical trial protocols. Institutional review board/ independent ethics committee Formulation and working procedures informed Consent process and procedures. HIPAA- new, requirement to clinical study process, pharmacovigilance safety monitoring in clinical trials. **12 Hrs**

## REFERENCES

1. Generic Drug Product Development, Solid Oral Dosage forms, Leon Shargel and IsaderKaufer, 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. [www.ich.org/](http://www.ich.org/)
8. [www.fda.gov/](http://www.fda.gov/)
9. [europa.eu/index\\_en.htm](http://europa.eu/index_en.htm)
10. <https://www.tga.gov.au/tga-basics>

## PHARMACEUTICS PRACTICALS - I

### (MPH 105P)

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 trans dermal 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 Heckal plot, Higuchi and peppas plot and determine similarity factors.

## MOLECULAR PHARMACEUTICS (NANO TECHNOLOGY & TARGETED DDS) (NTDS)

(MPH 201T)

### Scope

This course is designed to impart knowledge on the area of advances in novel drug delivery systems.

### Objectives

Upon completion of the course student shall be able to understand

- The various approaches for development of novel drug delivery systems.
- The criteria for selection of drugs and polymers for the development of NTDS
- The formulation and evaluation of novel drug delivery systems.

### THEORY

60 Hrs

1. **Targeted Drug Delivery Systems:** Concepts, Events and biological process involved in drug targeting. Tumor targeting and Brain specific delivery. **12Hrs**
2. **Targeting Methods:** Introduction preparation and evaluation. Nano Particles & Liposomes: Types, preparation and evaluation. **12Hrs**
3. **Micro Capsules / Micro Spheres:** Types, preparation and evaluation, Monoclonal Antibodies ; preparation and application, Hrs preparation and application of Niosomes, Aquasomes, Phytosomes, Ethosomes, transethosomes, cubosomes. **12Hrs**
4. **Pulmonary Drug Delivery Systems:** Aerosols, propellents, ContainersTypes, preparation and evaluation, Intra Nasal Route Delivery systems; Types, preparation and evaluation. **12 Hrs**
5. **Nucleic acid based therapeutic delivery system:** Gene therapy, introduction (ex-vivo & in-vivo gene therapy). Potential target diseases for gene therapy (inherited disorder and cancer). Gene expression systems (viral and nonviral gene transfer). Liposomal gene delivery systems.

Biodistribution and Pharmacokinetics: knowledge of therapeutic antisense molecules and aptamers as drugs of future, biologics and biosimilars. **12 Hrs**

## REFERENCES

1. Y W. Chien, Novel Drug Delivery Systems, 2nd edition, revised and expanded, Marcel Dekker, Inc., New York, 1992.
2. S.P.Vyas and R.K.Khar, Controlled Drug Delivery- concepts and advances, VallabhPrakashan, New Delhi, First edition 2002.
3. N.K. Jain, Controlled and Novel Drug Delivery, CBS Publishers & Distributors, NewDelhi, First edition 1997 (reprint in 2001).

## **ADVANCED BIOPHARMACEUTICS & PHARMACOKINETICS (MPH 202T)**

### **Scope**

This course is designed to impart knowledge and skills necessary for dose calculations, dose adjustments and to apply biopharmaceutics theories in practical problem solving. Basic theoretical discussions of the principles of biopharmaceutics and pharmacokinetics are provided to help the students' to clarify the concepts.

### **Objectives**

Upon completion of this course it is expected that students will be able understand,

- The basic concepts in biopharmaceutics and pharmacokinetics.
- The use raw data and derive the pharmacokinetic models and parameters the best describe the process of drug absorption, distribution, metabolism and elimination.
- The critical evaluation of biopharmaceutic studies involving drug product equivalency.
- The design and evaluation of dosage regimens of the drugs using pharmacokinetic and biopharmaceutic parameters.
- The potential clinical pharmacokinetic problems and application of basics of pharmacokinetic

### **THEORY**

**60 Hrs**

1. **Drug Absorption from the Gastrointestinal Tract:** Gastrointestinal tract, Mechanism of drug absorption, Factors affecting drug absorption, pH-partition theory of drug absorption.

Formulation and physicochemical factors: Dissolution rate, Dissolution process, Noyes-Whitney equation and drug dissolution, Factors affecting the dissolution rate.

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, Dissolution methods, Formulation and processing factors, Transport model: Permeability-Solubility-Charge State and the pH Partition Hypothesis, Properties of the Gastrointestinal Tract (GIT), pH Microclimate Intracellular pH Environment, Tight-Junction Complex.

**12 Hrs**

2. **Biopharmaceutic considerations in drug product design and In Vitro Drug Product Performance:** Introduction biopharmaceutic factors affecting drug bioavailability, rate-limiting steps in drug absorption, physicochemical nature of the drug formulation factors affecting drug product performance, in vitro: dissolution and drug release testing, compendial methods of dissolution, alternative methods of dissolution testing, meeting dissolution requirements, problems of variable control in dissolution testing performance of drug products. In vitro-in vivo correlation, dissolution profile comparisons, drug product stability, considerations in the design of a drug product. **12 Hrs**
3. **Pharmacokinetics:** Basic considerations, pharmacokinetic models, non-compartment model, compartment modeling: one compartment model- IV bolus, IV infusion, extra-vascular. Multi compartment model: two compartment - model in brief, non-linear pharmacokinetics: cause of non-linearity, Michaelis - Menten equation, estimation of  $k_{max}$  and  $v_{max}$ . Drug interactions: introduction, the effect of protein-binding interactions, the effect of tissue-binding interactions, cytochrome p450-based drug interactions, drug interactions linked to transporters. **12 Hrs**
4. **Drug Product Performance, In -Vivo: Bioavailability and Bioequivalence:** drug product performance, purpose of bioavailability studies, relative and absolute availability. Methods for assessing bioavailability, bioequivalence studies, design and evaluation of bioequivalence studies, study designs, crossover study designs, evaluation of the data, bioequivalence example, study submission and drug review process. Biopharmaceutics classification system, methods. 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. Regulatory guidelines USFDA & CDSCO under bioequivalence studies. **12 Hrs**
5. **Application of Pharmacokinetics: Modified-Release Drug Products, Targeted Drug Delivery Systems and Biotechnological Products.** Introduction to Pharmacokinetics and pharmacodynamic, drug interactions. Pharmacokinetics and pharmacodynamics of biotechnology drugs. Introduction, Proteins and peptides, Monoclonal antibodies, Oligonucleotides, Vaccines (immunotherapy), Gene therapies. **12 Hrs**

## REFERENCES

1. Biopharmaceutics and Clinical Pharmacokinetics by Milo Gibaldi, 4th edition, Philadelphia, Lea and Febiger, 1991
2. Biopharmaceutics and Pharmacokinetics, A. Treatise, D .M. Brahmkar and Sunil B. Jaiswal., VallabPrakashan, Pitampura, Delhi
3. Applied Biopharmaceutics and Pharmacokinetics by Shargel. Land YuABC, 2<sup>nd</sup> edition, Connecticut Appleton Century Crofts, 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, Lea and 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.
10. Biopharmaceutics and Relevant Pharmacokinetics by John. G Wagner and M. Pamarowski, 1st edition, Drug Intelligence Publications, Hamilton, Illinois, 1971.
11. Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James. G. Boylan, Marcel Dekker Inc, New York, 1996.
12. Basic Pharmacokinetics, 1st edition, Sunil S Jambhekar and Philip J Breen, pharmaceutical press, RPS Publishing, 2009.
13. Absorption and Drug Development- Solubility, Permeability, and Charge State, Alex Avdeef, John Wiley & Sons, Inc, 2003.

## COMPUTER AIDED DRUG DEVELOPMENT (MPH 203T)

### Scope

This course is designed to impart knowledge and 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. Basic theoretical discussions of the principles of more integrated and coherent use of computerized information (informatics) in the drug development process are provided to help the students to clarify the concepts.

### Objectives

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

- History of Computers in Pharmaceutical Research and Development
- Computational Modeling of Drug Disposition
- Computers in Preclinical Development
- Optimization Techniques in Pharmaceutical Formulation
- Computers in Market Analysis
- Computers in Clinical Development
- Artificial Intelligence (AI) and Robotics
- Computational fluid dynamics(CFD)

### THEORY

60 Hrs

1. **a. Computers in Pharmaceutical Research and Development:** A General Overview: History of Computers in Pharmaceutical Research and Development. Statistical modeling in Pharmaceutical research and development: Descriptive versus Mechanistic Modeling, Statistical Parameters, Estimation, Confidence Regions, Nonlinearity at the Optimum, Sensitivity Analysis, Optimal Design, Population Modeling. **12 Hrs**
- b. Quality-by-Design in Pharmaceutical Development:** Introduction, ICH Q8 guideline, Regulatory and industry views on QbD, Scientifically based QbD - examples of application.
2. **Computational Modeling Of Drug Disposition:** Introduction, Modeling Techniques: Drug Absorption, Solubility, Intestinal Permeation, Drug Distribution ,Drug Excretion, Active Transport; P-gp, BCRP, Nucleoside Transporters, hPEPT1, ASBT, OCT, OATP, BBB-Choline Transporter. **12 Hrs**

3. **Computer-aided formulation development:** Concept of optimization, Optimization parameters, Factorial design, Optimization technology & Screening design. Computers in Pharmaceutical Formulation: Development of pharmaceutical emulsions, microemulsion drug carriers Legal Protection of Innovative Uses of Computers in R&D, The Ethics of Computing in Pharmaceutical Research, Computers in Market analysis addition of computers in clinical development. **12 Hrs**
4. **a. Computer-aided biopharmaceutical characterization:** Gastrointestinal absorption simulation. Introduction, Theoretical background, Model construction, Parameter sensitivity analysis, Virtual trial, Fed vs. fasted state, In vitro dissolution and in vitro- in vivo correlation, Biowaiver considerations  
**b. Computer Simulations in Pharmacokinetics and Pharmacodynamics:** Introduction, Computer Simulation: Whole Organism, Isolated Tissues, Organs, Cell, Proteins and Genes.  
**c. Computers in Clinical Development:** Clinical Data Collection and Management, Regulation of Computer Systems **12 Hrs**
5. **Artificial Intelligence (AI), Robotics and Computational fluid dynamics:** General overview, “Ethical and Legal Considerations in AI and Drug Development”, Pharmaceutical Automation, Pharmaceutical applications, Advantages and Disadvantages. Tools for Machine Learning and AI in development of drug delivery systems. Current Challenges and Future Directions. **12 Hrs**

## REFERENCES

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

## COSMETICS AND COSMECEUTICALS (MPH 204T)

### Scope

This course is designed to impart knowledge and skills necessary for the fundamental need for cosmetic and cosmeceutical products.

### Objectives

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

- Key ingredients used in cosmetics and cosmeceuticals.
- Key building blocks for various formulations.
- Current technologies in the market
- Various key ingredients and basic science to develop cosmetics and cosmeceuticals
- Scientific knowledge to develop cosmetics and cosmeceuticals with desired Safety, stability and efficacy.

### THEORY 60 Hrs

1. **Cosmetics - Regulatory:** Definition of Cosmetics, Regulatory requirements for labeling of cosmetics, Regulatory provisions relating to manufacture of cosmetics- Licensing , prohibition of manufacturing and sale of cosmetics, loan licenses, offenses and penalties. misbranded and spurious cosmetics. Regulatory provisions for import of cosmetics. **12 Hrs**
2. **Cosmetics - Integumentary System and its disorder**
  - Skin Structure and its Function. Problems associated like dry skin, acne, pigmentation, heat, wrinkles and body odour.
  - Hair structure and hair growth cycle, hair related problems.
  - Oral cavity and its defects/problems associated with oral cavity.
  - Need for Cleansing and care of eye lids, lips, hands, feet, nail, scalp, neck, body and under-arms. **12 Hrs**
3. **Formulation Building blocks:** Building blocks for different product formulations of cosmetics/cosmeceuticals. Surfactants - Classification and application. Emollients, rheological additives: classification and application. Antimicrobial

used as preservatives, their merits and demerits. Factors affecting microbial preservative efficacy. Building blocks for formulation of a moisturizing cream, vanishing cream, cold cream, shampoo and toothpaste. Soaps and syndetbars.

Perfumes; Classification of perfumes. Perfume ingredients listed as allergens in EU regulation.

Controversial ingredients: Parabens, formaldehyde liberators, dioxane, sulphates. **12 Hrs**

4. **Design of cosmeceutical products:** Sun protection, sunscreens classification and regulatory aspects. Addressing dry skin, acne, sun-protection, pigmentation, prickly heat, wrinkles, body odor., dandruff, dental cavities, bleeding gums, mouth odor and sensitive teeth through cosmeceutical formulations. **12 Hrs**
5. **Herbal Cosmetics:** Herbal ingredients used in Hair care, skin care and oral care. Review of guidelines for herbal cosmetics by private bodies like cosmos with respect to preservatives, emollients, foaming agents, emulsifier and rheology modifiers. Challenges in formulating herbal cosmetics. **12 Hrs**

## REFERENCES

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

## PHARMACEUTICS PRACTICALS - II

### (MPH 205P)

1. To study the effect of temperature change , non solvent addition, incompatible polymer 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 Winnoline<sup>R</sup> software
11. In vitro cell studies for permeability and metabolism
12. DoE Using Design Expert<sup>®</sup> Software
13. Formulation data analysis Using Design Expert<sup>®</sup> Software
14. Quality-by-Design in Pharmaceutical Development
15. Computer Simulations in Pharmacokinetics and Pharmacodynamics
16. Computational Modeling 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

**PHARMACEUTICAL CHEMISTRY (MPC)**  
**MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES**  
**(MPC 101T)**

**Scope**

This subject deals with various advanced analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are NMR, Mass spectrometer, IR, HPLC, GC etc.

**Objectives**

After completion of course student is able to know about chemicals and excipients

- The analysis of various drugs in single and combination dosage forms
- Theoretical and practical skills of the instruments

**THEORY**

**60Hrs**

1. **a. UV-Visible spectroscopy:** Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV-Visible spectroscopy, Difference/ Derivative spectroscopy. **b. IR spectroscopy:** Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier - Transform IR Spectrometer, Factors affecting vibrational frequencies and Applications of IR spectroscopy, Data Interpretation. **c. Spectrofluorimetry:** Theory of Fluorescence, Factors affecting fluorescence (Characteristics of drugs that can be analysed by fluorimetry), Quenchers, Instrumentation and Applications of fluorescence spectrophotometer. **d. Flame emission spectroscopy and Atomic absorption spectroscopy:** Principle, Instrumentation, Interferences and Applications. **10 Hrs**
2. **NMR spectroscopy:** Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and <sup>13</sup>C NMR. Applications of NMR spectroscopy. **10 Hrs**
3. **Mass Spectroscopy:** Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and

MALDI, APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules, Meta stable ions, Isotopic peaks and Applications of Mass spectroscopy. **10 Hrs**

4. **Chromatography:** Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution, isolation of drug from excipients, data interpretation and applications of the following: a) Thin Layer chromatography b) High Performance Thin Layer Chromatography c) Ion exchange chromatography d) Column chromatography e) Gas chromatography f) High Performance Liquid chromatography g) Ultra High Performance Liquid chromatography h) Affinity chromatography i) Gel Chromatography. **10 Hrs**
5. **a. Electrophoresis:** Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following: a) Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresis d) Zone electrophoresis e) Moving boundary electrophoresis f) Iso electric focusing  
**b) X ray Crystallography:** Production of X rays, Different X ray methods, Bragg's law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X-ray diffraction. **10 Hrs**
6. **a. Potentiometry:** Principle, working, Ion selective Electrodes and Application of potentiometry.  
**b. Immunological assays:** RIA (Radio immuno assay), ELISA, Bioluminescence assays. **10 Hrs**

## REFERENCES

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Douglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Instrumental methods of analysis - Willards, 7th edition, CBS publishers.
4. Practical Pharmaceutical Chemistry - Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi, 1997.
5. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.

7. Pharmaceutical Analysis - Modern Methods - Part B - J W Munson, Vol 11, Marcel. Dekker Series
8. Spectroscopy of Organic Compounds, 2nd edn., P.S/Kalsi, Wiley estern Ltd., Delhi.
9. Textbook of Pharmaceutical Analysis, KA.Connors, 3rd Edition, John Wiley & Sons, 1982.

## 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

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

12 Hrs

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
- 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.

## REFERENCES

1. "Advanced Organic chemistry, Reaction, Mechanisms and Structure", J March, John Wiley and Sons, New York.
2. "Mechanism and Structure in Organic Chemistry", ES Gould, Hold Rinchart and Winston, New York.
3. "Organic Chemistry" Clayden, Greeves, Warren and Wothers., Oxford University Press 2001.
4. "Organic Chemistry" Vol I and II. I.L. Finar. ELBS, Pearson Education Lts, Dorling Kindersley (India) 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, 5<sup>th</sup> Edition (Viva Books Pvt. Ltd.)
9. Organic Synthesis - The Disconnection Approach, S. Warren, Wily India
10. Principles of Organic Synthesis, ROC Norman and JM Coxan, Nelson Thornes.
11. Organic Synthesis - Special Techniques. VK Ahluwalia and R Agarwal, Narosa Publishers.
12. Organic Reaction Mechanisms IV<sup>th</sup> Edtn, VK Ahluwalia and RK Parashar, Narosa Publishe

## 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 prerequisite 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

1. Medicinal Chemistry by Burger, Vol I -VI.
2. Wilson and Gisvold's Text book of Organic Medicinal and Pharmaceutical Chemistry, 12th 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
5. Introduction to Quantitative Drug Design by Y.C. Martin.Principles of Medicinal Chemistry by William Foye, 7th Edition, Ippincott
6. 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.

## 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  $\beta$  - 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 sylvestri*, *Salacia reticulata*, *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, <sup>1</sup>HNMR, <sup>13</sup>CNMR and MS Spectroscopy of specific drugs e.g., Penicillin, Morphine, Camphor, Vit-D, Quercetin and Digitalis glycosides. **12 Hrs**

## REFERENCES

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, Chapmanstall.
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, 13<sup>th</sup> edition.
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-schimidt reaction.
3. Benzylic 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  $\alpha, \beta$ -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**

## REFERENCES

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

## 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**

## REFERENCES

1. "Advanced Organic chemistry, Reaction, mechanisms and structure", J March, John Wiley and sons, New York.
2. "Mechanism and structure in organic chemistry", ES Gould, Hold Rinchart and Winston, New York.
3. "Organic Chemistry" Clayden, Greeves, Warren and Wothers., Oxford University Press 2001.
4. "Organic Chemistry" Vol I and II. I.L. Finar. ELBS, Sixth ed., 1995.
5. Carey, Organic chemistry, 5th edition (Viva Books Pvt. Ltd.)
6. Organic synthesis-the disconnection approach, S. Warren, Wily India
7. Principles of organic synthesis, ROC Norman and JMCoxan, 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**

- a) Extraction: Liquid equilibria, extraction with reflux, extraction with agitation, counter current extraction.
- b) Filtration: Theory of filtration, pressure and vacuum filtration, centrifugal filtration,
- c) Distillation: azeotropic and steam distillation
- d) Evaporation: Types of evaporators, factors affecting evaporation.
- e) 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<sub>2</sub>O<sub>2</sub>, sodium hypochlorite, Oxygen gas, ozonolysis, Metallic oxidizing agents.
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: B<sub>2</sub> and B<sub>12</sub>. 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, 3<sup>rd</sup> edition, Volume 2.
3. Medicinal Chemistry by Burger, 6<sup>th</sup> edition, Volume 1-8.

4. W.L. McCabe, J.C Smith, Peter Harriott. Unit operations of chemical engineering, 7th edition, McGraw Hill
5. Polymorphism in Pharmaceutical Solids .Dekker Series Volume 95 Ed: H G Brittain (1999)
6. Regina M. Murphy: Introduction to Chemical Processes: Principles, Analysis, Synthesis
7. Peter J. Harrington: Pharmaceutical Process Chemistry for Synthesis: Rethinking the Routes to Scale-Up
8. P.H.Groggins: Unit processes in organic synthesis (MGH)
9. F.A.Henglein: Chemical Technology (Pergamon)
10. M.Gopal: Dryden's Outlines of Chemical Technology, 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](http://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. NaBH<sub>4</sub> reduction of vanillin to vanillyl alcohol
14. Preparation of umbelliferone by Pechhman reaction
15. Preparation of triphenyl imidazole
16. To perform the Microwave irradiated reactions of synthetic importance (Any two)
17. Determination of log P, MR, hydrogen bond donors and acceptors of selected drugs using softwares
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

**PHARMACEUTICAL QUALITY ASSURANCE (MQA)**  
**MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES**  
**(MQA 101T)**

**Scope**

This subject deals with various advanced analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are NMR, Mass spectrometer, IR, HPLC, GC etc.

**Objectives**

After completion of course student is able to know about chemicals and excipients

- The analysis of various drugs in single and combination dosage forms
- Theoretical and practical skills of the instruments

**THEORY**

**60Hrs**

1. **a. UV-Visible spectroscopy:** Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV-Visible spectroscopy, Difference/ Derivative spectroscopy. **b. IR spectroscopy:** Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier - Transform IR Spectrometer, Factors affecting vibrational frequencies and Applications of IR spectroscopy, Data Interpretation. **c. Spectrofluorimetry:** Theory of Fluorescence, Factors affecting fluorescence (Characteristics of drugs that can be analysed by fluorimetry), Quenchers, Instrumentation and Applications of fluorescence spectrophotometer. **d. Flame emission spectroscopy and Atomic absorption spectroscopy:** Principle, Instrumentation, Interferences and Applications. **10 Hrs**
  
2. **NMR spectroscopy:** Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and <sup>13</sup>C NMR. Applications of NMR spectroscopy. **10 Hrs**
  
3. **Mass Spectroscopy:** Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight, Mass

fragmentation and its rules, Meta stable ions, Isotopic peaks and Applications of Mass spectroscopy. **10 Hrs**

4. **Chromatography:** Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution, isolation of drug from excipients, data interpretation and applications of the following: a) Thin Layer chromatography b) High Performance Thin Layer Chromatography c) Ion exchange chromatography d) Column chromatography e) Gas chromatography f) High Performance Liquid chromatography g) Ultra High Performance Liquid chromatography h) Affinity chromatography i) Gel Chromatography **10 Hrs**

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

b. **X ray Crystallography:** Production of X rays, Different X ray methods, Bragg's law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X-ray diffraction. **10 Hrs**

6. a. **Potentiometry:** Principle, working, Ion selective Electrodes and Application of potentiometry.

b. **Thermal Techniques:** 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). TGA: Principle, instrumentation, factors affecting results, advantage and disadvantages, pharmaceutical applications. **10 Hrs**

## REFERENCES

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Douglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Instrumental methods of analysis - Willards, 7th edition, CBS publishers.
4. Practical Pharmaceutical Chemistry - Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi, 1997.

5. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis - Modern Methods - Part B - J W Munson, Vol 11, Marcel. Dekker Series
8. Spectroscopy of Organic Compounds, 2nd edn., P.S/Kalsi, Wiley eastern Ltd., Delhi.
9. Textbook of Pharmaceutical Analysis, KA.Connors, 3rd Edition, John Wiley & Sons, 1982.

## QUALITY MANAGEMENT SYSTEMS

(MQA 102T)

### Scope

This course is designed to impart fundamental knowledge and concepts about various quality management principles and systems utilized in the manufacturing industry. It also aids in understanding the quality evaluation in the pharmaceutical industries.

### Objectives

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

- The importance of quality
- ISO management systems
- Tools for quality improvement
- Analysis of issues in quality
- Quality evaluation of pharmaceuticals
- Stability testing of drug and drug substances
- Statistical approaches for quality

### THEORY

60 Hrs

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

**Quality as a Strategic Decision:** Meaning of strategy and strategic quality management, mission and vision statements, quality policy, Quality objectives, strategic planning and implementation, McKinsey 7s model, Competitive analysis, Management commitment to quality  
**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 behavior, concept of internal and external customers. Case studies. **Cost of Quality:** Cost of quality, Categories of cost of Quality, Models of cost of quality, Optimising costs, Preventing cost of quality.

12 Hrs

2. **Pharmaceutical quality Management:** Basics of Quality Management, Total Quality Management (TQM), Principles of Six sigma, ISO 9001:2008, 9001:2015, ISO 14001:2004, Pharmaceutical Quality Management - ICH Q10, Knowledge management, Quality Metrics, Operational Excellence and Quality Management Review. OSHAS guidelines, NABL certification and accreditation, CFR-21 part 11, WHO-GMP requirements. **12 Hrs**
3. **Six System Inspection model:** Quality Management system, Production system, Facility and Equipment system, Laboratory control system, Materials system, Packaging and labeling system. Concept of self inspection.  
  
**Quality systems:** Change Management/ Change control. Deviations, Out of Specifications (OOS), Out of Trend (OOT), Complaints - evaluation and handling, Investigation and determination of root cause, Corrective & Preventive Actions (CAPA), Returns and Recalls, Vendor Qualification, Annual Product Reviews, Batch Review and Batch Release. Concept of IPQC, area clearance/ Line clearance. **12 Hrs**
4. **Drug Stability:** ICH guidelines for stability testing of drug substances and drug products.  
  
**Study of ICH Q8, Quality by Design and Process development report**  
  
**Quality risk management:** Introduction, risk assessment, risk control, risk review, risk management tools, HACCP, risk ranking and filtering according to ICH Q9 guidelines. **12 Hrs**
5. **Statistical Process control (SPC):** Definition and Importance of SPC, Quality measurement in manufacturing, Statistical control charts - concepts and general aspects, Advantages of statistical control, Process capability, Estimating Inherent or potential capability from a control chart analysis, Measuring process control and quality improvement, Pursuit of decreased process variability. **8 Hrs**
6. **Regulatory Compliance through Quality Management and development of Quality Culture Benchmarking:** Definition of benchmarking, Reasons for benchmarking, Types of Benchmarking, Benchmarking process, Advantages of benchmarking, Limitations of benchmarking. **4 Hrs**

## REFERENCES

1. Implementing Juran's Road Map for Quality Leadership: Benchmarks and Results, By Al Endres, Wiley, 2000
2. Understanding, Managing and Implementing Quality: Frameworks, Techniques and Cases, By Jiju Antony; David Preece, Routledge, 2002

3. Organizing for High Performance: Employee Involvement, TQM, Reengineering, and Knowledge Management in the Fortune 1000: The CEO Report By Edward E. Lawler; Susan Albers Mohrman; George Benson, Jossey-Bass, 2001
4. Corporate Culture and the Quality Organization By James W. 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.

## QUALITY CONTROL AND QUALITY ASSURANCE (MQA 103T)

### Scope

This course deals with the various aspects of quality control and quality assurance aspects of pharmaceutical industries. It covers the important aspects like cGMP, QC tests, documentation, quality certifications, GLP and regulatory affairs.

### Objectives

Upon completion of this course the student should be able to

- Understand the cGMP aspects in a pharmaceutical industry
- To appreciate the importance of documentation
- To understand the scope of quality certifications applicable to Pharmaceutical industries
- To understand the responsibilities of QA & QC departments.

### THEORY

**60 Hrs**

1. **Introduction:** Concept and evolution and scopes of Quality Control and Quality Assurance, Good Laboratory Practice, GMP, Overview of ICH Guidelines - QSEM, with special emphasis on Qseries guidelines.

Good Laboratory Practices: Scope of GLP, Definitions, Quality assurance unit, protocol for conduct of non clinical testing, control on animal house, report preparation and documentation. CPCSEA guidelines. **12 Hrs**

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 lay out, maintenance, sanitation, environmental control, utilities and maintenance of sterile areas, control of contamination and Good Warehousing Practice.

**12 Hrs**

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

In process quality control and finished products quality control for following dosage forms in Pharma industry according to Indian, US and British

pharmacopoeias: tablets, capsules, ointments, suppositories, creams, parenterals, ophthalmic and surgical products (How to refer pharmacopoeias).

**12 Hrs**

4. **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. Concepts of controlled and uncontrolled documents. Risk Management in Pharmaceutical Documentation.

Submission documents for regulators DMFs, as Common Technical Document and Electronic Common Technical Documentation (CTD, eCTD). Concept of regulated and non regulated markets.

**12 Hrs**

5. **Manufacturing operations and controls:** 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.

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

**12 Hrs**

## REFERENCES

1. Quality Assurance Guide by organization of Pharmaceutical Procedures of India, 3<sup>rd</sup> revised edition, Volume I & II, Mumbai, 1996.
2. Good Laboratory Practice Regulations, 2<sup>nd</sup> Edition, Sandy Weinberg Vol. 69, Marcel Dekker Series, 1995.
3. Quality Assurance of Pharmaceuticals- A compedium of Guide lines and Related materials Vol I & II, 2<sup>nd</sup> 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, 5. Excipients and Dosage forms, 3<sup>rd</sup> 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, 4<sup>th</sup> edition, Susmit Publishers, 2006.
10. QA Manual - D.H. Shah, 1<sup>st</sup> edition, Business Horizons, 2000.
11. Good Manufacturing Practices for Pharmaceuticals a plan for total quality control - Sidney H. Willig, Vol. 52, 3<sup>rd</sup> 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.

## PRODUCT DEVELOPMENT AND TECHNOLOGY TRANSFER (MQA 104T)

### Scope

This deal with technology transfer covers the activities associated with Drug Substance, Drug Product and analytical tests and methods, required following candidate drug selection to completion of technology transfer from R&D to the first receiving site and technology transfer related to post-marketing changes in manufacturing places.

### Objectives

Upon completion of this course the student should be able to

- To understand the new product development process
- To understand the necessary information to transfer technology from R&D to actual manufacturing by sorting out various information obtained during R&D
- To elucidate necessary information to transfer technology of existing products between various manufacturing places

### THEORY 60 Hrs

1. **Principles of Drug discovery and development:** Introduction, Clinical research process. Development and informational content for Investigational New Drugs Application (IND), New Drug Application (NDA), Abbreviated New Drug Application (ANDA), Supplemental New Drug Application (SNDA), Scale Up Post Approval Changes (SUPAC) and Bulk active chemical Post approval changes (BACPAC), Post marketing surveillance, Product registration guidelines - CDSCO, USFDA. **12 Hrs**
2. **Pre-formulation studies:** Introduction/concept, organoleptic properties, purity, impurity profiles, particle size, shape and surface area. Solubility, Methods to improve solubility of Drugs: Surfactants & its importance, co-solvency. Techniques for the study of Crystal properties and polymorphism. Pre-formulation protocol, Stability testing during product development. **12 Hrs**
3. **Pilot plant scale up:** 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. New era of drug products: opportunities and

challenges. Supply Chain Management (SCM): Ensuring the efficient and reliable flow of materials and products. **12 Hrs**

4. **Pharmaceutical packaging:** Pharmaceutical dosage form and their packaging requirements, Pharmaceutical packaging materials, Medical device packaging, Enteral Packaging, Aseptic packaging systems, Container closure systems, Issues facing modern drug packaging, Selection and evaluation of Pharmaceutical packaging materials.

**Quality control test:** Containers, closures and secondary packing materials. **12 Hrs**

5. **Technology transfer:** Development of technology by R & D, Technology transfer from R & D to production, Optimization and Production, Qualitative and quantitative technology models. Documentation in technology transfer: Development report, technology transfer plan and Exhibit. **12 Hrs**

## REFERENCES

1. The process of new drug discovery and development. I and II Edition (2006) by Charles G. Smith, James T and O. Donnell. CRC Press, Group of Taylor and Francis.
2. Leon Lac Lachman, Herbert A. Liberman, Theory and Practice of Industrial Pharmacy. Marcel Dekker Inc. New York.
3. Sidney H Willing, Murray M, Tuckerman. Williams Hitchings IV, Good manufacturing of pharmaceuticals (A Plan for total quality control) 3rd Edition. Bhalani publishing house Mumbai.
4. Tablets Vol. I, II, III by Leon Lachman, Herbert A. Liberman, Joseph B. Schwartz, 2nd Edn. (1989) Marcel Dekker Inc. New York.
5. Text book of Bio- Pharmaceutics and clinical Pharmacokinetics by Milo Gibaldi, 3<sup>rd</sup> Edn, Lea & Febriger, Philadelphia.
6. Pharmaceutical product development. Vandana V. Patreval. 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. 1<sup>st</sup> Edition(Reprint 2006). Taylor and Francis. London and New York.

**QUALITY ASSURANCE**  
**PRACTICAL - I (MQA 105P)**

**PRACTICALS**

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

15. Quality control tests for Primary and secondary packaging materials
16. Accelerated stability studies (1 experiment)
17. Improved solubility of drugs using surfactant systems (1 experiment)
18. Improved solubility of drugs using co-solvency method (1 experiment)
19. Determination of Pka and Log p of drugs.

## HAZARDS AND SAFETY MANAGEMENT

(MQA 201T)

### Scope

This course is designed to convey the knowledge necessary to understand issues related to different kinds of hazard and their management. Basic theoretical and practical discussions integrate the proficiency to handle the emergency situation in the pharmaceutical product development process and provides the principle based approach to solve the complex tribulations.

### Objectives

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

- Understand about environmental problems among learners.
- Impart basic knowledge about the environment and its allied problems.
- Develop an attitude of concern for the industry environment.
- Ensure safety standards in pharmaceutical industry
- Provide comprehensive knowledge on the safety management
- Empower an ideas to clear mechanism and management in different kinds of hazard management system
- Teach the method of Hazard assessment, procedure, methodology for provide safe industrial atmosphere.

### THEORY

60Hrs

1. **Multidisciplinary nature of environmental studies:** Natural Resources, Renewable and non-renewable resources, Natural resources and associated problems,  
a) Forest resources; b) Water resources; c) Mineral resources; d) Energy resources; e) Land resources  
**Ecosystems:** Concept of an ecosystem and Structure and function of an ecosystem. Environmental hazards: Hazards based on Air, Water, Soil and Radioisotopes. **12 Hrs**
2. **Air based hazards:** Sources, Types of Hazards, Air circulation maintenance industry for sterile area and non sterile area, Preliminary Hazard Analysis (PHA) Fire protection system. **12 Hrs**

- 3 **Chemical based hazards:** Sources of chemical hazards, Hazards of Organic synthesis, sulphonating hazard, Organic solvent hazard, Control measures for chemical hazards, Management of combustible gases, Toxic gases and Oxygen displacing gases management, Regulations for chemical hazard, Management of over-Exposure to chemicals and TLV concept. **12 Hrs**
- 4 **Fire and Explosion:** Introduction, Industrial processes and hazards potential, mechanical electrical, thermal and process hazards. Safety and hazards regulations, 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. Preventive and protective management from fires and explosion- electricity passivation, ventilation, and sprinkling, proofing, relief systems -relief valves, flares, scrubbers. **12 Hrs**
- 5 **Hazard and risk management:** Self-protective measures against workplace hazards. Critical training for risk management, Process of hazard management, ICH guidelines on risk assessment and Risk management methods and Tools Factory act and rules, fundamentals of accident prevention, elements of safety programme and safety management, Physicochemical measurements of effluents, BOD, COD, Determination of some contaminants, Effluent treatment procedure, Role of emergency services. **12 Hrs**

## REFERENCES

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

## PHARMACEUTICAL VALIDATION (MQA 202T)

### Scope

The main purpose of the subject is to understand about validation and how it can be applied to industry and thus improve the quality of the products. The subject covers the complete information about validation, types, methodology and application.

### Objectives

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

- The concepts of calibration, qualification and validation
- The qualification of various equipments and instruments
- Process validation of different dosage forms
- Validation of analytical method for estimation of drugs
- Cleaning validation of equipments employed in the manufacture of pharmaceuticals

### THEORY

60 Hrs

1. **Introduction to validation:** Definition of Calibration, Qualification and Validation, Scope, frequency and importance. Difference between calibration and validation. Calibration of weights and measures. Advantages of Validation, scope of Validation, Organization for Validation, Validation Master plan, Types of Validation, Streamlining of qualification & Validation process and Validation Master Plan.

**Qualification:** User requirement specification, Design qualification, Factory Acceptance Test (FAT)/Site Acceptance Test (SAT), Installation qualification, Operational qualification, Performance qualification, Re-Qualification (Maintaining status- Calibration Preventive Maintenance, Change management). **10 Hrs**

2. **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. Qualification of analytical instruments: UV-Visible spectrophotometer, FTIR, DSC, GC, HPLC, HPTLC, LC-MS. **10 Hrs**

3. **Qualification of laboratory equipments:** Hardness tester, Friability test apparatus, tap density tester, Disintegration tester, Dissolution test apparatus  
Validation of Utility systems: Pharmaceutical water system & pure steam, HVAC system, Compressed air and nitrogen. **10 Hrs**
4. **Process Validation:** 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 validation, USFDA guidelines on Process Validation- A life cycle approach. Analytical method validation: General principles, Validation of analytical method as per ICH guidelines and USP. **10 Hrs**
5. **Cleaning Validation:** Cleaning Method development, Validation of analytical method used in cleaning, Cleaning of Equipment, Cleaning of Facilities. Cleaning in place (CIP). Validation of facilities in sterile and non-sterile plant. Computerized system validation: Electronic records and digital signature - 21 CFR Part 11 and GAMP **10 Hrs**
6. **General Principles of Intellectual Property:** 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 applications; 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. Significance of transfer technology (TOT), IP and ethics-positive and negative aspects of IPP; Societal responsibility, avoiding unethical practices. **10Hrs**

## REFERENCES

1. B. T. Loftus & R. A. Nash, "Pharmaceutical Process Validation", Drugs and Pharm Sci. Series, Vol. 129, 3rd Ed., Marcel Dekker Inc., N.Y.
2. The Theory & Practice of Industrial Pharmacy, 3rd edition, Leon Lachman, Herbert A. Lieberman, Joseph. L. Karig, Varghese Publishing House, Bombay.
3. Validation Master plan by Terveeks or Deeks, Davis Harwood International publishing.

4. Validation of Aseptic Pharmaceutical Processes, 2nd Edition, by Carleton & Agalloco,
5. Pharmaceutical Processes Validation an international 3rd Edition, -Marcel Dekker AG.
6. Michael Levin, Pharmaceutical Process Scale-Up”, Drugs and Pharm. Sci. Series, Vol. 157,2nd Ed., Marcel Dekker Inc., N.Y.
7. Validation Standard Operating Procedures: A Step by Step Guide for Achieving Compliance in the Pharmaceutical, Medical Device, and Biotech Industries, Syed Imtiaz Haider
8. Pharmaceutical Equipment Validation: The Ultimate Qualification Handbook, Phillip A. Cloud, Interpharm Press
9. Validation of Pharmaceutical Processes: Sterile Products, Frederick J. Carlton (Ed.) and James Agalloco (Ed.), Marcel Dekker
10. Analytical Method validation and Instrument Performance Verification by Churg Chan, Heiman Lam, Y.C. Lee, Yue. Zhang, Wiley Interscience.
11. Huber L. Validation and Qualification in Analytical Laboratories. Informa Healthcare
12. Wingate G. Validating Corporate Computer Systems: Good IT Practice for Pharmaceutical Manufacturers. Interpharm Press
13. LeBlanc DA. Validated Cleaning Technologies for Pharmaceutical Manufacturing. Interpharm Press.

## AUDITS AND REGULATORY COMPLIANCE

(MPA 203T)

### Scope

This course deals with the understanding and process for auditing in pharmaceutical industries. This subject covers the methodology involved in the auditing process of different in pharmaceutical industries.

### Objectives

Upon completion of this course the student should be able to

- To understand the importance of auditing
- To understand the methodology of auditing
- To carry out the audit process
- To prepare the auditing report
- To prepare the check list for auditing

### THEORY

60 Hrs

1. **Introduction:** Objectives, Management of audit, Responsibilities, Planning process, information gathering, administration, Classifications of deficiencies  
12 Hrs
2. **Role of quality systems and audits in pharmaceutical manufacturing environment:** cGMP Regulations, Quality assurance functions, Quality systems approach, Management responsibilities, Resource, Manufacturing operations, Evaluation activities, Transitioning to quality system approach, Audit checklist for drug industries.  
12 Hrs
3. **Auditing of vendors and production department:** Bulk Pharmaceutical Chemicals and packaging material Vendor audit, Warehouse and weighing, Dry Production: Granulation, tableting, coating, capsules, sterile production and packaging.  
12 Hrs
4. **Auditing of Microbiological laboratory:** Auditing the manufacturing process, Product and process information, General areas of interest in the building raw materials, Water, Packaging materials. Auditing of Sterilization Processes  
12 Hrs

5. **Auditing of Quality Assurance and engineering department:** Quality Assurance Maintenance, Critical systems: HVAC, Water, Water for Injection systems, ETP. **12 Hrs**

#### **REFERENCES**

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

## PHARMACEUTICAL MANUFACTURING TECHNOLOGY (MQA 204T)

### Scope

This course is designed to impart knowledge and skills necessary to train the students with the industrial activities during Pharmaceutical Manufacturing.

### Objectives

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

- The common practice in the pharmaceutical industry developments, plant layout and production planning
- Will be familiar with the principles and practices of aseptic process technology, non sterile manufacturing technology and packaging technology.
- Have a better understanding of principles and implementation of Quality by design (QbD) and process analytical technology (PAT) in pharmaceutical manufacturing

### THEORY

60 Hrs

**Pharmaceutical industry developments:** Legal requirements and Licenses for API and formulation industry, Plant location Factors influencing **Plant layout:** Factors influencing, Special provisions, Storage space requirements, sterile and aseptic area layout. Waste management in pharmaceutical industry

1. **Production planning:** General principles, production systems, calculation of standard cost, process planning, routing, loading, scheduling, dispatching of records, production control. **12 Hrs**
2. **Aseptic process technology:** Manufacturing, manufacturing flowcharts, in process-quality control tests for following sterile dosage forms: Ointment, Suspension and Emulsion, Dry powder, Solution (Small Volume & large Volume).

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

**Process Automation in Pharmaceutical Industry:** With specific reference to manufacturing of sterile semisolids, Small Volume Parenterals & Large Volume

Parenterals (SVP & LVP), Monitoring of Parenteral manufacturing facility, Cleaning in Place (CIP), Sterilization in Place (SIP), Prefilled Syringe, Powdered Jet, Needle Free Injections, and Form Fill Seal Technology (FFS).

**Lyophilization technology: Principles, process, equipment. 12 Hrs**

3. **Non sterile manufacturing process technology:** Manufacturing, manufacturing flowcharts, in process-quality control tests for following Non-Sterile solid dosage forms: Tablets (compressed & coated), Capsules (Hard & Soft). **Advance non-sterile solid product manufacturing technology:** Process Automation in Pharmaceutical Industry with specific reference to manufacturing of tablets and coated products, Improved Tablet Production: Tablet production process, granulation and pelletization equipments, continuous and batch mixing, rapid mixing granulators, rota granulators, spheronizers and marumerisers, and other specialized granulation and drying equipments. Problems encountered.

**Coating technology:** Process, equipments, particle coating, fluidized bed coating, application techniques. Problems encountered. **12 Hrs**

- 4 **Containers and closures for pharmaceuticals:** Types, performance, assuring quality of glass; types of plastics used, Drug plastic interactions, biological tests, modification of plastics by drugs; different types of closures and closure liners; film wrapper; blister packs; bubble packs; shrink packaging; foil / plastic pouches, bottle seals, tape seals, breakable seals and sealed tubes; quality control of packaging material and filling equipment, flexible packaging, product package compatibility, transit worthiness of package, Stability aspects of packaging. Evaluation of stability of packaging material. **12 Hrs**
- 5 **Quality by design (QbD) and process analytical technology (PAT):** Current approach and its limitations. Why QbD is required, Advantages, Elements of QbD, Terminology: QTPP. CMA, CQA, CPP, RLD, Design space, Design of Experiments, Risk Assessment and mitigation/minimization. Quality by Design, Formulations by Design, QbD for drug products, QbD for Drug Substances, QbD for Excipients, Analytical QbD. FDA initiative on process analytical technology. PAT as a driver for improving quality and reducing costs: quality by design (QbD), QA, QC and GAMP. PAT guidance, standards and regulatory requirements. **12 Hrs**

## REFERENCES

1. Lachman L, Lieberman HA, Kanig JL. The theory and practice of industrial pharmacy, 3 rd ed., Varghese Publishers, Mumbai 1991.

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

**QUALITY ASSURANCE PRACTICAL - II PRACTICALS  
(MQA 205P)**

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 SO<sub>2</sub> using Colorimetric method
7. Qualification of following Pharma equipment
  - a. Autoclave
  - b. Hotair oven
  - c. Powder Mixer (Dry)
  - d. Tablet Compression Machine
8. Validation of an analytical method for a drug
9. Validation of a processing area
10. Qualification of at least two analytical instruments
11. Cleaning validation of one equipment
12. Qualification of Pharmaceutical Testing Equipment (Dissolution testing apparatus, Friability Apparatus, Disintegration Tester)
13. Check list for Bulk Pharmaceutical Chemicals vendors
14. Check list for tableting production.
15. Check list for sterile production area
16. Check list for Water for injection.
17. Design of plant layout: Sterile and non-sterile
18. Case study on application of QbD
19. Case study on application of PAT

**PHARMACY PRACTICE (MPP)**  
**CLINICAL PHARMACY PRACTICE**  
**(MPP 101T)**

**Scope**

This course is designed to impart the basic knowledge and skills that are required to practice pharmacy including the provision of pharmaceutical care services to both healthcare professionals and patients in clinical settings.

**Objectives**

Upon completion of this course it is expected that students shall be able to:

- Understand the elements of pharmaceutical care and provide comprehensive patient care services
- Interpret the laboratory results to aid the clinical diagnosis of various disorders
- Provide integrated, critically analyzed medicine and poison information to enable healthcare professionals in the efficient patient management

**THEORY**

**60 Hrs**

1. **Introduction to Clinical Pharmacy:** Definition, evolution and scope of clinical pharmacy, International and national scenario of clinical pharmacy practice, Pharmaceutical care Clinical Pharmacy Services: Ward round participation, Drug therapy review (Drug therapy monitoring including medication order review, chart endorsement, clinical review and pharmacist interventions) **12 Hrs**
2. **Clinical Pharmacy Services:** Patient medication history interview, Basic concept of medicine and poison information services, Basic concept of pharmacovigilance, Hemovigilance, Materiovigilance and AEFI, Patient medication counselling, Drug utilisation evaluation, Documentation of clinical pharmacy services, Quality assurance of clinical pharmacy services. **12 Hrs**
3. **Patient Data Analysis:** Patient Data & Practice Skills: Patient's case history - its structure and significances in drug therapy management, Common medical abbreviations and terminologies used in clinical practice, Communication skills: verbal and non-verbal communications, its applications in patient care services.

**Lab Data Interpretation:** Hematological tests, Renal function tests, Liver function tests **12 Hrs**

4. **Lab Data Interpretation:** Tests associated with cardiac disorders, Pulmonary function tests, Thyroid function tests, Fluid and electrolyte balance, Microbiological culture sensitivity tests. **12 Hrs**
5. **Medicines & Poison Information Services Medicine Information Service:** Definition and need for medicine information service, Medicine information resources, Systematic approach in answering medicine information queries, Preparation of verbal and written response, Establishing a drug information centre. **Poison Information Service:** Definition, need, organization and functions of poison information centre. **12 Hrs**

## **REFERENCES**

1. A Textbook of Clinical Pharmacy Practice - Essential concepts and skills - Parthasarathi G, Karin Nyfort-Hansen and Milap Nahata.
2. Practice Standards and Definitions - The Society of Hospital Pharmacists of Australia.
3. Basic skills in interpreting laboratory data - Scott LT, American Society of Health System Pharmacists Inc.
4. Relevant review articles from recent medical and pharmaceutical literature.

## PHARMACOTHERAPEUTICS-I

(MPP 102T)

### Scope

This course aims to enable the students to understand the different treatment approaches in managing various disease conditions. Also, it imparts knowledge and skills in optimizing drug therapy of a patient by individualizing the treatment plan through evidence-based medicines.

### Objectives

- Upon completion of this course it is expected that students shall be able to:
- Describe and explain the rationale for drug therapy
- Summarize the therapeutic approach for management of various disease conditions including reference to the latest available evidence
- Discuss the clinical controversies in drug therapy and evidence based medicine
- Prepare individualized therapeutic plans based on diagnosis
- Identify the patient specific parameters relevant in initiating drug therapy, and monitoring therapy (including alternatives, time- course of clinical and laboratory indices of therapeutic response and adverse effect/s)

### THEORY

60 Hrs

Etiopathogenesis and pharmacotherapy of diseases associated with following systems

1. **Cardiovascular system:** Hypertension, Congestive cardiac failure, Acute coronary syndrome, Arrhythmias, Hyperlipidemias. **12 Hrs**
2. **Respiratory system:** Asthma, Chronic obstructive airways disease, Drug induced pulmonary diseases  
**Endocrine system:** Diabetes Mellitus, Thyroid diseases **12 Hrs**
3. **Gastrointestinal system:** Peptic ulcer diseases, Reflux esophagitis, Inflammatory bowel diseases, Jaundice & hepatitis **12 Hrs**
4. **Gastrointestinal system:** Cirrhosis, Diarrhea and Constipation, Drug-induced liver disease

**Hematological diseases:** Anemia, Deep vein thrombosis, Drug induced hematological disorders. **12 Hrs**

5. **Bone and joint disorders:** Rheumatoid arthritis, Osteoarthritis, Gout, Osteoporosis

**Dermatological Diseases:** Psoriasis, Eczema and scabies, impetigo, drug induced skin disorders

**Ophthalmology:** Conjunctivitis, Glaucoma **12 Hrs**

## REFERENCES

1. Roger and Walker. Clinical Pharmacy and Therapeutics - Churchill Livingstone publication
2. Joseph T. Dipiro et al. Pharmacotherapy: A Pathophysiologic Approach- Appleton & Lange
3. Robins SL. Pathologic basis of disease -W.B. Saunders publication
4. Eric T. Herfindal. Clinical Pharmacy and Therapeutics- Williams and Wilkins Publication
5. Lloyd Young and Koda-Kimble MA Applied Therapeutics: The clinical Use of Drugs- LippincottWilliams and Wilkins
6. Chisholm- Burns Wells Schwinghammer Malone and Joseph P Dipiro. Pharmacotherapy Principles and practice-- McGraw Hill Publication
7. Carol Mattson Porth. Principles of Pathophysiology- Lippincott Williams and Wilkins
8. Harrison's. Principles of Internal Medicine - McGraw Hill
9. Relevant review articles from recent medical and pharmaceutical literature

## HOSPITAL & COMMUNITY PHARMACY (MPP 103T)

### Scope

This course is designed to impart basic knowledge and skills that are required to practice pharmacy in both hospital and community settings.

### Objectives

Upon completion of this course it is expected that students shall be able to:

- Understand the organizational structure of hospital pharmacy
- Understand drug policy and drug committees
- Know about procurement & drug distribution practices
- Know the admixtures of radiopharmaceuticals
- Understand the community pharmacy management
- Know about value added services in community pharmacies

### THEORY

**60 Hrs**

1. **Introduction to Hospitals** - Definition, classification, organizational structure  
**Hospital Pharmacy:** Definition, Relationship of hospital pharmacy department with other departments, Organizational structure, legal requirements, work load statistics, Infrastructural requirements, Hospital Pharmacy Budget and Hospital Pharmacy management  
**Hospital Drug Policy:** Pharmacy & Therapeutics Committee, Infection Control committee, Research & Ethics Committee, Management of Medicines as per NABH **12 Hrs**
2. **Hospital Formulary Guidelines** and its development, Developing Therapeutic guidelines, Drug procurement process, and methods of Inventory control, Methods of Drug distribution, Intravenous admixtures, Hospital Waste Management . **12 Hrs**
3. **Continuing Pharmacy Education (CPE) & Its importance:** Training of technical staff, training and continuing education for pharmacists, Pharmacy students, Medical staff and students, Nursing staff and students, Formal and informal meetings and lectures, Drug and therapeutics newsletter. **Community**

**Pharmacy Practice:** Definition, roles & responsibilities of community pharmacists, and their relationship with other health care providers.

**Community Pharmacy management:** Legal requirements to start community pharmacy, site selection, lay out & design, drug display, super drug store model, accounts and audits, Good dispensing practices, Different softwares & databases used in community pharmacies. Entrepreneurship in community pharmacy. **12 Hrs**

4. **Handling of prescription** - Legal requirements & interpretation, prescription related problems

**Good Pharmacy practice guidelines:** Head ache, pyrexia, menstrual pains, food and drug allergy

**Good Dispensing practice guidelines:** Rational use of over the counter medications Medication counseling and use of patient information leaflets Medication adherence - Definition, factors influencing adherence behavior, strategies to improve medication adherence Patient referrals to the doctors ADR monitoring in community pharmacies **12 Hrs**

5. **National Health Promotion : Dengue & Corona control programs** Definition and health promotion activities, family planning, Health screening services, first aid, prevention of communicable and non-communicable diseases, smoking cessation, Child & mother care

**National Health Programs-** Role of Community Pharmacist in Malaria and TB control programs

**Home Medicines review program** - Definition, objectives, Guidelines, method and outcomes

**Research in community pharmacy Practice** **12 Hrs**

## REFERENCES

1. Hospital Pharmacy - Hassan WE. Lea and Febiger publication.
2. Textbook of hospital pharmacy - Allwood MC and Blackwell.
3. Avery's Drug Treatment, Adis International Limited.
4. Community Pharmacy Practice - Ramesh Adepur, BSP Publishers, Hyderabad
5. Remington Pharmaceutical Sciences.
6. Relevant review articles from recent medical and pharmaceutical literature

## CLINICAL RESEARCH

(MPP 104T)

### Scope

This course aims to provide the students an opportunity to learn drug development process especially the phases of clinical trials and also the ethical issues involved in the conduct of clinical research. Also, it aims to impart knowledge and develop skills on conceptualizing, designing, conducting and managing clinical trials.

### Objectives

Upon completion of this course it is expected that students shall be able to:

- Know the new drug development process.
- Understand the regulatory and ethical requirements.
- Appreciate and conduct the clinical trials activities
- Know safety monitoring and reporting in clinical trials
- Manage the trial coordination process

### THEORY

60 Hrs

1. **Drug development process:** Introduction, various approaches to drug discovery, Investigational new drug application submission Ethics in Biomedical Research: Ethical Issues in Biomedical Research - Principles of ethics in biomedical research, Ethical committee [institutional review board] - its constitution and functions, Challenges in implementation of ethical guidelines, ICH GCP guidelines and ICMR guidelines in conduct of Clinical trials, **New NDCT guidelines 2019:** Constitution, Roles and responsibilities of ethics committee as per NDCT guidelines, Drug Safety Reporting. **12 Hrs**
2. **Types and Designs used in Clinical Research:** Planning and execution of clinical trials, Various Phases of clinical trials, Bioavailability and Bioequivalence studies, Randomization techniques (Simple randomization, restricted randomization, blocking method and stratification), Types of research designs based on Controlling Method (Experimental, Quasi experimental, and Observational methods) Time Sequences (Prospective and Retrospective), Sampling methods (Cohort study, case Control study and cross sectional study), Health outcome measures (Clinical & Physiological, Humanistic and economic) Clinical Trial Study team: Roles and responsibilities of: Investigator, Study Coordinator, Sponsor, Monitor, Contract Research Organization. **12 Hrs**

3. **Clinical trial Documents:** Guidelines to the preparation of following documents: Protocols, Investigator's Brochure, Informed Consent Form, Case report forms, Contracts and agreements, Dairy Cards

**Clinical Trial Start up activities:** Site Feasibility Studies, Site/Investigator selection, Pre-study visit, Investigator meeting, Clinical trial agreement execution, Ethics committee document preparation and submission **12 Hrs**

4. **Investigational Product:** Procurement and Storage of investigation product

**Filing procedures:** Essential documents for clinical trial, Trial Master File preparation and maintenance, Investigator Site File, Pharmacy File, Site initiation visit, Conduct, Report and Follow up

**Clinical Trial Monitoring and Close out:**

**Preparation and conduct of monitoring visit:** Review of source documents, CRF, ICF, IP storage, accountability and reconciliation, Study Procedure, EC communications, Safety reporting, Monitoring visit reporting and follow-up  
**Close-Out visit:** Study related documents collection, Archival requirement, Investigational Product reconciliation and destruction,

**Close-Out visit report.**

**12 Hrs**

5. **Quality Assurance and Quality Control in Clinical Trials:** Types of audits, Audit criteria, Audit process, Responsibilities of stakeholders in audit process, Audit follow-up and documentation, Audit resolution and Preparing for FDA inspections, Fraud and misconduct management

**Data Management**

**Infrastructure and System Requirement for Data Management:** Electronic data capture systems, Selection and implementation of new systems, System validation and test procedures, Coding dictionaries, Data migration and archival  
**Clinical Trial Data Management:** Standard Operating Procedures, Data management plan, CRF & Data base design considerations, Study set-up, Data entry, CRF tracking and corrections, Data cleaning, Managing laboratory and ADR data, Data transfer and database lock, Quality Control and Quality Assurance in CDM, Data mining and warehousing. **12 Hrs**

## REFERENCES

1. Principles and practice of pharmaceutical medicine, Second edition. Authors:Lionel. D. Edward, Aadrew.J.Flether Anthony W Fos , Peter D Sloaier Publisher:Wiley;

2. Handbook of clinical research. Julia Lloyd and Ann Raven Ed. Churchill Livingstone
3. Principles of Clinical Research edited by Giovanna di Ignazio, Di Giovanna and Haynes.
4. Central Drugs Standard Control Organization. Good Clinical Practices-Guidelines for Clinical Trials on Pharmaceutical Products in India. New Delhi: Ministry of Health.
5. International Conference on Harmonisation of Technical requirements for registration of Pharmaceuticals for human use. ICH Harmonised Tripartite Guideline. Guideline for Good Clinical Practice.E6; May 1996.
6. Ethical Guidelines for Biomedical Research on Human Subjects. Indian Council of Medical Research, New Delhi.
7. Textbook of Clinical Trials edited by David Machin, Simon Day and Sylvan Green, John Wiley and Sons.
8. Clinical Data Management edited by R K Rondels, S A Varley, C F Webbs. Second Edition, Jan 2000, Wiley Publications.
9. Goodman & Gilman: JG Hardman, LE Limbard, McGraw Hill Publications.
10. Relevant review articles from recent medical and pharmaceutical literature.

## **PHARMACY PRACTICE PRACTICAL - I**

### **(MPP 105P)**

Pharmacy Practice practical component includes experiments covering important topics of the courses Clinical Pharmacy Practice, Pharmacotherapeutics-I, Hospital & Community Pharmacy and Clinical Research.

#### **List of Experiments (24)**

1. Treatment Chart Review (one)
2. Medication History Interview (one)
3. Patient Medication Counseling (two)
4. Drug Information Query (two)
5. Poison Information Query (one)
6. Lab Data Interpretation (two)
7. Presentation of clinical cases of various disease conditions adopting Pharmaceutical Care Plan Model (eight)
8. ABC Analysis of a given list of medications (one)
9. Preparation of content of a medicine, with proper justification, for the inclusion in the hospital formulary (one)
10. Formulation and dispensing of a given IV admixtures (one)
11. Preparation of a patient information leaflet (two)
12. Preparation of Study Protocol (one)
13. Preparation of Informed Consent Form (one)

## PRINCIPLES OF QUALITY USE OF MEDICINES (MPP 201T)

### Scope:

This course is designed to impart basic knowledge and skills that are required to practice quality use of medicines (QUM) in different healthcare settings and also to promote quality use of medicines, in clinical practice, through evidence-based medicine approach.

### Objectives:

Upon completion of this course it is expected that students shall be able to:

- Understand the principles of quality use of medicines
- Know the benefits and risks associated with use of medicines
- Understand regulatory aspects of quality use of medicines
- Identify and resolve medication related problems
- Promote quality use of medicines
- Practice evidence-based medicines

### THEORY

60 Hrs

1. **Introduction to Quality use of medicines (QUM):** Definition and Principles of QUM, Key partners and responsibilities of the partners, Building blocks in QMC, Evaluation process in QMC, Communication in QUM, Cost effective prescribing. **12 Hrs**
2. **Concepts in QUM Evidence based medicine:** Definition, concept of evidence based medicine, Approach and practice of evidence based medicine in clinical settings  
  
**Essential drugs:** Definition, need, concept of essential drug, National essential drug policy and list  
  
**Rational drug use:** Definition, concept and need for rational drug use, Rational drug prescribing, Role of pharmacist in rational drug use. **12 Hrs**
3. **QUM in various settings:** Hospital settings, Ambulatory care/Residential care, Role of health care professionals in promoting the QUM, Strategies to promote the QUM, Impact of QUM on E-health, integrative medicine and multidisciplinary care.

**QUM in special population:** Pediatric prescribing, Geriatric prescribing, Prescribing in pregnancy and lactation, Prescribing in immune compromised and organ failure patients. **12 Hrs**

4. **Regulatory aspects of QUM in India:** Regulation including scheduling, Regulation of complementary medicines, Regulation of OTC medicines, Professional responsibility of pharmacist, Role of industry in QUM in medicine development. **12 Hrs**

5. **Medication errors:** Definition, categorization and causes of medication errors, Detection and prevention of medication errors, Role of pharmacist in monitoring and management of medication errors

**Pharmacovigilance:** Definition, aims and need for pharmacovigilance, Types, predisposing factors and mechanism of adverse drug reactions (ADRs), Detection, reporting and monitoring of ADRs, Causality assessment of ADRs, Management of ADRs, Role of pharmacist in pharmacovigilance. **12 Hrs**

#### REFERENCES:

1. A Textbook of Clinical Pharmacy Practice - Essential concepts and skills - Parthasarathi G, Karin Nyfort-Hansen and Milap Nahata
2. Andrews EB, Moore N. Mann's Pharmacovigilance
3. Dipiro JT, Talbert RL, Yee GC. Pharmacotherapy: A Pathophysiologic Approach
4. Straus SE, Richardson WS, Glasziou P, Haynes RB. Evidence-Based Medicine: How to practice and teach it
5. Cohen MR. Medication Errors
6. Online:
  - [http://medicinesaustralia.com.au/files/2012/05/MA\\_QUM\\_External\\_Reduced.pdf](http://medicinesaustralia.com.au/files/2012/05/MA_QUM_External_Reduced.pdf)
  - <http://curriculum.racgp.org.au/statements/quality-use-of-medicines/>
  - [http://www.rug.nl/research/portal/files/14051541/Chapter\\_2.pdf](http://www.rug.nl/research/portal/files/14051541/Chapter_2.pdf)
7. Relevant review articles from recent medical and pharmaceutical literature.

## PHARMACOTHERAPEUTICS II

(MPP 202T)

### Scope

This course aims to enable the students to understand the different treatment approaches in managing various disease conditions. Also, it imparts knowledge and skills in optimizing drug therapy of a patient by individualizing the treatment plan through evidence-based medicines.

### Objectives

Upon completion of this course it is expected that students shall be able to:

- Describe and explain the rationale for drug therapy
- Summarize the therapeutic approach for management of various disease conditions including reference to the latest available evidence
- Discuss the clinical controversies in drug therapy and evidence based medicine
- Prepare individualized therapeutic plans based on diagnosis
- Identify the patient specific parameters relevant in initiating drug therapy, and monitoring therapy (including alternatives, time- course of clinical and laboratory indices of therapeutic response and adverse effect/s)

### THEORY

60 Hrs

1. **Nervous system:** Epilepsy, Parkinson's disease, Stroke, Headache, Alzheimer's disease, Neuralgias and Pain pathways and Pain management. **12 Hrs**
2. **Psychiatric disorders:** Schizophrenia, Depression, Anxiety disorders, Sleep disorders, Drug induced psychiatric disorders  
**Renal system:** Acute renal failure, Chronic renal failure, Renal dialysis, Drug induced renal disease **12 Hrs**
3. **Infectious diseases:** General guidelines for the rational use of antibiotics and surgical prophylaxis, Urinary tract infections, Respiratory tract infections, Gastroenteritis, Tuberculosis, Malaria, Bacterial endocarditis, Septicemia. **12 Hrs**
4. **Infectious diseases:** Meningitis, HIV and opportunistic infections, Rheumatic fever, Dengue fever, H1N1, Helmenthiasis, Fungal infections  
**Gynecological disorders:** Dysmenorrhea, Hormone replacement therapy. **12 Hrs**

5. **Oncology:** General principles of cancer chemotherapy, pharmacotherapy of breast cancer, lung cancer, head & neck cancer, hematological malignancies, Management of nausea and vomiting, Palliative care **12 Hrs**

## REFERENCES

1. Roger and Walker. Clinical Pharmacy and Therapeutics - Churchill Livingstone publication.
2. Joseph T. Dipiro et al. Pharmacotherapy: A Pathophysiologic Approach- Appleton & Lange
3. Robins SL. Pathologic basis of disease -W.B. Saunders publication
4. Eric T. Herfindal. Clinical Pharmacy and Therapeutics- Williams and Wilkins Publication
5. Lloyd Young and Koda-Kimble MA Applied Therapeutics: The clinical Use of Drugs- Lippincott Williams and Wilkins
6. Chisholm- Burns Wells Schwinghammer Malone and Joseph P Dipiro. Pharmacotherapy Principles and practice-- McGraw Hill Publication
7. Carol Mattson Porth. Principles of Pathophysiology- Lippincott Williams and Wilkins
8. Harrison's. Principles of Internal Medicine - McGraw Hill
9. Relevant review articles from recent medical and pharmaceutical literature

## CLINICAL PHARMACOKINETICS AND THERAPEUTIC DRUG MONITORING (MPP 203T)

### Scope

This course is designed to enable students to understand the basic principles and applications of pharmacokinetics in designing the individualized dosage regimen, to interpret the plasma drug concentration profile in altered pharmacokinetics, drug interactions and in therapeutic drug monitoring processes to optimize the drug dosage regimen. Also, it enables students to understand the basic concepts of pharmacogenetics, pharmacometrics for modeling and simulation of pharmacokinetic data.

### Objectives

Upon completion of this course it is expected that students shall be able to:

- Design the drug dosage regimen for individual patients
- Interpret and correlate the plasma drug concentrations with patients' therapeutic outcomes
- Recommend dosage adjustment for patients with renal/ hepatic impairment
- Recommend dosage adjustment for paediatrics and geriatrics
- Manage pharmacokinetic drug interactions
- Apply pharmacokinetic parameters in clinical settings
- Interpret the impact of genetic polymorphisms of individuals on pharmacokinetics and or pharmacodynamics of drugs
- Do pharmacokinetic modeling for the given data using the principles of pharmacometrics

### THEORY

60 Hrs

1. **Introduction to Clinical pharmacokinetics:** Compartmental and Non compartmental models, Renal and non-renal clearance, Organ extraction and models of hepatic clearance, Estimation and determinants of bioavailability, Multiple dosing, Calculation of loading and maintenance doses

**Designing of dosage regimens:** Determination of dose and dosing intervals, Conversion from intravenous to oral dosing, Nomograms and Tabulations in designing dosage regimen.

12 Hrs

2. **Pharmacokinetics of Drug Interaction:** Pharmacokinetic drug interactions, Inhibition and Induction of Drug metabolism, Inhibition of Biliary Excretion  
  
**Pharmacogenetics:** Genetic polymorphism in Drug metabolism: Cytochrome P-450 Isoenzymes, Genetic Polymorphism in Drug Transport and Drug Targets, Pharmacogenetics and Pharmacokinetic / Pharmacodynamic considerations  
  
**Introduction to Pharmacometrics:** Introduction to Bayesian Theory, Adaptive method or Dosing with feedback, Analysis of Population pharmacokinetic Data. **12 Hrs**
3. **Non Linier Mixed Effects Modelling:** The Structural or Base Model, Modeling Random Effects, Modeling Covariate Relationships, Mixture Model, Estimation Methods, Model Building Techniques, Covariate Screening Methods, Testing the model assumptions, Precision of the parameter estimates and confidence intervals, Model misspecification and violation of the model assumptions, Model Validation, Simulation of dosing regimens and dosing recommendations, Pharmacometrics software. **12 Hrs**
- 4 **Altered Pharmacokinetics:** Drug dosing in the elderly, Drug dosing in the paediatrics, Drug dosing in the obese patients, Drug dosing in the pregnancy and lactation, Drug dosing in the renal failure and extracorporeal removal of drugs, Drug dosing in the in hepatic failure. **12 Hrs**
5. **Therapeutic Drug monitoring:** Introduction, Individualization of drug dosage regimen (Variability - Genetic, age, weight, disease and Interacting drugs), Indications for TDM, Protocol for TDM, Pharmacokinetic/Pharmacodynamic Correlation in drug therapy, TDM of drugs used in the following conditions: Cardiovascular disease: Digoxin, Lidocaine, Amiodarone; Seizure disorders: Phenytoin, Carbamazepine, Sodium Valproate; Psychiatric conditions: Lithium, Fluoxetine, Amitriptyline; Organ transplantations: Cyclosporine; Cytotoxic Agents: Methotrexate, 5-FU, Cisplatin; Antibiotics: Vancomycin, Gentamicin, Meropenem. **12Hrs**

## REFERENCES

1. Leon Shargel, Susanna Wu-Pong, Andrew Yu. Applied Biopharmaceutics & Pharmacokinetics. New York: Mc Graw Hill.
2. Peter L. Bonate. Pharmacokinetic - Pharmacodynamic Modeling and Simulation. Springer Publications.
3. Michael E. Burton, Leslie M. Shaw, Jerome J. Schentag, William E. Evans. Applied Pharmacokinetics & Pharmacodynamics: 5. Principles of Therapeutic Drug Monitoring. lippincott Williams & Wilkins.

4. Steven How-Yan Wong, Irving Sunshine. Handbook of Analytical Therapeutic Drug Monitoring and Toxicology. CRC Press, USA.
5. Soraya Dhillon, Andrzej Kostrzewski. Clinical pharmacokinetics. 1st edition. London: Pharmaceutical Press.
6. Joseph T. Dipiro, William J. Spruill, William E. Wade, Robert A. Blouin and Jane M. Pruemer. Concepts in Clinical Pharmacokinetics. American Society of Health-System Pharmacists, USA.
7. Malcolm Rowland, Thomas N. Tozer. Clinical Pharmacokinetics and pharmacodynamics: concepts and applications. Lippincott Williams & Wilkins, USA.
8. Evans, Schentag, Jusko. Applied pharmacokinetics. American Society of Health system Pharmacists, USA.
9. Michael E. Winter. Basic Clinical Pharmacokinetics. Lippincott Williams & Wilkins, USA.
10. Milo Gibaldi. Biopharmaceutics and Clinical Pharmacokinetics. Pharma Book Syndicate, USA.
11. Dhillon and Kostrzewski. Clinical pharmacokinetics. Pharmaceutical Press, London.
12. John E. Murphy. Clinical Pharmacokinetics. 5th edition. US: American Society of Health- System Pharmacist, USA.
13. Relevant review articles from recent medical and pharmaceutical literature

## PHARMACOEPIDEMIOLOGY & PHARMACOECONOMICS (MPP 204T)

### Scope

This course enables students to understand various pharmacoepidemiological methods and their clinical applications. Also, it aims to impart knowledge on basic concepts, assumptions, terminology, and methods associated with Pharmacoeconomics and health related outcomes, and when should be appropriate Pharmacoeconomic model should be applied for a health care regimen.

### Objectives

Upon completion of this course it is expected that students shall be able to:

- Understand the various epidemiological methods and their applications
- Understand the fundamental principles of Pharmacoeconomics.
- Identify and determine relevant cost and consequences associated with pharmacy products and services.
- Perform the key Pharmacoeconomics analysis methods
- Understand the Pharmacoeconomic decision analysis methods and its applications.
- Describe current Pharmacoeconomic methods and issues.
- Understand the applications of Pharmacoeconomics to various pharmacy settings.

### THEORY

60Hrs

1. **Introduction to Pharmacoepidemiology:** Definition, Scope, Need, Aims & Applications; Outcome measurement: Outcome measures, Drug use measures: Monetary units, Number of prescriptions, units of drug dispensed, defined daily doses, prescribed daily doses, Diagnosis and Therapy surveys, Prevalence, Incidence rate, Monetary units, number of prescriptions, unit of drugs dispensed, defined daily doses and prescribed daily doses, medications adherence measurements. Concept of risk: Measurement of risk, Attributable risk and relative risk, Time- risk relationship and odds ratio **12 Hrs**
2. **Pharmacoepidemiological Methods:** Qualitative models: Drug Utilization Review; Quantitative models: case reports, case series, Cross sectional studies,

Cohort and case control studies, Calculation of Odds' ratio, Meta analysis models, Drug effects study in populations: Spontaneous reporting, Prescription event monitoring, Post marketing surveillance, Record linkage systems, Applications of Pharmacoepidemiology. **12 Hrs**

3. **Introduction to Pharmacoeconomics:** Definition, history of Pharmacoeconomics, Need of Pharmacoeconomic studies in Indian healthcare system.

**Cost categorization and resources for cost estimation:** Direct costs. Indirect costs. Intangible costs.

**Outcomes and Measurements of Pharmacoeconomics:** Types of outcomes: Clinical outcome, Economic outcomes, Humanistic outcomes; Quality Adjusted Life Years, Disability Adjusted Life Years Incremental Cost Effective Ratio, Average Cost Effective Ratio. Person Time, Willingness to Pay, Time Trade Off and Discounting. **12 Hrs**

4. **Pharmacoeconomic evaluations:** Definition, Steps involved, Applications, Advantages and disadvantages of the following Pharmacoeconomic models: Cost Minimization Analysis (CMA), Cost Benefit Analysis (CBA), Cost Effective Analysis (CEA), Cost Utility Analysis (CUA), Cost of Illness (COI), Cost Consequences Analysis (COA). **12 Hrs**

5. **Definition, Steps involved, Applications, Advantages and disadvantages of the following: Health related quality of life (HRQOL):** Definition, Need for measurement of HRQOL, Common HRQOL measures.

**Definition, Steps involved, Applications of the following:** Decision Analysis and Decision tree, Sensitivity analysis, Markov Modeling, Software used in pharmacoeconomic analysis, Applications of Pharmacoeconomics. **12 Hrs**

## REFERENCES

1. Rascati K L. Essentials of Pharmacoeconomics, Woulters Kluwer Lippincott Williams & Wilkins, Philadelphia.
2. Thomas E Getzen. Health economics. Fundamentals and Flow of Funds. John Wiley & Sons, USA.
3. Andrew Briggs, Karl Claxton, Mark Sculpher. Decision Modelling for Health Economic Evaluation, Oxford University Press, London.
4. Michael Drummond, Mark Sculpher, George Torrence, Bernie O'Brien and Greg Stoddart. Methods for the Economic Evaluation of Health Care

Programmes Oxford University Press, London.5. George E Mackinnon III.  
Understanding health outcomes and pharmacoeconomics.

6. Graker, Dennis. Pharmacoeconomics and outcomes.
7. Walley, Pharmacoeconomics.
8. Pharmacoeconomic - ed. by Nowakowska - University of Medical Sciences,  
Poznan.
9. Relevant review articles from recent medical and pharmaceutical literature

## PHARMACY PRACTICE PRACTICAL - II

### (MPP 205P)

Pharmacy Practice practical component includes experiments covering important topics of the courses Principles of Quality Use of Medicines, Pharmacotherapeutics-II, Clinical Pharmacokinetics & Therapeutic Drug Monitoring and Pharmacoepidemiology and Pharmacoeconomics.

#### List of Experiments (24)

1. Causality assessment of adverse drug reactions (three)
2. Detection and management of medication errors (three)
3. Rational use of medicines in special population (three)
4. Presentation of clinical cases of various disease conditions adopting Pharmaceutical Care Plan Model (eight)
5. Calculation of Bioavailability and Bioequivalence from the given data (two)
6. Interpretation of Therapeutic Drug Monitoring reports of a given patient (three)
7. Calculation of various Pharmacoeconomic outcome analysis for the given data (two)

## PHARMACOLOGY (MPL)

### MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES (MPL 101T)

#### Scope

This subject deals with various advanced analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are NMR, Mass spectrometer, IR, HPLC, GC etc.

#### Objectives

- After completion of course student is able to know about, Chemicals and Excipients
- The analysis of various drugs in single and combination dosage forms
- Theoretical and practical skills of the instruments

#### THEORY

60 Hrs

1. **a. UV-Visible spectroscopy:** Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV-Visible spectroscopy, Difference/ Derivative spectroscopy. **b. IR spectroscopy:** Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier - Transform IR Spectrometer, Factors affecting vibrational frequencies and Applications of IR spectroscopy, Data Interpretation. **c. Spectrofluorimetry:** Theory of Fluorescence, Factors affecting fluorescence (Characteristics of drugs that can be analysed by fluorimetry), Quenchers, Instrumentation and Applications of fluorescence spectrophotometer. **d. Flame emission spectroscopy and Atomic absorption spectroscopy:** Principle, Instrumentation, Interferences and Applications. **10 Hrs**
2. **NMR spectroscopy:** Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and <sup>13</sup>C NMR. Applications of NMR spectroscopy. **10 Hrs**
3. **Mass Spectroscopy:** Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight, Mass

fragmentation and its rules, Meta stable ions, Isotopic peaks and Applications of Mass spectroscopy. **10 Hrs**

4. **Chromatography:** Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution, isolation of drug from excipients, data interpretation and applications of the following: a) Thin Layer chromatography b) High Performance Thin Layer Chromatography c) Ion exchange chromatography d) Column chromatography e) Gas chromatography f) High Performance Liquid chromatography g) Ultra High Performance Liquid chromatography h) Affinity chromatography i) Gel Chromatography **10 Hrs**
5. **a. Electrophoresis:** Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following: a) Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresis d) Zone electrophoresis e) Moving boundary electrophoresis f) Iso electric focusing  
**b. X ray Crystallography:** Production of X rays, Different X ray methods, Bragg's law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X-ray diffraction. **10 Hrs**
6. **a. Potentiometry:** Principle, working, Ion selective Electrodes and Application of potentiometry.  
**b. Immunological assays:** RIA (Radio immuno assay), ELISA, Bioluminescence assays. **10 Hrs**

## REFERENCES

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Douglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Instrumental methods of analysis - Willards, 7th edition, CBS publishers.
4. Practical Pharmaceutical Chemistry - Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi, 1997.
5. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.

7. Pharmaceutical Analysis - Modern Methods - Part B - J W Munson, Vol 11, Marcel. Dekker Series
8. Spectroscopy of Organic Compounds, 2nd edn., P.S/Kalsi, Wiley estern Ltd., Delhi.
9. Textbook of Pharmaceutical Analysis, KA.Connors, 3rd Edition, John Wiley & Sons, 1982.

**ADVANCED PHARMACOLOGY - I**  
**(MPL 102T)**

**Scope**

The subject is designed to strengthen the basic knowledge in the field of pharmacology and to impart recent advances in the drugs used for the treatment of various diseases. In addition, this subject helps the students to understand the concepts of drug action and mechanisms involved

**Objectives**

Upon completion of the course the student shall be able to:

- Discuss the pathophysiology and pharmacotherapy of certain diseases
- Explain the mechanism of drug actions at cellular and molecular level
- Understand the adverse effects, contraindications and clinical uses of drugs used in treatment of diseases

**THEORY**

**60 Hrs**

**1. General Pharmacology**

- a. Pharmacokinetics: The dynamics of drug absorption, distribution, biotransformation and elimination. Concepts of linear and non-linear compartment models. Significance of Protein binding.
- b. Pharmacodynamics: Mechanism of drug action and the relationship between drug concentration and effect. Receptors, structural and functional families of receptors, quantitation of drug receptors interaction and elicited effects.

**12 Hrs**

**2. Neurotransmission**

- a. General aspects and steps involved in neurotransmission.
- b. Neurohumoral transmission in autonomic nervous system (Detailed study about neurotransmitters- Adrenaline and Acetyl choline).
- c. Neurohumoral transmission in central nervous system (Detailed study about neurotransmitters- histamine, serotonin, dopamine, GABA, glutamate and glycine].
- d. Non adrenergic non cholinergic transmission (NANC). Cotransmission

**12 Hrs**

### **Systemic Pharmacology**

A detailed study on pathophysiology of diseases, mechanism of action, pharmacology and toxicology of existing as well as novel drugs used in the following systems

**Autonomic Pharmacology** Parasympathomimetics and lytics, sympathomimetics and lytics, agents affecting neuromuscular junction

### **3. Central nervous system Pharmacology**

General and local anesthetics

Sedatives and hypnotics, drugs used to treat anxiety. Depression, psychosis, mania, epilepsy, neurodegenerative diseases.

Narcotic and non-narcotic analgesics. **12 Hrs**

### **4. Cardiovascular Pharmacology**

Diuretics, antihypertensives, antiischemics, anti-arrhythmics, drugs for heart failure and hyperlipidemia.

Hematinics, coagulants, anticoagulants, fibrinolytics and antiplatelet drugs **12 Hrs**

### **5. Autocoid Pharmacology**

The physiological and pathological role of Histamine, Serotonin, Kinins Prostaglandins Opioid autocoids. Pharmacology of antihistamines, 5HT antagonists. **12 Hrs**

## **REFEREENCES**

1. The Pharmacological Basis of Therapeutics, Goodman and Gillman's
2. Principles of Pharmacology. The Pathophysiologic basis of drug Therapy by David E Golan, Armen
- H, Tashjian Jr, Ehrin J, Armstrong, April W, Armstrong, Wolters, Kluwer-Lippincott Williams & Wilkins Publishers.
3. Basic and Clinical Pharmacology by B.G Katzung
4. Hand book of Clinical Pharmacokinetics by Gibaldi and Prescott.
5. Applied biopharmaceutics and Pharmacokinetics by Leon Shargel and Andrew B.C.Yu.

6. Graham Smith. Oxford textbook of Clinical Pharmacology.
7. Avery Drug Treatment
8. Dipiro Pharmacology, Pathophysiological approach.
9. Green Pathophysiology for Pharmacists.
10. Robbins & Cortan Pathologic Basis of Disease, 9<sup>th</sup> Ed. (Robbins Pathology)
11. A Complete Textbook of Medical Pharmacology by Dr. S.K Srivastava published by APC Avichal Publishing Company
12. KD.Tripathi. Essentials of Medical Pharmacology.
13. Modern Pharmacology with Clinical Applications, Craig Charles R. & Stitzel Robert E., Lippincott Publishers.
14. Clinical Pharmacokinetics & Pharmacodynamics: Concepts and Applications - Malcolm Rowland and Thomas N.Tozer, Wolters Kluwer, Lippincott Williams & Wilkins Publishers.
15. Applied biopharmaceutics and Pharmacokinetics, Pharmacodynamics and Drug metabolism for industrial scientists.
16. Modern Pharmacology, Craig CR. & Stitzel RE, Little Brown & Company.

## PHARMACOLOGICAL AND TOXICOLOGICAL SCREENING METHODS - I (MPL 103T)

### Scope

This subject is designed to impart the knowledge on preclinical evaluation of drugs and recent experimental techniques in the drug discovery and development. The subject content helps the student to understand the maintenance of laboratory animals as per the guidelines, basic knowledge of various *in-vitro* and *in-vivo* preclinical evaluation processes

### Objectives

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

- Appraise the regulations and ethical requirement for the usage of experimental animals.
- Describe the various animals used in the drug discovery process and good laboratory practices in maintenance and handling of experimental animals
- Describe the various newer screening methods involved in the drug discovery process
- Appreciate and correlate the preclinical data to humans

### THEORY

60 Hrs

1. **Laboratory Animals Common laboratory animals:** Description, handling and applications of different species and strains of animals. Transgenic animals: Production, maintenance and applications Anaesthesia and euthanasia of experimental animals. Maintenance and breeding of laboratory animals. CPCSEA guidelines to conduct experiments on animals. Good laboratory practice. Bioassay-Principle, scope and limitations and methods **12 Hrs**
2. **Preclinical screening of new substances for the pharmacological activity using *in vivo*, *in vitro*, and other possible animal alternative models.**

General principles of preclinical screening. CNS Pharmacology: behavioral and muscle co ordination, CNS stimulants and depressants, anxiolytics, anti-psychotics, anti epileptics and nootropics. Drugs for neurodegenerative diseases like Parkinsonism, Alzheimers and multiple sclerosis. Drugs acting on Autonomic Nervous System. **12 Hrs**

3. **Preclinical screening of new substances for the pharmacological activity using *in vivo*, *in vitro*, and other possible animal alternative models.**

Respiratory Pharmacology: anti-asthmatics, drugs for COPD and anti allergics. Reproductive Pharmacology: Aphrodisiacs and antifertility agents Analgesics, antiinflammatory and antipyretic agents. Gastrointestinal drugs: anti ulcer, anti -emetic, anti-diarrheal and laxatives. **12 Hrs**

4. **Preclinical screening of new substances for the pharmacological activity using *in vivo*, *in vitro*, and other possible animal alternative models.**

Cardiovascular Pharmacology: antihypertensives, antiarrhythmics, antianginal, antiatherosclerotic agents and diuretics. Drugs for metabolic disorders like anti-diabetic, antidyslipidemic agents. Anti cancer agents. Hepatoprotective screening methods. **12 Hrs**

5. **Preclinical screening of new substances for the pharmacological activity using *in vivo*, *in vitro*, and other possible animal alternative models.** Alternative animal models for different pharmacological activities: Diabetes Mellitus, CNS stimulants and depressant activity using Zebra fish, *Drosophila melanogaster* and *Caenorhabditis elegans*.

**General principles of immunoassay:** Theoretical basis and optimization of immunoassay, heterogeneous and homogenous immunoassay systems. Immunoassay methods evaluation; protocol outline, objectives and preparation. Immunoassay for digoxin and insulin Limitations of animal experimentation and alternate animal experiments. Extrapolation of *in vitro* data to preclinical and preclinical to humans **12 Hrs**

## REFERENCES

1. Biological standardization by J.H. Burn D.J. Finney and I.G. Goodwin
2. Screening methods in Pharmacology by Robert Turner. A
3. Evaluation of drugs activities by Laurence and Bachrach
4. Methods in Pharmacology by Arnold Schwartz.
5. Fundamentals of experimental Pharmacology by M.N.Ghosh
6. Pharmacological experiment on intact preparations by Churchill Livingstone
7. Drug discovery and Evaluation by Vogel H.G.
8. Experimental Pharmacology by R.K.Goyal.

9. Preclinical evaluation of new drugs by S.K. Gupta
10. Handbook of Experimental Pharmacology, SK.Kulkarni
11. Practical Pharmacology and Clinical Pharmacy, SK.Kulkarni, 3<sup>rd</sup> Edition.
12. David R.Gross. Animal Models in Cardiovascular Research, 2<sup>nd</sup> Edition, Kluwer Academic Publishers, London, UK.
13. Screening Methods in Pharmacology, Robert A.Turner.
14. Rodents for Pharmacological Experiments, Dr.Tapan Kumar chatterjee.
15. Practical Manual of Experimental and Clinical Pharmacology by Bikash Medhi (Author), Ajay Prakash (Author)

## CELLULAR AND MOLECULAR PHARMACOLOGY

(MPL 104T)

### Scope:

The subject imparts a fundamental knowledge on the structure and functions of cellular components and help to understand the interaction of these components with drugs. This information will further help the student to apply the knowledge in drug discovery process.

### Objectives:

- Upon completion of the course, the student shall be able to,
- Explain the receptor signal transduction processes. Explain the molecular pathways affected by drugs.
- Appreciate the applicability of molecular pharmacology and biomarkers in drug discovery process.
- Demonstrate molecular biology techniques as applicable for pharmacology

### THEORY

60 Hrs

#### 1. Cell biology

Structure and functions of cell and its organelles

Genome organization. Gene expression and its regulation, importance of siRNA and micro RNA, gene mapping and gene sequencing

Cell cycles and its regulation.

Cell death- events, regulators, intrinsic and extrinsic pathways of apoptosis.

Necrosis and autophagy.

12 Hrs

#### 2. Cell signaling Intercellular and intracellular signaling pathways.

Classification of receptor family and molecular structure ligand gated ion channels; G-protein coupled receptors, tyrosine kinase receptors and nuclear receptors.

Secondary messengers: cyclic AMP, cyclic GMP, calcium ion, inositol 1,4,5-trisphosphate, (IP3), NO, and diacylglycerol. Detailed study of following intracellular signaling pathways: cyclic AMP signaling pathway, mitogen-

activated protein kinase (MAPK) signaling, Janus kinase (JAK)/signal transducer and activator of transcription (STAT) signaling pathway. **12 Hrs**

3. **Principles and applications of genomic and proteomic tools** DNA electrophoresis, PCR (reverse transcription and real time), Gene sequencing, micro array technique, SDS page, ELISA and western blotting, Recombinant DNA technology and gene therapy Basic principles of recombinant DNA technology-Restriction enzymes, various types of vectors. Applications of recombinant DNA technology.

Gene therapy- Various types of gene transfer techniques, clinical applications and recent advances in gene therapy. **12 Hrs**

4. **Pharmacogenomics**

Gene mapping and cloning of disease gene.

Genetic variation and its role in health/ pharmacology Polymorphisms affecting drug metabolism

Genetic variation in drug transporters

Genetic variation in G protein coupled receptors

Applications of proteomics science: Genomics, proteomics, metabolomics, functionomics, nutrigenomics

**Immunotherapeutics** Types of immunotherapeutics, humanisation antibody therapy, Immunotherapeutics in clinical practice. **12 Hrs**

5. a. **Cell culture techniques**

Basic equipments used in cell culture lab. Cell culture media, various types of cell culture, general procedure for cell cultures; isolation of cells, subculture, cryopreservation, characterization of cells and their application. Principles and applications of cell viability assays, glucose uptake assay, Calcium influx assays Principles and applications of flow cytometry

b. **Biosimilars**

**12 Hrs**

#### **REFERENCES:**

1. The Cell, A Molecular Approach. Geoffrey M Cooper.
2. Pharmacogenomics: The Search for Individualized Therapies. Edited by J. Licinio and M -L. Wong

3. Handbook of Cell Signaling (Second Edition) Edited by Ralph A. et.al
4. Molecular Pharmacology: From DNA to Drug Discovery. John Dickenson et.al
5. Basic Cell Culture protocols by Cheril D.Helgason and Cindy L.Miller
6. Basic Cell Culture (Practical Approach ) by J. M. Davis (Editor)
7. Animal Cell Culture: A Practical Approach by John R. Masters (Editor)
8. Current protocols in molecular biology vol I to VI edited by Frederick M.Ausvel et al.

## PHARMACOLOGY PRACTICAL - I

(MPL 105P)

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

### Handling of laboratory animals.

1. Various routes of drug administration.
2. Techniques of blood sampling, anesthesia and euthanasia of experimental animals.
3. Functional observation battery tests (modified Irwin test)
4. Evaluation of CNS stimulant, depressant, anxiogenics and anxiolytic, anticonvulsant activity.
5. Evaluation of analgesic, anti-inflammatory, local anesthetic, mydriatic and miotic activity.
6. Evaluation of diuretic activity.
7. Evaluation of antiulcer activity by pylorus ligation method.
8. Oral glucose tolerance test.
9. Isolation and identification of DNA from various sources (Bacteria, Cauliflower, onion, Goat liver).
10. Isolation of RNA from yeast
11. Estimation of proteins by Bradford/Lowry's in biological samples.
12. Estimation of RNA/DNA by UV Spectroscopy
13. Gene amplification by PCR.

14. Protein quantification Western Blotting.
15. Enzyme based in-vitro assays (MPO, AChEs, á amylase, á glucosidase).
16. Cell viability assays (MTT/Trypan blue/SRB).
17. DNA fragmentation assay by agarose gel electrophoresis.
18. DNA damage study by Comet assay.
19. Apoptosis determination by fluorescent imaging studies.
20. Pharmacokinetic studies and data analysis of drugs given by different routes of administration using softwares
21. Enzyme inhibition and induction activity
22. Extraction of drug from various biological samples and estimation of drugs in biological fluids using different analytical techniques (UV)
23. Extraction of drug from various biological samples and estimation of drugs in biological fluids using different analytical techniques (HPLC)

## REFERENCES

1. CPCSEA, OECD, ICH, USFDA, Schedule Y, EPA guidelines,
2. Fundamentals of experimental Pharmacology by M.N.Ghosh
3. Handbook of Experimental Pharmacology by S.K. Kulkarni.
4. Drug discovery and Evaluation by Vogel H.G.
5. Spectrometric Identification of Organic compounds - Robert M Silverstein,
6. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman,
7. Vogel's Text book of quantitative chemical analysis - Jeffery, Basset, Mendham, Denney,
8. Basic Cell Culture protocols by Cheril D. Helgason and Cindy L.Mille
9. Basic Cell Culture (Practical Approach ) by J. M. Davis (Editor)
10. Animal Cell Culture: A Practical Approach by John R. Masters (Editor)
11. Practical Manual of Experimental and Clinical Pharmacology by Bikash Medhi(Author), Ajay Prakash (Author) Jaypee brothers' medical publishers Pvt. Ltd

## ADVANCED PHARMACOLOGY - II

(MPL 201T)

### Scope

The subject is designed to strengthen the basic knowledge in the field of pharmacology and to impart recent advances in the drugs used for the treatment of various diseases. In addition, the subject helps the student to understand the concepts of drug action and mechanism involved

### Objectives

Upon completion of the course the student shall be able to:

- Explain the mechanism of drug actions at cellular and molecular level
- Discuss the Pathophysiology and pharmacotherapy of certain diseases
- Understand the adverse effects, contraindications and clinical uses of drugs used in treatment of diseases

### THEORY

60 Hrs

#### 1. Endocrine Pharmacology

Molecular and cellular mechanism of action of hormones such as growth hormone, prolactin, thyroid, insulin and sex hormones. Anti-thyroid drugs, Oral hypoglycemic agents, Oral contraceptives, Corticosteroids.

Drugs affecting calcium regulation

12 Hrs

#### 2. Chemotherapy

Cellular and molecular mechanism of actions and resistance of antimicrobial agents such as  $\beta$ -lactams, aminoglycosides, quinolones, Macrolide antibiotics. Antifungal, antiviral, and anti-TB drugs.

12 Hrs

#### 3. Chemotherapy

Drugs used in Protozoal Infections Drugs used in the treatment of Helminthiasis, Chemotherapy of cancer Immunopharmacology Cellular and biochemical mediators of inflammation and immune response. Allergic or hypersensitivity reactions. Pharmacotherapy of asthma and COPD. Immunosuppressants and Immunostimulants

12 Hrs

#### 4. GIT Pharmacology

Antiulcer drugs, Prokinetics, antiemetics, anti-diarrheals and drugs for constipation and irritable bowel syndrome.

**Chronopharmacology** Biological and circadian rhythms, applications of chronotherapy in various diseases like cardiovascular disease, diabetes, asthma and peptic ulcer **12 Hrs**

5. **Free radicals Pharmacology** Generation of free radicals, role of free radicals in etiopathology of various diseases such as diabetes, neurodegenerative diseases and cancer. Protective activity of certain important antioxidant

**Recent Advances in Treatment:** Alzheimer's disease, Parkinson's disease, Cancer, Diabetes mellitus **12 Hrs**

## REFERENCES

1. The Pharmacological basis of therapeutics- Goodman and Gilman's.
2. Principles of Pharmacology. The Pathophysiologic basis of drug therapy by David E Golan et al.
3. Basic and Clinical Pharmacology by B.G -Katzung.
4. Pharmacology by H.P. Rang and M.M. Dale.
5. Hand book of Clinical Pharmacokinetics by Gibaldi and Prescott.
6. Text book of Therapeutics, drug and disease management by E T. Herfindal and Gourley.
7. Applied biopharmaceutics and Pharmacokinetics by Leon Shargel and Andrew B.C.Yu.
8. Handbook of Essential Pharmacokinetics, Pharmacodynamics and Drug Metabolism for Industrial Scientists.
9. Robbins & Cotran Pathologic Basis of Disease, 9<sup>th</sup> Ed. (Robbins Pathology).
10. A Complete Textbook of Medical Pharmacology by Dr. S.K Srivastava published by APC Avichal Publishing Company.
11. KD.Tripathi. Essentials of Medical Pharmacology.
12. Principles of Pharmacology. The Pathophysiologic basis of drug Therapy by David E Golan, Armen H, Tashjian Jr, Ehrin J, Armstrong, April W, Armstrong, Wolters, Kluwer-Lippincott Williams & Wilkins Publishers.

**PHARMACOLOGY AND TOXICOLOGY SCREENING METHODS-II**  
**(MPL-202T)**

**Scope:**

This subject imparts knowledge on the preclinical safety and toxicological evaluation of drug & new chemical entity. This knowledge will make the student competent in regulatory toxicological evaluation.

**Objectives:**

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

- Explain the various types of toxicity studies.
- Appreciate the importance of ethical and regulatory requirements for toxicity studies.
- Demonstrate the practical skills required to conduct the preclinical toxicity studies.

**THEORY**

**60 Hrs**

1. **Basic definition and types of toxicology** (general, mechanistic, regulatory and descriptive) Regulatory guidelines for conducting toxicity studies OECD, ICH, EPA and Schedule Y, OECD principles of Good laboratory practice (GLP) History, concept and its importance in drug development **12 Hrs**
2. Acute, sub-acute and chronic- oral, dermal and inhalational studies as per OECD guidelines. Acute eye irritation, skin sensitization, dermal irritation & dermal toxicity studies. n Test item characterization- importance and methods in regulatory toxicology studies **12 Hrs**
3. Reproductive toxicology studies, Male reproductive toxicity studies, female reproductive studies (segment I and segment III), teratogenicity studies (segment II) Genotoxicity studies (Ames Test, in vitro and in vivo Micronucleus and Chromosomal aberrations studies) *In vivo* carcinogenicity studies **12 Hrs**
4. IND enabling studies (IND studies)- Definition of IND, importance of IND, industry perspective, list of studies needed for IND submission. Safety pharmacology studies- origin, concepts and importance of pharmacology. Tier1- CVS, CNS and respiratory safety pharmacology, HERG assay. Tier2- GI, renal and other studies **12 Hrs**

5. **Toxicokinetics**- Toxicokinetic evaluation in preclinical studies, 12 saturation kinetics Importance and applications of toxicokinetic Hrs studies. Alternative methods to animal toxicity testing **12 Hrs**

## REFERENCES

1. Hand book on GLP, Quality practices for regulated non-clinical research and development (<http://www.who.int/tdr/publications/documents/glp-handbook.pdf>).
2. Schedule Y Guideline: drugs and cosmetics (second amendment) rules, 2005, ministry of health and family welfare (department of health) New Delhi.
3. Drugs from discovery to approval by Rick NG.
4. Animal Models in Toxicology, 3<sup>rd</sup> Edition, Lower and Bryan.
5. OECD test guidelines.
6. Principles of toxicology by Karen E. Stine, Thomas M. Brown.
7. Guidance for Industry M3(R2) Nonclinical Safety Studies for the Conduct of Human Clinical Trials and Marketing Authorization for Pharmaceuticals. ([http://www.fda.gov/downloads/drugs/guidance compliance regulatory information/guidances/ucm073246.pdf](http://www.fda.gov/downloads/drugs/guidance%20compliance%20regulatory%20information/guidances/ucm073246.pdf))

## PRINCIPLES OF DRUG DISCOVERY

(MPL 203T)

### Scope:

The subject imparts basic knowledge of drug discovery process. This information will make the student competent in drug discovery process

### Objectives:

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

- Explain the various stages of drug discovery.
- Appreciate the importance of the role of genomics, proteomics and bioinformatics in drug discovery.
- Explain various targets for drug discovery.
- Explain various lead seeking method and lead optimization.
- Appreciate the importance of the role of computer aided drug design in drug discovery.

### THEORY

60 Hrs

1. **An overview of modern drug discovery process:** Target identification, target validation, lead identification and lead Optimization. Economics of drug discovery.  
  
Target Discovery and validation-Role of Genomics, Proteomics and Bioinformatics. Role of Nucleic acid microarrays, Protein microarrays, Antisense technologies, siRNAs, antisense oligonucleotides, Zinc finger proteins. Role of transgenic animals in target validation. **12 Hrs**
2. Lead Identification- combinatorial chemistry & high throughput screening, in silico lead discovery techniques, Assay development for hit identification. Protein structure Levels of protein structure, Domains, motifs, and folds in protein structure. Computational prediction of protein structure: Threading and homology modeling methods. Application of NMR and X-ray crystallography in protein structure prediction. **12 Hrs**
3. Rational Drug Design Traditional vs rational drug design, Methods followed in traditional drug design, High throughput screening, Concepts of Rational Drug Design, Rational Drug Design Methods: Structure and Pharmacophore

based approaches Virtual Screening techniques: Drug likeness screening, Concept of pharmacophore mapping and pharmacophore based Screening.

**12 Hrs**

4. **Molecular docking:** Rigid docking, flexible docking, manual docking; Docking based screening. De novo drug design. Quantitative analysis of Structure Activity Relationship History and development of QSAR, SAR versus QSAR, Physicochemical parameters, Hansch analysis, Fee Wilson analysis and relationship between them.

Computational and Network Biology Approaches

- Overview of biological networks: Gene regulatory, metabolic, and protein-protein interaction networks
- Network- based drug target identification systems,
- Pharmacology and network based ploypharmacology

**12Hrs**

- 5 **QSAR Statistical methods** - regression analysis, partial least square analysis (PLS) and other multivariate statistical methods. 3D-QSAR approaches like COMFA and COMSIA.

Prodrug design-Basic concept, 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.

**12Hrs**

## REFERENCES

1. MouldySioud. Target Discovery and Validation Reviews and Protocols: Volume 2 Emerging Molecular Targets and Treatment Options. 2007 Humana Press Inc.
2. Darryl León. Scott Markelln. Silico Technologies in Drug Target Identification and Validation. 2006 by Taylor and Francis Group, LLC.
3. Johanna K. DiStefano. Disease Gene Identification. Methods and Protocols. Springer New York Dordrecht Heidelberg London.
4. Hugo Kubiny. QSAR: Hansch Analysis and Related Approaches. Methods and Principles in Medicinal Chemistry. Publisher Wiley-VCH.

5. Klaus Gubernator, Hans-Joachim Böhm. Structure-Based Ligand Design. Methods and Principles in Medicinal Chemistry. Publisher Wiley-VCH.
6. Abby L . Parrill. M . Rami Reddy. Rational Drug Design. Novel Methodology and Practical Applications. ACS Symposium Series; American Chemical Society: Washington, DC, 1999.
7. J. Rick Turner. New drug development design, methodology and, analysis. John Wiley & Sons, Inc., New Jersey.

## CLINICAL RESEARCH AND PHARMACOVIGILANCE (MPL 204T)

### Scope:

This subject will provide a value addition and current requirement for the students in clinical research and pharmacovigilance. It will teach the students on conceptualizing, designing, conducting, managing and reporting of clinical trials. This subject also focuses on global scenario of Pharmacovigilance in different methods that can be used to generate safety data. It will teach the students in developing drug safety data in Pre-clinical, Clinical phases of Drug development and post market surveillance.

### Objectives:

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

- Explain the regulatory requirements for conducting clinical trial
- Demonstrate the types of clinical trial designs
- Explain the responsibilities of key players involved in clinical trials
- Execute safety monitoring, reporting and close-out activities
- Explain the principles of Pharmacovigilance
- Detect new adverse drug reactions and their assessment
- Perform the adverse drug reaction reporting systems and communication in Pharmacovigilance

### THEORY

60 Hrs

1. **Regulatory Perspectives of Clinical Trials:** Origin and Principles of International Conference on Harmonization - Good Clinical Practice (ICH-GCP) guidelines.  
**Ethical Committee:** Institutional Review Board, Ethical Guidelines for Biomedical Research and Human Participant Schedule Y, ICMR.  
**Informed Consent Process:** Structure and content of an Informed Consent Process Ethical principles governing informed consent process. 12 Hrs
2. **Clinical Trials:** Types and Design Experimental Study- RCT and Non RCT, Observation Study: Cohort, Case Control, Cross sectional.

**Clinical Trial Study Team** Roles and responsibilities of Clinical Trial Personnel: Investigator, Study Coordinator, Sponsor, Contract Research Organization and its management. **12 Hrs**

3. **Clinical Trial Documentation-** Guidelines to the preparation of documents, Preparation of protocol, Investigator Brochure, Case Report Forms, Clinical Study Report Clinical Trial Monitoring Safety Monitoring in CT.

**Adverse Drug Reactions:** Definition and types. Detection and reporting methods. Severity and seriousness assessment. Predictability and preventability assessment, Management of adverse drug reactions; Terminologies of ADR. **12 Hrs**

4. **Basic aspects, terminologies and establishment of pharmacovigilance** History and progress of pharmacovigilance, Significance of safety monitoring, Pharmacovigilance in India and international aspects, WHO international drug monitoring programme, WHO and Regulatory terminologies of ADR, evaluation of medication safety, Establishing pharmacovigilance centres in Hospitals, Industry and National programmes related to pharmacovigilance. Roles and responsibilities in Pharmacovigilance. **12 Hrs**

5. **Methods, ADR reporting and tools used in Pharmacovigilance** International classification of diseases, International Nonproprietary names for drugs, Passive and Active surveillance, Comparative observational studies, Targeted clinical investigations and Vaccine safety surveillance. Spontaneous reporting system and Reporting to regulatory authorities, Guidelines for ADRs reporting. Argus, Aris G Pharmacovigilance, VigiFlow, Statistical methods for evaluating medication safety data.

6. **A) Pharmacoepidemiology**

- **Introduction to Pharmacoepidemiology:** definition, scope and significance
- **Study Designs in Pharmacoepidemiology:** Descriptive studies (case reports, cross sectional studies), Analytical studies (Cohort, case control and nested case control studies), Experimental studies ( randomized controlled trials, pragmatic trials)
- **Measures of Disease frequency and association:** Incidence, prevalence, relative risk and odds ratio, post marketing surveillance (PMS) and pharmacovigilance Adverse drug reactions(ADR) monitoring and reporting systems.

## **B) Pharmacoeconomics**

- **Introduction to pharmacoeconomics-** Definition, scope and importance in healthcare decision making.
- **Health Economics and Economics evaluation-** Concepts of scarcity, opportunity cost, supply-demand and economic efficiency.
- **Types of pharmacoeconomic evaluations-** Cost minimization analysis(CMA), Cost effectiveness analysis (CEA), cost utility analysis (CUA), Cost benefit Analysis (CBA)

## **C) Safety Pharmacology**

- **Introduction to safety pharmacology-** Importance in drug development and regulatory compliance.
- **ICH guidelines for safety pharmacology (ICH S7A &S7B)-** Key regulatory requirements
- **Core battery studies in safety pharmacology-** Cardiovascular system(QT prolongation, hERG assay), Central nervous system (locomotor activity, behavioral tests), Respiratory system (pulmonary function tests)
- **Supplimentary Safety Pharmacology studies-** Renal, Gastrointestinal, and endocrine safety testing. **12 Hrs**

## **REFERENCES**

1. Central Drugs Standard Control Organization- Good Clinical Practices, Guidelines for Clinical Trials on Pharmaceutical Products in India. New Delhi: Ministry of Health;2001.
2. International Conference on Harmonization of Technical requirements for registration of Pharmaceuticals for human use. ICH Harmonized Tripartite Guideline. Guideline for Good Clinical Practice.E6; May 1996.
3. Ethical Guidelines for Biomedical Research on Human Subjects 2000. Indian Council of Medical Research, New Delhi.
4. Textbook of Clinical Trials edited by David Machin, Simon Day and Sylvan Green, March 2005, John Wiley and Sons.

5. Clinical Data Management edited by R K Rondels, S A Varley, C F Webbs. Second Edition, Jan 2000, Wiley Publications.
6. Handbook of clinical Research. Julia Lloyd and Ann Raven Ed. Churchill Livingstone.
7. Principles of Clinical Research edited by Giovanna di Ignazio, Di Giovanna and Haynes.

## PHARMACOLOGY PRACTICAL - II

### (MPL 205P)

1. To record the DRC of agonist using suitable isolated tissues preparation.
2. To study the effects of antagonist/potentiating agents on DRC of agonist using suitable isolated tissue preparation.
3. To determine to the strength of unknown sample by matching bioassay by using suitable tissue preparation.
4. To determine to the strength of unknown sample by interpolation bioassay by using suitable tissue preparation
5. To determine to the strength of unknown sample by bracketing bioassay by using suitable tissue preparation
6. To determine to the strength of unknown sample by multiple point bioassay by using suitable tissue preparation.
7. Estimation of PA<sub>2</sub> values of various antagonists using suitable isolated tissue preparations.
8. To study the effects of various drugs on isolated heart preparations
9. Recording of rat BP, heart rate and ECG.
10. Recording of rat ECG
11. Drug absorption studies by averted rat ileum preparation.
12. Acute oral toxicity studies as per OECD guidelines.
13. Acute dermal toxicity studies as per OECD guidelines.
14. Repeated dose toxicity studies- Serum biochemical, haematological, urine analysis, functional observation tests and histological studies.
15. Drug mutagenicity study using mice bone-marrow chromosomal aberration test.
16. Protocol design for clinical trial.(3 Nos.)
17. Design of ADR monitoring protocol.
18. In-silico docking studies. (2 Nos.)
19. In-silico pharmacophore based screening.

20. In-silico QSAR studies.

21. ADR reporting

## REFERENCES

1. Fundamentals of experimental Pharmacology-by M.N.Ghosh
2. Hand book of Experimental Pharmacology-S.K.Kulakarni
3. Text book of in-vitro practical Pharmacology by Ian Kitchen
4. Bioassay Techniques for Drug Development by Atta-ur-Rahman, Iqbal choudhary and William Thomsen
5. Applied biopharmaceutics and Pharmacokinetics by Leon Shargel and Andrew B.C.Yu.
6. Handbook of Essential Pharmacokinetics, Pharmacodynamics and Drug Metabolism for Industrial Scientists.

## PHARMACOGNOSY (MPG)

### MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES (MPG 101T)

#### Scope

This subject deals with various advanced analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are NMR, Mass spectrometer, IR, HPLC, GC etc.

#### Objectives

- After completion of course student is able to know about, Chemicals and Excipients
- The analysis of various drugs in single and combination dosage forms
- Theoretical and practical skills of the instruments

#### THEORY 60Hrs

1. **a. UV-Visible spectroscopy:** Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV-Visible spectroscopy **b. IR spectroscopy:** Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier - Transform IR Spectrometer, Factors affecting vibrational frequencies and Applications of IR spectroscopy, Data Interpretation. **c. Spectrofluorimetry:** Theory of Fluorescence, Factors affecting fluorescence (Characteristics of drugs that can be analysed by fluorimetry), Quenchers, Instrumentation and Applications of fluorescence spectrophotometer. **d. Flame emission spectroscopy and Atomic absorption spectroscopy:** Principle, Instrumentation, Interferences and Applications. **10 Hrs**
2. **NMR spectroscopy:** Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and <sup>13</sup>C NMR. Applications of NMR spectroscopy. **10 Hrs**
3. **Mass Spectroscopy:** Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight, Mass

fragmentation and its rules, Meta stable ions, Isotopic peaks and Applications of Mass spectroscopy. **10 Hrs**

4. **Chromatography:** Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution, isolation of drug from excipients, data interpretation and applications of the following: a) Thin Layer chromatography b) High Performance Thin Layer Chromatography c) Ion exchange chromatography d) Column chromatography e) Gas chromatography f) High Performance Liquid chromatography g) Ultra High Performance Liquid chromatography h) Affinity chromatography i) Gel Chromatography **10 Hrs**
5. **a. Electrophoresis:** Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following: a) Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresis d) Zone electrophoresis e) Moving boundary electrophoresis f) Iso electric focusing
- b. X ray Crystallography:** Production of X rays, Different X ray methods, Bragg's law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X-ray diffraction. **10 Hrs**
6. **a. Potentiometry:** Principle, working, Ion selective Electrodes and Application of potentiometry.
- b. Immunological assays:** RIA (Radioimmuno assay), ELISA, Bioluminescence assays **10 Hrs**

## REFERENCES

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Douglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Instrumental methods of analysis - Willards, 7th edition, CBS publishers.
4. Practical Pharmaceutical Chemistry - Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi, 1997.
5. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.

7. Pharmaceutical Analysis - Modern Methods - Part B - J W Munson, Vol 11, Marcel. Dekker Series
8. Spectroscopy of Organic Compounds, 2nd edn., P.S/Kalsi, Wiley estern Ltd., Delhi.
9. Textbook of Pharmaceuical Analysis, KA.Connors, 3rd Edition, John Wil e & Sons, 1982.

**ADVANCED PHARMACOGNOSY - I**  
**(MPG 102T)**

**SCOPE**

To learn and understand the advances in the field of cultivation and isolation of drugs of natural origin, various phytopharmaceuticals, nutraceuticals and their medicinal use and health benefits.

**OBJECTIVES**

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

- Advances in the cultivation and production of drugs
- Various phyto-pharmaceuticals and their source, its utilization and medicinal value
- Various nutraceuticals/herbs and their health benefits
- Drugs of marine origin
- Pharmacovigilance of drugs of natural origin

**THEORY**

**60 Hrs**

1. **Plant drug cultivation:** General introduction to the importance of Pharmacognosy in herbal drug industry, Indian Council of Agricultural Research, Current Good Agricultural Practices, Current Good Cultivation Practices, Current Good Collection Practices, Conservation of medicinal plants- Ex-situ and Insitu conservation of medicinal plants. Good Agricultural and Collection practices (GACP) guidelines, methods of cultivation. **12 Hrs**
2. **Marine natural products:** General methods of isolation and purification, Study of Marine toxins, Recent advances in research in marine drugs, Problems faced in research on marine drugs such as taxonomical identification, chemical screening and their solution. Marine organism and Metabolites from Marine organism. **12 Hrs**
3. **Nutraceuticals:** Current trends and future scope, Inorganic mineral supplements, Vitamin supplements, Digestive enzymes, Dietary fibres, Cereals and grains, Health drinks of natural origin, Antioxidants, Polyunsaturated fatty acids, Herbs as functional foods, Formulation and standardization of neutraceuticals, Toxicological studies, Regulatory aspects, FSSAI guidelines,

Sources, name of marker compounds and their chemical nature, medicinal uses and health benefits of following

- i) Spirulina ii) Soya bean iii) Ginseng iv) Garlic v) Broccoli vi) Green and Herbal Tea vii) Flax seeds viii) Black cohosh ix) Turmeric. **12 Hrs**

**4. Phytopharmaceuticals:** Occurrence, isolation and characteristic features (Chemical nature, uses in pharmacy, medicinal and health benefits) of following.

- a) Carotenoids - i)  $\alpha$  and  $\beta$  - Carotene ii) Xanthophyll (Lutein)
- b) Limonoids - i) d-Limonene ii)  $\alpha$  - Terpineol
- c) Saponins - i) Shatavarins
- d) Flavonoids - i) Resveratrol ii) Rutin iii) Hesperidin iv) Naringin v) Quercetin
- e) Phenolic acids- Ellagic acid
- f) A,D,K,E Vitamins
- g) Tocotrienols and Tocopherols
- h) Andrographolide, Glycolipids, Gugulipids, Withanolides, Vascine, Taxol
- i) Miscellaneous **12 Hrs**

**5. Pharmacovigilance of drugs of natural origin:** WHO and AYUSH guidelines for safety monitoring of natural medicine, Spontaneous reporting schemes for biodrug adverse reactions, bio drug-drug and bio drug-food interactions with suitable examples. **12 Hrs**

**REFERENCES (Latest Editions of)**

1. Pharmacognosy - G. E. Trease and W.C. Evans. Saunders Edinburgh,
2. Pharmacognosy-Tyler, Brady, Robbers
3. Modern Methods of Plant Analysis- Peach & M.V. Tracey, Vol. I&II
4. Text Book of Pharmacognosy by T.E. Wallis
5. Marine Natural Products-Vol. I to IV.
6. Natural products: A lab guide by Raphael Ikan , Academic Press 1991.
7. Glimpses of Indian Ethano Pharmacology, P. Pushpangadam.Ulf Nyman. V.George Tropical Botanic Garden & Research Institute, 1995.

8. Medicinal natural products (a biosynthetic approach), Paul M. Dewick, John Wiley & Sons Ltd., England, 1998.
9. Chemistry of Marine Natural Products- Paul J. Schewer 1973.
10. Herbal Drug Industry by RD. Choudhary, Eastern Publisher, New Delhi, 1996.
11. Cultivation of Medicinal Plants by C.K. Atal & B.M. Kapoor.
12. Cultivation and Utilization of Aromatic Plants, C.K. Atal & B.M. Kapoor
13. Cultivation of medicinal and aromatic crops, AA Farooqui and B.S. Sreeramu. University Press, 2001.
14. Natural Products from Plants, 1st edition, by Peter B. Kaufman, CRC Press, New York, 1998
15. Recent Advances in Phytochemistry- Vol. 1&4: Scikel Runeckles- Appleton Century crofts.
16. Text book of Pharmacognosy, C.K.Kokate, Purohit, Ghokhale, Nirali Prakasshan, 1996.
17. Pharmacognosy and Pharmacobiotechnology, Ashutoshkar, New Age Publications, New Delhi
18. Unit 1- Pharmacognostic and phytochemical studies of crude drugs listed in Ayurvedic Pharmacopoeia of India (API).
19. Jalalpure SS and Patil AK. Textbook of Pharmacognosy and Phytochemistry I, 2024, Nirali Prakashan, Pune.
20. Jalalpure SS and Patil AK. Textbook of Pharmacognosy and Phytochemistry II, 2025, Nirali Prakashan, Pune.
21. Jalalpure SS, Kurangi BK, Suryawanshi SS. Quality Control and Standardization of Phytomedicines. 2022. Nirali Prakashan, Pune.

## PHYTOCHEMISTRY (MPG 103T)

### SCOPE

Students shall be equipped with the knowledge of natural product drug discovery and will be able to isolate, identify and extract and the phyto-constituents

### OBJECTIVES

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

- Different classes of phytoconstituents, their biosynthetic pathways, their properties, extraction and general process of natural product drug discovery
- Phytochemical fingerprinting and structure elucidation of phytoconstituents.

### THEORY

60 Hrs

1. **Biosynthetic pathways and Radio tracing techniques:** Constituents & their Biosynthesis, Techniques for investigation of biosynthetic pathway, Isolation, Characterization and purification with a special reference to their importance in herbal industries of following phyto-pharmaceuticals containing drugs: a) Alkaloids: Ephedrine, Quinine, Strychnine, Piperine, Berberine, Taxol, Vinca alkaloids.  
b) Glycosides: Digitoxin, Glycyrrhizin, Sennosides, Bacosides, Quercitin.  
c) Steroids: Hecogenin, guggulosterone and withanolides  
d) Coumarin: Umbelliferone.  
e) Terpenoids: Cucurbitacins 12 Hrs
2. **Drug discovery and development:** History of herbs as source of drugs and drug discovery, the lead structure selection process, structure development, product discovery process and drug registration, Selection and optimization of lead compounds with suitable examples from the following source : artemesin, andrographolides. Clinical studies emphasising on phases of clinical trials, protocol design for lead molecules. 12 Hrs
3. **Extraction and Phytochemical studies:** Recent advances in extractions with emphasis on selection of method and choice of solvent for extraction, successive and exhaustive extraction and other methods of extraction commonly used like microwave assisted extraction, Methods of fractionation. Separation of phytoconstituents by latest CCCET, SCFE techniques including

preparative HPLC and Flash column chromatography, Subcritical water extraction method. **12 Hrs**

4. **Phytochemical finger printing:** HPTLC and LCMS/GCMS applications in the characterization of herbal extracts. **12 Hrs**
5. Structure elucidation of the following compounds by spectroscopic techniques like UV, IR, MS, NMR (<sup>1</sup>H, <sup>13</sup>C)
  - a. Carvone, Citral, Menthol
  - b. Luteolin, Kaempferol
  - c. Nicotine, Caffeine iv) Glycyrrhizin. **12 Hrs**

#### REFERENCES (Latest Editions of)

1. Organic chemistry by I.L. Finar Vol.II.
2. Pharmacognosy by Trease and Evans, ELBS.
3. Pharmacognosy by Tylor and Brady.
4. Text book of Pharmacognosy by Wallis.
5. Clark's isolation and Identification of drugs by A.C. Mottal.
6. Plant Drug Analysis by Wagner & Blatt.
7. Wilson and Gisvolds text book of Organic Medicinnal and Pharmaceutical Chemistry by Deorge. R.F.
8. The Chemistry of Natural Products, Edited by R.H. Thomson, Springer International Edn. 1994.
9. Natural Products Chemistry Practical Manual by Anees A Siddiqui and SeemiSiddiqui.
10. Organic Chemistry of Natural Products, Vol. 1&2. Gurdeep R Chatwal.
11. Chemistry of Natural Products- Vol. 1 onwards IWPAC.
12. Modem Methods of Plant Analysis- Peach & M.V. Tracey, Vol. I&II.
13. Medicinal Natural products - a biosynthetic approach, Dewick PM, John Wiley & Sons, Toronto, 1998.
14. Chemistry of Natural Products, Bhat SV, Nagasampagi BA, Meenakshi S, Narosa Publishing House, New Delhi.
15. Pharmacognosy & Phytochemistry of Medicinal Plants, 2nd edition, J, Interceptt Ltd., New York, 1999.
16. Jalalpure SS and Patil AK. Textbook of Pharmacognosy and Phytochemistry I & II, Nirali Prakashan, Pune.
17. Dr. Javesh Kashinath Patil, Dr. Sunil S. Jalalpure, Hamid Yahiya Hasni Syyed. Chemistry of natural products. Nirali Prakashan, Pune.

## INDUSTRIAL PHARMACOGNOSTICAL TECHNOLOGY

(MPG 104T)

### SCOPE

To understand the Industrial and commercial potential of drugs of natural origin, integrate traditional Indian systems of medicine with modern medicine and also to know regulatory and quality policy for the trade of herbals and drugs of natural origin.

### OBJECTIVES

By the end of the course the student shall be able to know,

- The requirements for setting up the herbal/natural drug industry.
- The guidelines for quality of herbal/natural medicines and regulatory issues.
- The patenting/IPR of herbals/natural drugs and trade of raw and finished materials.

### THEORY

60 Hrs

1. **Herbal drug industry:** Infrastructure of herbal drug industry involved in production of standardized extracts and various dosage forms. Current challenges in upgrading and modernization of herbal formulations. Entrepreneurship Development, Project selection, project report, technical knowledge, Capital venture, plant design, layout and construction. Pilot plant scale -up techniques, case studies of herbal extracts. Formulation and production management of herbals. **12 Hrs**

2. **Regulatory requirements for setting herbal drug industry:** Global marketing management. Indian and international patent law as applicable herbal drugs and natural products. Export - Import (EXIM) policy, TRIPS.

Quality assurance in herbal/natural drug products.

Concepts of TQM, GMP, GLP, ISO-9000.

12 Hrs

3. **Monographs of herbal drugs:** General parameters of monographs of herbal drugs and comparative study in IP, USP, Ayurvedic Pharmacopoeia, Siddha and Unani Pharmacopoeia, American herbal pharmacopoeia, British herbal pharmacopoeia, WHO guidelines in quality assessment of herbal drugs. **12 Hrs**

4. **Testing of natural products and drugs:** Herbal medicines - clinical laboratory testing. Stability testing of natural products, protocols, Standardization of phytopharmaceuticals **12 Hrs**
5. **Patents:** Indian and international patent laws, proposed amendments as applicable to herbal/natural products and process. Geographical indication, Copyright, Patentable subject matters, novelty, non obviousness, utility, enablement and best mode, procedure for Indian patent filing, patent processing, grant of patents, rights of patents, cases of patents, opposition and revocation of patents, patent search and literature, Controllers of patents. **12 Hrs**

#### REFERENCES (Latest Editions of)

1. Herbal drug industry by R.D. Choudhary (1996), Eastern Publisher, New Delhi.
2. GMP for Botanicals - Regulatory and Quality issues on Phytomedicine by Pulok K Mukharjee (2003), 1st Edition, Business horizons Robert Verpoorte, New Delhi.
3. Quality control of herbal drugs by Pulok K Mukarjee (2002), Business Horizons Pharmaceutical Publisher, New Delhi.
4. PDR for Herbal Medicines (2000), Medicinal Economic Company, New Jersey.
5. Indian Herbal Pharmacopoeia (2002), IDMA, Mumbai.
6. Text book of Pharmacognosy by C.K. Kokate, Purohit, Gokhlae (1996), Nirali Prakashan, New Delhi.
7. Text book of Pharmacognosy and Phytochemistry by Vinod D. Rangarl (2002), Part I & II, Career Publication, Nasik, India.
8. Plant drug analysis by H. Wagner and S. Bladt, Springer, Berlin.
9. Standardization of Botanicals. Testing and extraction methods of medicinal herbs by V. Rajpal (2004), Vol. I, Eastern Publisher, New Delhi.
10. Phytochemical Dictionary. Handbook of Bioactive Compounds from Plants by J.B. Harborne, (1999), 11th Edition, Taylor and Francis Ltd, UK.
11. Herbal Medicine. Expanded Commission E Monographs by M. Blumenthal, (2004), 1st Edition,
12. Drug Formulation Manual by D.P.S. Kohli and D.H. Shah (1998), Eastern Publisher, New Delhi.
13. Jalalpure, S.S. & Kurangi, B.K. (2022). Textbook of Herbal Drug Products Technology, Vallabh Prakashan, Delhi.
14. Jalalpure, S.S., Kurangi, B.K., & Nirmale, D.M. (2023). Intellectual Property Rights. Nirali, Prakashan, Pune.

## PHARMACOGNOSY PRACTICAL - I

### (MPG I05P)

1. Analysis of Pharmacopoeial compounds of natural origin and their formulations by UV Vis spectrophotometer.
2. Analysis of recorded spectra of simple phytoconstituents.
3. Experiments based on Gas Chromatography.
4. Estimation of sodium/potassium by flame photometry.
5. Development of fingerprint of selected medicinal plant extracts commonly used in herbal drug industry viz. Ashwagandha, Tulsi, Bael, Amla, Ginger, Aloe, Vidang, Senna, Lawsonia by TLC/HPTLC method.
6. Methods of extraction.
7. Phytochemical screening.
8. Demonstration of HPLC- estimation of glycerrhizin.
9. Monograph analysis of clove oil.
10. Monograph analysis of castor oil.
11. Identification of bioactive constituents from plant extracts.
12. Formulation of different dosage forms and their standardisation.
13. Separation of volatile oils by Clevenger's apparatus

## MEDICINAL PLANT BIOTECHNOLOGY

(MPG 201T)

### SCOPE

To explore the knowledge of Biotechnology and its application in the improvement of quality of medicinal plants

### OBJECTIVES

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

- Know the process like genetic engineering in medicinal plants for higher yield of Phytopharmaceuticals.
- Use the biotechnological techniques for obtaining and improving the quality of natural products/medicinal plants

### THEORY

60 Hrs

1. **Introduction to Plant biotechnology:** Historical perspectives, prospects for development of plant biotechnology as a source of medicinal agents. Applications in pharmacy and allied fields. Genetic and molecular biology as applied to pharmacognosy, study of DNA, RNA and protein replication, genetic code, regulation of gene expression, structure and complicity of genome, cell signaling, DNA recombinant technology. Bioinformatics in plant Biotechnolgy, Metabolomics in phytochemistry. **12 Hrs**
2. **Different tissue culture techniques:** Organogenesis and embryogenesis, synthetic seed and monoclonal variation, Protoplast fusion, Hairy root multiple shoot cultures and their applications. Micro propagation of medicinal and aromatic plants. Sterilization methods involved in tissue culture, gene transfer in plants and their applications. **15 Hrs**
3. **Immobilisation techniques & Secondary Metabolite Production:** Immobilization techniques of plant cell and its application on secondary metabolite Production. Cloning of plant cell: Different methods of cloning and its applications. Advantages and disadvantages of plant cell cloning. Secondary metabolism in tissue cultures with emphasis on production of medicinal agents. Precursors and elicitors on production of secondary metabolites. **15 Hrs**
4. **Biotransformation and Transgenesis:** Biotransformation, bioreactors for pilot and large scale cultures of plant cells and retention of biosynthetic potential

in cell culture. Transgenic plants, methods used in gene identification, localization and sequencing of genes. Application of PCR in plant genome analysis. **13 Hrs**

5. **Fermentation technology:** Application of Fermentation technology, Production of ergot alkaloids, single cell proteins, enzymes of pharmaceutical interest. **05 Hrs**

#### REFERENCES (Latest Editions of)

1. Plant tissue culture, Bhagwani, vol 5, Elsevier Publishers.
2. Plant cell and Tissue Culture (Lab. Manual), JRMM. Yeoman.
3. Elements in biotechnology by PK. Gupta, Rastogi Publications, New Delhi.
4. An introduction to plant tissue culture by MK. Razdan, Science Publishers.
5. Experiments in plant tissue culture by John HD and Lorin WR., Cambridge University Press.
6. Pharmaceutical biotechnology by SP. Vyas and VK. Dixit, CBS Publishers.
7. Plant cell and tissue culture by Jeffrey W. Pollard and John M Walker, Humana press.
8. Plant tissue culture by Dixon, Oxford Press, Washington DC, 1985
9. Plant tissue culture by Street.
10. Pharmacognosy by G. E. Trease and WC. Evans, Elsevier.
11. Biotechnology by Purohit and Mathur, Agro-Bio, 3<sup>rd</sup> revised edition.
12. Biotechnological applications to tissue culture by Shargool, Peter D, Shargool, CKC Press.
13. Pharmacognosy by Varo E. Tyler, Lynn R. Brady and James E. Robberrt, That Tjen, NGO.
14. Plant Biotechnology, Ciddi Veerasham.
15. Kokate CK, Jalalpure SS and Hurakadle PH. Textbook of Pharmaceutical Biotechnology. Elsevier Health - INR; 1st edition (1 January 2011); CBSPD - NEW DELHI -110092.
16. Jalalpure SS and Patil AK. Textbook of Pharmacognosy and Phytochemistry I, 2024, Nirali Prakashan, Pune.

## ADVANCED PHARMACOGNOSY - II (MPG 202T)

### SCOPE

To know and understand the Adulteration and Deterioration that occurs in herbal/natural drugs and methods of detection of the same. Study of herbal remedies and their validations, including methods of screening

### OBJECTIVES

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

- Validation of herbal remedies
- Methods of detection of adulteration and evaluation techniques for the herbal drugs
- Methods of screening of herbals for various biological properties

### THEORY

60 Hrs

1. **Herbal remedies** - Toxicity and Regulations: Herbals vs Conventional drugs, Efficacy of Herbal medicine products, Validation of herbal therapies, Pharmacodynamic and Pharmacokinetic issues. **12 Hrs**
2. **Adulteration and Deterioration:** Introduction, Types of Adulteration/ Substitution of Herbal drugs, Causes and Measures of Adulteration, Sampling Procedures, Determination of Foreign Matter, DNA Finger printing techniques in identification of drugs of natural origin, detection of heavy metals, pesticide residues, phytotoxin, microbial contamination in herbs and their formulations. **12 Hrs**
3. **Ethnobotany and Ethnopharmacology:** Ethnobotany in herbal drug evaluation, Impact of Ethnobotany in traditional medicine, New development in herbals, Bio-prospecting tools for drug discovery, Role of Ethnopharmacology in drug evaluation, Reverse Pharmacology. Plant based new drug delivery systems **12 Hrs**
4. **Analytical Profiles of herbal drugs:** *Andrographis paniculata*, *Boswellia serata*, *Coleus forskholii*, *Curcuma longa*, *Embelica officinalis*, *Psoralea corylifolia*. **12 Hrs**
5. **Biological screening of herbal drugs:** Introduction and Need for Phyto-Pharmacological Screening, New Strategies for evaluating Natural Products,

In vitro evaluation techniques for Antioxidants, Antimicrobial, Anti-diabetic, Anti-inflammatory and Anticancer drugs. In vivo evaluation techniques for Anti-inflammatory, Antiulcer, Anticancer, Wound healing, Antidiabetic, Hepatoprotective, Cardio protective, Diuretics and Antifertility, Toxicity studies as per OECD guidelines. **12 Hrs**

#### REFERENCES (Latest Editions of)

1. Glimpses of Indian Ethano Pharmacology by P. Pushpangadam. Ulf .Nyman. V.George Tropical Botanic Garden & Research Institute.
2. Natural products: A lab guide by Raphael Ikan, Academic Press.
3. Pharmacognosy - G. E. Trease and W.C. Evans. WB. Saunders Edinburgh, New York.
4. Pharmacognosy-Tyler, Brady, Robbers, Lee & Fetiger.
5. Modern Methods of Plant Analysis- Peach & M.V. Tracey, Vol. I & II, Springer Publishers.
6. Herbal Drug Industry by RD. Choudhary, Eastern Publishers, New Delhi.
7. Text book of Pharmacognosy by C.K.Kokate, Purohit, Ghokhale, Nirali Prakashan.
8. Text Book of Pharmacognosy by T.E. Wallis, J & A Churchill Ltd., London.
9. Quality control of herbal drugs by Pulok K Mukherjee, Business Horizons Pharmaceutical Publishers, New Delhi.
10. Indian Herbal Pharmacopoeia, IDMA, Mumbai.
11. Text book of Pharmacognosy and Phytochemistry by Vinod D. Rangarl, Part I & II, Career Publication, Nasik, India.
12. Plant drug analysis by H.Wagner and S.Bladt, 2nd edition, Springer, Berlin.
13. Standardization of Botanicals. Testing and extraction methods of medicinal herbs by V. Rajpal (2004), Vol.I, Eastern PublisherS, New Delhi.
14. Herbal Medicine. Expanded Commission E Monographs, M.Blumenthal.
15. Jalalpure SS and Patil AK. Textbook of Pharmacognosy and Phytochemistry I, 2024, Nirali Prakashan, Pune.
16. Jalalpure SS, Kurangi BK, Suryawanshi SS. Quality Control and Standardization of Phytomedicines. 2022. Nirali Prakashan, Pune.

## INDIAN SYSTEMS OF MEDICINE

(MPG 203T)

### SCOPE

To make the students understand thoroughly the principles, preparations of medicines of various Indian systems of medicine like Ayurveda, Siddha, Homeopathy and Unani. Also focusing on clinical research of traditional medicines, quality assurance and challenges in monitoring the safety of herbal medicines.

### OBJECTIVES

After completion of the course, student is able to

- To understand the basic principles of various Indian systems of medicine
- To know the clinical research of traditional medicines, Current Good Manufacturing Practice of Indian systems of medicine and their formulations.

### THEORY

60 Hrs

1. Fundamental concepts of Ayurveda, Siddha, Unani and Homoeopathy systems of medicine Different dosage forms of the ISM.

**Ayurveda:** Ayurvedic Pharmacopoeia, Analysis of formulations and bio crude drugs with references to: Identity, purity and quality, Pharmacognostic and phytochemical studies of crude drugs listed in Ayurvedic Pharmacopoeia of India (API).

**Siddha:** Gunapadam (Siddha Pharmacology), raw drugs/Dhatu/Jeevam in Siddha system of medicine, Purification process (Suddhi). **12 Hrs**

2. **Naturopathy, Yoga and Aromatherapy practices**

a) Naturopathy - Introduction, basic principles and treatment modalities.

b) Yoga - Introduction and Streams of Yoga. Asanas, Pranayama, Meditations and Relaxation techniques.

c) Aromatherapy - Introduction, aroma oils for common problems, carrier oils. **12 Hrs**

3. **Formulation development of various systems of medicine** Salient features of the techniques of preparation of some of the important class of Formulations as per Ayurveda, Siddha, Homeopathy and Unani Pharmacopoeia and texts. Standardization, Shelf life and Stability studies of ISM formulations. **12 Hrs**
4. **Schedule T - Good Manufacturing Practice of Indian systems of medicine** Components of GMP (Schedule - T) and its objectives, Infrastructural

requirements, working space, storage area, machinery and equipments, standard operating procedures, health and hygiene, documentation and records. Quality assurance in ISM formulation industry - GAP, GMP and GLP. Preparation of documents for new drug application and export registration.

Challenges in monitoring the safety of herbal medicines: Regulation, quality assurance and control, National/Regional Pharmacopoeias. **12 Hrs**

5. TKDL, Geographical indication Bill, Government bills in AYUSH, ISM, CCRAS, CCRS, CCRH, CCRU **12 Hrs**

#### REFERENCES (Latest Editions of)

1. Ayurvedic Pharmacopoeia, The Controller of Publications, Civil Lines, Govt. of India, New Delhi.
2. Hand Book on Ayurvedic Medicines, H. Panda, National Institute of Industrial Research, New Delhi.
3. Ayurvedic System of Medicine, Kaviraj Nagendranath Sengupata, Sri Satguru Publications, New Delhi.
4. Ayurvedic Pharmacopoeia. Formulary of Ayurvedic Medicines, IMCOPS, Chennai.
5. Homeopathic Pharmacopoeia. Formulary of Homeopathic Medicines, IMCOPS, Chennai.
6. Homeopathic Pharmacy : An introduction & Hand book, Steven B. Kayne, Churchill Livingstone, New York.
7. Indian Herbal Pharmacopoeia, IDMA, Mumbai.
8. British Herbal Pharmacopoeia, bRITISH Herbal Medicine Association, UK.
9. GMP for Botanicals - Regulatory and Quality issues on Phytomedicine, Pulok K Mukharjee, Business Horizons, New Delhi.
10. Indian System of Medicine and Homeopathy in India, Planning and Evaluation Cell, Govt. of India, New Delhi.
11. Essential of Food and Nutrition, Swaminathan, Bappco, Bangalore.
12. Clinical Dietitics and Nutrition, F.P. Antia, Oxford University Press, Delhi.
13. Yoga - The Science of Holistic Living by V.K.Yoga, Vivekananda Yoga Prakashna Publishing, Bangalore.
14. Jalalpure SS and Patil AK. Textbook of Pharmacognosy and Phytochemistry I, 2024, Nirali Prakashan, Pune.
15. Jalalpure SS, Kurangi BK, Suryawanshi SS. Quality Control and Standardization of Phytomedicines. 2022. Nirali Prakashan, Pune.

## HERBAL COSMETICS

(MPG 204T)

### SCOPE

This subject deals with the study of preparation and standardization of herbal/natural cosmetics. This subject gives emphasis to various national and international standards prescribed regarding herbal cosmeceuticals.

### OBJECTIVES

After completion of the course, student shall be able to,

- Understand the basic principles of various herbal/natural cosmetic preparations
- Current Good Manufacturing Practices of herbal/natural cosmetics as per the regulatory authorities

### THEORY

60 Hrs

1. **Introduction:** Herbal/natural cosmetics, Classification & Economic aspects; Sources, chemical constituents, commercial preparations, therapeutic and cosmetic use of : Aloe Vera gel, Almond oil, Lavender oil, Olive oil, Rosemary oil, Sandal wood oil  
**Regulatory Provisions relation to manufacture of cosmetics:** - License, GMP, offences & Penalties, Import & Export of Herbal/natural cosmetics, Industries involved in the production of Herbal/natural cosmetics. **12 Hrs**
2. Commonly used herbal cosmetics, raw materials, preservatives, surfactants, humectants, oils, colors, and some functional herbs, preformulation studies, compatibility studies, possible interactions between chemicals and herbs, design of herbal cosmetic formulation. **12 Hrs**
3. **Herbal Cosmetics :** Physiology and chemistry of skin and pigmentation, hairs, scalp, lips and nail, Cleansing cream, Lotions, Face powders, Face packs, Lipsticks, Bath products, soaps and baby product, Preparation and standardisation of the following : Tonic, Bleaches, Dentifrices and Mouth washes & Tooth Pastes, Cosmetics for Nails. **12 Hrs**
4. **Cosmeceuticals of herbal and natural origin:** Hair growth formulations, Shampoos, Conditioners, Colorants & hair oils, Fairness formulations, vanishing & foundation creams, anti-sun burn preparations, moisturizing creams, deodorants. **12 Hrs**

5. Analysis of Cosmetics, Toxicity screening and test methods: Quality control and toxicity studies as per Drug and Cosmetics Act. **12 Hrs**

**REFERENCES** (Latest Editions of)

1. Panda H. Herbal Cosmetics (Hand book), Asia Pacific Business Press Inc, New Delhi.
2. Thomson EG. Modern Cosmetics, Universal Publishing Corporation, Mumbai.
3. P.P.Sharma. Cosmetics - Formulation, Manufacturing & Quality Control, Vandana Publications, New Delhi.
4. Supriya K B. Handbook of Aromatic Plants, Pointer Publishers, Jaipur.
5. Skaria P. Aromatic Plants (Horticulture Science Series), New India Publishing Agency, New Delhi.
6. Kathi Keville and Mindy Green. Aromatherapy (A Complete Guide to the Healing Art), Sri Satguru Publications, New Delhi.
7. Chattopadhyay PK. Herbal Cosmetics & Ayurvedic Medicines (EOU), National Institute of Industrial Research, Delhi.
8. Balsam MS & Edward Sagarin. Cosmetics Science and Technology, Wiley Interscience, New York.

**PHARMACOGNOSY PRACTICAL - II**  
**(MPG 205P)**

1. Isolation of nucleic acid from cauliflower heads.
2. Isolation of RNA from yeast.
3. Quantitative estimation of DNA.
4. Immobilization technique.
5. Establishment of callus culture.
6. Establishment of suspension culture.
7. Estimation of aldehyde contents of volatile oils.
8. Estimation of total phenolic content in herbal raw materials.
9. Estimation of total alkaloid content in herbal raw materials.
10. Estimation of total flavonoid content in herbal raw materials.
11. Preparation and standardization of various simple dosage forms from Ayurvedic, Siddha, Homoeopathy and Unani formulary.
12. Preparation of certain Aromatherapy formulations.
13. Preparation of herbal cosmetic formulation such as lip balm, lipstick, facial cream, herbal hair and nail care products.
14. Evaluation of herbal tablets and capsules.
15. Preparation of sunscreen, UV protection cream, skin care formulations.
16. Formulation & standardization of herbal cough syrup.
17. In-Vitro evaluation techniques for Antioxidants(DPPH),Antimicrobial (Agar Well)

## MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES (MPA 101T)

### Scope

This subject deals with various advanced analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are NMR, Mass spectrometer, IR, HPLC, GC etc.

### Objectives

After completion of course student is able to know about chemicals and excipients

- The analysis of various drugs in single and combination dosage forms
- Theoretical and practical skills of the instruments

### THEORY

60 Hrs

1. **a. UV-Visible spectroscopy:** Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV-Visible spectroscopy, Difference/ Derivative spectroscopy.
  - b. **IR spectroscopy:** Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier - Transform IR Spectrometer, Factors affecting vibrational frequencies and Applications of IR spectroscopy, Data Interpretation.
  - c. **Spectrofluorimetry:** Theory of Fluorescence, Factors affecting fluorescence (Characteristics of drugs that can be analysed by fluorimetry), Quenchers, Instrumentation and Applications of fluorescence spectrophotometer.
  - d. **Flame emission spectroscopy and Atomic absorption spectroscopy:** Principle, Instrumentation, Interferences and Applications. 10 Hrs
2. **NMR spectroscopy:** Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and <sup>13</sup>C NMR. Applications of NMR spectroscopy. 10 Hrs

3. **Mass Spectroscopy:** Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules, Meta stable ions, Isotopic peaks and Applications of Mass spectroscopy. **10 Hrs**
4. **Chromatography:** Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution, isolation of drug from excipients, data interpretation and applications of the following:
- Thin Layer chromatography
  - High Performance Thin Layer Chromatography
  - Ion exchange chromatography
  - Column chromatography
  - Gas chromatography
  - High Performance Liquid chromatography
  - Ultra High Performance Liquid chromatography
  - Affinity chromatography
  - Gel Chromatography **10Hrs.**
5. **a. Electrophoresis:** Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following:  
 Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresis d) Zone electrophoresis e) Moving boundary electrophoresis f) Isoelectric focusing
- b. X ray Crystallography:** Production of X rays, Different X ray methods, Bragg's law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X-ray diffraction. **10 Hrs**
6. **a. Potentiometry:** Principle, working, Ion selective Electrodes and Application of potentiometry.
- b. Thermal Techniques:** 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). TGA: Principle, instrumentation, factors affecting results, advantage and disadvantages, pharmaceutical applications. **10 Hrs**

## REFERENCES

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Douglas A Skoog, F. James Holler, Timothy A. Nieman, 5<sup>th</sup> edition, Eastern press, Bangalore, 1998.
3. Instrumental methods of analysis - Willards, 7th edition, CBS publishers.
4. Practical Pharmaceutical Chemistry - Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi, 1997.
5. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis - Modern Methods - Part B - J W Munson, Vol 11, Marcel. Dekker Series
8. Spectroscopy of Organic Compounds, 2<sup>nd</sup> edn., P.S./Kalsi, Wiley eastern Ltd., Delhi.
9. Textbook of Pharmaceutical Analysis, K.A.Connors, 3<sup>rd</sup> Edition, John Wiley & Sons, 1982.

## ADVANCED PHARMACEUTICAL ANALYSIS

(MPA 102T)

### Scope:

This subject deals with the various aspects of Impurity, Impurities in new drug products, in residual solvents, Elemental impurities, Impurity profiling and characterization of degradants, Stability testing of phytopharmaceuticals and their protocol preparation. It also covers the biological testing of various vaccines and their principle and procedure.

### Objectives:

After completion of the course students shall able to know, Appropriate analytical skills required for the analytical method development. Principles of various reagents used in functional group analysis that renders necessary support in research methodology and demonstrates its application in the practical related problems. Analysis of impurities in drugs, residual solvents and stability studies of drugs and biological products

### THEORY

60 Hrs

#### 1. Impurity and stability studies:

Definition, classification of impurities in drug Substance or Active Pharmaceutical Ingredients and quantification of impurities as per ICH guidelines

**Impurities in new drug products:** Rationale for the reporting and control of degradation products, reporting degradation products content of batches, listing of degradation products in specifications, qualification of degradation products. **Impurities in residual solvents:** General principles, classification of residual solvents, Analytical procedures, limits of residual solvents, reporting levels of residual solvents. **10 Hrs**

#### 2. Elemental impurities: Element classification, control of elemental impurities, Potential Sources of elemental Impurities, Identification of Potential Elemental Impurities, analytical procedures, instrumentation & C, H, N and S analysis Stability testing protocols: Selection of batches, container orientation, test parameters, sampling frequency, specification, storage conditions, recording of results, concept of stability, commitment etc. Important mechanistic and stability related information provided by results of study of factors like temperature, pH, buffering species ionic

strength and dielectric constant etc. on the reaction rates. With practical considerations. **10 Hrs**

3. **Impurity profiling and degradant characterization:** Method development, Stability studies and concepts of validation accelerated stability testing & shelf life calculation, WHO and ICH stability testing guidelines, Stability zones, steps in development, practical considerations. Basics of impurity profiling and degradant characterization with special emphasis. Photostability testing guidelines, ICH stability guidelines for biological products
4. **Stability testing of phytopharmaceuticals:** Regulatory requirements, protocols, HPTLC/HPLC finger printing, interactions and complexity. **10 Hrs**
5. **Biological tests and assays of the following:** a. Adsorbed Tetanus vaccine b. Adsorbed Diphtheria vaccine c. Human anti haemophilic vaccine d. Rabies vaccine e. Tetanus Anti toxin f. Tetanus Anti serum g. Oxytocin h. Heparin sodium IP i. Antivenom. PCR, PCR studies for gene regulation, instrumentation (Principle and Procedures). **10 Hrs**
6. Immunoassays (IA) Basic principles, Production of antibodies, Separation of bound and unbound drug, Radioimmunoassay, Optical IA, Enzyme IA, Fluoro IA, Luminiscence IA, Quantification and applications of IA. **10 Hrs**

#### REFERENCES:

1. Vogel's textbook of quantitative chemical analysis - Jeffery J Bassett, J. Mendham, R. C. Denney, 5th edition, ELBS, 1991.
2. Practical Pharmaceutical Chemistry - Beckett and Stenlake, Vol II, 4th Edition, CBS publishers, New Delhi, 1997.
3. Textbook of Pharmaceutical Analysis - K A Connors, 3rd Edition, John Wiley & Sons, 1982. 103
4. Pharmaceutical Analysis - Higuchi, Brochmman and Hassen, 2nd Edition, Wiley - Inter science Publication, 1961.
5. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers New Delhi, 1997.

6. Pharmaceutical Analysis- Modern methods - J W Munson - Part B, Volume 11, Marcel Dekker Series.
7. The Quantitative analysis of Drugs - D C Carratt, 3rd edition, CBS Publishers, NewDelhi, 1964.
8. Indian Pharmacopoeia Vol I , II & III 2007, 2010, 2014.
9. Methods of sampling and microbiological examination of water, first revision, BIS 10. Practical HPLC method development - Snyder, Kirkland, Glajch, 2nd edition, John Wiley & Sons.
11. Analytical Profiles of drug substances - Klaus Florey, Volume 1 - 20, Elsevier, 2005 12. Analytical Profiles of drug substances and Excipients - Harry G Brittan, Volume 21 - 30, Elsevier, 2005.
13. The analysis of drugs in biological fluids - Joseph Chamberlain, 2nd edition, CRC press, London.
14. ICH Guidelines for impurity profiles and stability studies.

## PHARMACEUTICAL VALIDATION

(MPA 103T)

### Scope:

The main purpose of the subject is to understand about validation and how it can be applied to industry and thus to improve the quality of the products. The subject covers the complete information about validation, types, methodology and application.

### Objectives:

Upon completion of the subject student shall be able to

- Explain the aspect of validation
- Carryout validation of manufacturing processes
- Apply the knowledge of validation to instruments and equipments
- Validate the manufacturing facilities

### THEORY 60 Hrs

1. **Introduction:** Definition of Qualification and Validation, Advantage of Validation, Streamlining of Qualification & Validation process and Validation Master Plan.

**Qualification:** User Requirement Specification, Design Qualification, Factory Acceptance Test (FAT)/ Site Acceptance Test (SAT), Installation Qualification, Operational Qualification, Performance Qualification, Re- Qualification (Maintaining status Calibration Preventive Maintenance, Change management), Qualification of Manufacturing Equipments, Qualification of Analytical Instruments and Laboratory equipments. **12 Hrs**

2. **Qualification of analytical instruments:** Electronic balance, pH meter, UV-Visible spectrophotometer, FTIR, GC, HPLC, HPTLC Qualification of Glassware: Volumetric flask, pipette, Measuring cylinder, beakers and burette. **12 Hrs**

3. **Validation of Utility systems:** Pharmaceutical Water System & pure steam, HVAC system, Compressed air and nitrogen. Cleaning Validation: Cleaning Validation - Cleaning Method development, Validation and validation of

analytical method used in cleaning. Cleaning of Equipment, Cleaning of Facilities. Cleaning in place (CIP).

4. **Analytical method validation:** General principles, Validation of analytical method as per ICH guidelines and USP Computerized system validation: Electronic records and digital significance-21 CFR part 11 and GAMP 5. **12 Hrs**
5. **General Principles of Intellectual Property:** 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 applications; 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. Significance of transfer technology (TOT), IP and ethics-positive and negative aspects of IPP; Societal responsibility, avoiding unethical practices. **12 Hrs**

## REFERENCES:

1. B. T. Loftus & R. A. Nash, "Pharmaceutical Process Validation", Drugs and Pharm Sci. Series, Vol. 129, 3rd Ed., Marcel Dekker Inc., N.Y.
2. The Theory & Practice of Industrial Pharmacy, 3rd edition, Leon Lachman, Herbert A. Lieberman, Joseph. L. Karig, Varghese Publishing House, Bombay.
3. Validation Master plan by Terveeks or Deeks, Davis Harwood International publishing.
4. Validation of Aseptic Pharmaceutical Processes, 2nd Edition, by Carleton & Agalloco, (Marcel Dekker).
5. Michael Levin, Pharmaceutical Process Scale-Up , Drugs and Pharm. Sci. Series, Vol. 157,2nd Ed., Marcel Dekker Inc., N.Y.
6. Validation Standard Operating Procedures: A Step by Step Guide for Achieving Compliance in the Pharmaceutical, Medical Device, and Biotech Industries, Syed Imtiaz Haider

7. Pharmaceutical Equipment Validation: The Ultimate Qualification Handbook, Phillip A. Cloud, Interpharm Press
8. Validation of Pharmaceutical Processes: Sterile Products, Frederick J. Carlton (Ed.) and James Agalloco (Ed.), Marcel Dekker, 2nd Ed.
9. Analytical Method validation and Instrument Performance Verification by Churg Chan, Heiman Lam, Y.C. Lee, Yue. Zhang, Wiley Inter Science.

## FOOD ANALYSIS

(MPA 104T)

### Scope:

This course is designed to impart knowledge on analysis of food constituents and finished food products. The course includes application of instrumental analysis in the determination of pesticides in variety of food products.

### Objectives:

At completion of this course student shall be able to understand various analytical techniques in the determination of

- Food constituents
- Food additives
- Finished food products
- Pesticides in food
- And also student shall have the knowledge on food regulations and legislations

### THEORY

60 Hrs

1. **Carbohydrates:** classification and properties of food carbohydrates, General methods of analysis of food carbohydrates, Changes in food carbohydrates during processing, Digestion, absorption and metabolism of carbohydrates, Dietary fibre, Crude fibre and application of food carbohydrates  
**Proteins:** Chemistry and classification of amino acids and proteins, Physico-Chemical properties of protein and their structure, general methods of analysis of proteins and amino acids, Digestion, absorption and metabolism of proteins. **12 Hrs**
2. **Lipids:** Classification, general methods of analysis, refining of fats and oils; hydrogenation of vegetable oils, Determination of adulteration in fats and oils, Various methods used for measurement of spoilage of fats and fatty foods.  
**Vitamins:** classification of vitamins, methods of analysis of vitamins, Principles of microbial assay of vitamins of B-series. **12 Hrs**

3. **Food additives:** Introduction, analysis of Preservatives, antioxidants, artificial sweeteners, flavors, flavor enhancers, stabilizers, thickening and jelling agents. Pigments and synthetic dyes: Natural pigments, their occurrence and characteristic properties, permitted synthetic dyes, Non-permitted synthetic dyes used by industries, Method of detection of natural, permitted and non-permitted dyes. **12 Hrs**
4. General Analytical methods for milk, milk constituents and milk products like ice cream, milk powder, butter, margarine, cheese including adulterants and contaminants of milk. Analysis of fermentation products like wine, spirits, beer and vinegar. **12 Hrs**
5. **Pesticide analysis:** Effects of pest and insects on various food, use of pesticides in agriculture, pesticide cycle, organophosphorus and organochlorine pesticides analysis, determination of pesticide residues in grain, fruits, vegetables, milk and milk products. Legislation regulations of food products with special emphasis on BIS, Agmark, FDA and US-FDA. **12 Hrs**

#### REFERENCES:

1. The chemical analysis of foods - David Pearson, Seventh edition, Churchill Livingstone, Edinburgh London, 1976
2. Introduction to the Chemical analysis of foods - S. Nielsen, Jones & Bartlett publishers, Boston London, 1994.
3. Official methods of analysis of AOAC International, sixth edition, Volume I & II, 1997.
4. Analysis of Food constituents - Multon, Wiley VCH.
5. Dr. William Horwitz, Official methods of analysis of AOAC International, 18th edition, 2005

**PHARMACEUTICAL ANALYSIS PRACTICALS - I**  
**(MPA 105P)**

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. Assay of official compounds by different titrations
8. Assay of official compounds by instrumental techniques.
9. Quantitative determination of hydroxyl group.
10. Quantitative determination of amino group
11. Colorimetric determination of drugs by using different reagents
12. Impurity profiling of drugs
13. Calibration of glasswares
14. Calibration of pH meter
15. Calibration of UV-Visible spectrophotometer
16. Calibration of FTIR spectrophotometer
17. Calibration of GC instrument
18. Calibration of HPLC instrument
19. Cleaning validation of any one equipment
20. Determination of total reducing sugar
21. Determination of proteins

22. Determination of saponification value, Iodine value, Peroxide value, Acid value in food products
23. Determination of fat content and rancidity in food products
24. Analysis of natural and synthetic colors in food
25. Determination of preservatives in food
26. Determination of pesticide residue in food products
27. Analysis of vitamin content in food products
28. Determination of density and specific gravity of foods
29. Determination of food additives

## ADVANCED INSTRUMENTAL ANALYSIS

(MPA 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, and hyphenated techniques.

### Objectives:

After completion of course student is able to know,

- interpretation of the NMR, Mass and IR spectra of various organic compounds
- theoretical and practical skills of the hyphenated instruments
- identification of organic compounds

### THEORY 60 Hrs

1. **HPLC:** Principle, instrumentation, pharmaceutical applications, peak shapes, capacity factor, selectivity, plate number, plate height, resolution, band broadening, pumps, injector, detectors, columns, column problems, gradient HPLC, HPLC solvents, trouble shooting, sample preparation, method development, New developments in HPLC-role and principles of ultra, nano liquid chromatography in pharmaceutical analysis. Immobilized polysaccharide CSP's: Advancement in enantiomeric separations, reversed phase Chiral method development and HILIC approaches. HPLC in Chiral analysis of pharmaceuticals. Preparative HPLC, practical aspects of preparative HPLC. **12 Hrs**
2. **Biochromatography:** Size exclusion chromatography, ion exchange chromatography, ion pair chromatography, affinity chromatography general principles, stationary phases and mobile phases.  
**Gas chromatography:** Principles, instrumentation, derivatization, head space sampling, columns for GC, detectors, quantification. High performance Thin Layer chromatography: Principles, instrumentation, pharmaceutical applications. **12 Hrs**
3. **Super critical fluid chromatography:** Principles, instrumentation, pharmaceutical applications. Capillary electrophoresis: Overview of CE

in pharmaceutical analysis, basic configuration, CE characteristics, principles of CE, methods and modes of CE. General considerations and method. **12 Hrs**

4. **Mass spectrometry:** Principle, theory, instrumentation of mass spectrometry, different types of ionization like electron impact, chemical, field, FAB and MALD, APCI, ESI, APPI mass fragmentation and its rules, meta stable ions, isotopic peaks and applications of mass spectrometry. LC-MS hyphenation and DART MS analysis. Mass analysers (Quadrpole, Time of flight, FT-ICR, ion trap and Orbitrap) instruments. MS/MS systems (Tandem: QqQ, TOF-TOF; Q-IT, Q-TOF, LTQ-FT, LTQ-Orbitrap). **12 Hrs**
5. **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 with reference to <sup>13</sup>CNMR: Spin spin and spin lattice relaxation phenomenon. <sup>13</sup>C NMR, 1-D and 2-D NMR, NOESY and COSY techniques, Interpretation and Applications of NMR spectroscopy. LC-NMR hyphenations. **12 Hrs**

## REFERENCES:

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

## MODERN BIO-ANALYTICAL TECHNIQUES (MPA 202T)

### Scope:

This subject is designed to provide detailed knowledge about the importance of analysis of drugs in biological matrices.

### Objectives:

Upon completion of the course, the student shall be able to understand Extraction of drugs from biological samples Separation of drugs from biological samples using different techniques Guidelines for BA/BE studies.

### THEORY

60 Hrs

1. **Extraction of drugs and metabolites from biological matrices:** General need, principle and procedure involved in the Bioanalytical methods such as Protein precipitation, Liquid - Liquid extraction and Solid phase extraction and other novel sample preparation approach. Bioanalytical method validation: USFDA and EMEA guidelines. 12 Hrs
2. **Biopharmaceutical Consideration:** Introduction, Biopharmaceutical Factors Affecting Drug Bioavailability, In Vitro: Dissolution and Drug Release Testing, Alternative Methods of Dissolution Testing Transport models, Biopharmaceutics Classification System. Solubility: Experimental methods. Permeability: In-vitro, in-situ and In-vivo methods. 12 Hrs
3. **Pharmacokinetics and Toxicokinetics:** Basic consideration, Drug interaction (PK-PD interactions), The effect of protein-binding interactions, The effect of tissue-binding interactions, Cytochrome P450-based drug interactions, Drug interactions linked to transporters. Microsomal assays Toxicokinetics-Toxicokinetic evaluation in preclinical studies, Importance and applications of toxicokinetic studies. LC-MS in bioactivity screening and proteomics. 12 Hrs
4. **Cell culture techniques** Basic equipments used in cell culture lab. Cell culture media, various types of cell culture, general procedure for cell cultures; isolation of cells, subculture, cryopreservation, characterization of cells and their applications. Principles and applications of cell viability assays (MTT assays), Principles and applications of flow cytometry. 12 Hrs

5. **Metabolite identification:** In-vitro / in-vivo approaches, protocols and sample preparation. Microsomal approaches (Rat liver microsomes (RLM) and Human liver microsomes (HLM) in Met-ID. Regulatory perspectives. In-vitro assay of drug metabolites & drug metabolizing enzymes.

**Drug Product Performance, In Vivo:** Bioavailability and Bioequivalence: Drug Product Performance, Purpose of Bioavailability Studies, Relative and Absolute Availability. Methods for Assessing Bioavailability, Bioequivalence Studies, Design and Evaluation of Bioequivalence Studies, Study Designs, Crossover Study Designs, Generic Biologics (Biosimilar Drug Products), Clinical Significance of Bioequivalence Studies. 12 Hrs

## REFERENCES:

1. Analysis of drugs in Biological fluids - Joseph Chamberlain, 2nd Edition. CRC Press, Newyork. 1995. 2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Pharmaceutical Analysis - Higuchi, Brochmman and Hassen, 2nd Edition, Wiley - Interscience Publications, 1961.
4. Pharmaceutical Analysis- Modern methods - Part B - J W Munson, Volume 11, Marcel Dekker Series 5. Practical HPLC method Development - Snyder, Kirkland, Glaich, 2nd Edition, John Wiley & Sons, New Jerco. USA.
6. Chromatographic Analysis of Pharmaceuticals - John A Adamovics, 2nd Edition, Marcel Dekker, Newyork, USA. 1997.
7. Chromatographic methods in clinical chemistry & Toxicology - Roger L Bertholf, Ruth E Winecker, John Wiley & Sons, New Jerco, USA. 2007.
8. Good Laboratory Practice Regulations, 2nd Edition, Sandy Weinberg Vol. 69, Marcel Dekker Series, 1995.
9. Good laboratory Practice Regulations - Allen F. Hirsch, Volume 38, Marcel Dekker Series, 1989.
10. ICH, USFDA & CDSCO Guidelines.
11. Palmer

## QUALITY CONTROL AND QUALITY ASSURANCE (MPA 203T)

### Scope:

This course deals with the various aspects of quality control and quality assurance aspects of pharmaceutical industries. It covers the important aspects like cGMP, QC tests, documentation, quality certifications, GLP and regulatory affairs.

### Objectives:

At the completion of this subject it is expected that the student shall be able to know

- the cGMP aspects in a pharmaceutical industry
- to appreciate the importance of documentation
- to understand the scope of quality certifications applicable
- to Pharmaceutical industries to understand the responsibilities of QA & QC departments.

### THEORY

**60 hrs**

1. Concept and Evolution of Quality Control and Quality Assurance Good Laboratory Practice, GMP, Overview of ICH Guidelines - QSEM, with special emphasis on Q-series guidelines. Good Laboratory Practices: Scope of GLP, Definitions, Quality assurance unit, protocol for conduct of non clinical testing, control on animal house, report preparation and documentation. **12 Hrs**
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 lay out, maintenance, sanitation, environmental control, utilities and maintenance of sterile areas, control of contamination and Good Warehousing Practice. CPCSEA guidelines. **12 Hrs**
3. Analysis of raw materials, finished products, packaging materials, in process quality control (IPQC), Developing specification (ICH Q6 and Q3) Purchase specifications and maintenance of stores for raw materials. In process quality control and finished products quality control for following formulation in Pharma industry according to Indian, US and

British pharmacopoeias: tablets, capsules, ointments, suppositories, creams, parenterals, ophthalmic and surgical products (How to refer pharmacopoeias), Quality control test for containers, closures and secondary packing materials. **12 Hrs**

4. **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 Formula Record, Batch Formula Record, Quality audit plan and reports. Specification and test procedures, Protocols and reports. Distribution records. Electronic data. **12 Hrs**
5. **Manufacturing operations and controls:** 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. **12 Hrs**

## REFERENCES:

1. Quality Assurance Guide by organization of Pharmaceutical Procedures of India, 3rd revised edition, Volume I & II, Mumbai, 1996.
2. Good Laboratory Practice Regulations, 2nd Edition, Sandy Weinberg Vol. 69, Marcel Dekker Series, 1995.
3. Quality Assurance of Pharmaceuticals- A compedium of Guide lines and Related materials Vol I & II, 2nd edition, WHO Publications, 1999.
4. How to Practice GMP's - P P Sharma, Vandana Publications, Agra, 1991.
5. The International Pharmacopoeia - vol I, II, III, IV & V - General Methods of Analysis and Quality specification for Pharmaceutical Substances, Excepients 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.

## HERBAL AND COSMETIC ANALYSIS

(MPA 204T)

### Scope:

This course is designed to impart knowledge on analysis of herbal products. Regulatory requirements, herbal drug interaction with monographs. Performance evaluation of cosmetic products is included for the better understanding of the equipments used in cosmetic industries for the purpose.

### Objectives:

At completion of this course student shall be able to understand Determination of herbal remedies and regulations Analysis of natural products and monographs Determination of Herbal drug-drug interaction Principles of performance evaluation of cosmetic products.

### THEORY

60 Hrs

1. **Herbal remedies- Toxicity and Regulations:** Herbals vs Conventional drugs, Efficacy of herbal medicine products, Validation of Herbal Therapies, Pharmacodynamic and Pharmacokinetic issues. Herbal drug standardization: WHO and AYUSH guidelines. **12 Hrs**
2. **Adulteration and Deterioration:** Introduction, types of adulteration/ substitution of herbal drugs, Causes and Measure of adulteration, Sampling Procedures, Determination of Foreign Matter, DNA Finger printing techniques in identification of drugs of natural origin, heavy metals, pesticide residues, phototoxin and microbial contamination in herbal formulations. Regulatory requirements for setting herbal drug industry: Global marketing management, Indian and international patent law as applicable herbal drugs and natural products and its protocol. **12 Hrs**
3. **Testing of natural products and drugs:** Effect of herbal medicine on clinical laboratory testing, Adulterant Screening using modern analytical instruments, Regulation and dispensing of herbal drugs, Stability testing of natural products, protocol. Monographs of Herbal drugs: Study of monographs of herbal drugs and comparative study in IP, USP, Ayurvedic Pharmacopoeia, American herbal Pharmacopoeia, British herbal Pharmacopoeia, Siddha and Unani Pharmacopoeia, WHO guidelines in quality assessment of herbal drugs. **12 Hrs**

4. **Herbal drug-drug interaction:** WHO and AYUSH guidelines for safety monitoring of natural medicine, Spontaneous reporting schemes for bio drug adverse reactions, bio drug-drug and bio drug-food interactions with suitable examples. Challenges in monitoring the safety of herbal medicines. **12 Hrs**
5. **Evaluation of cosmetic products:** Determination of acid value, ester value, saponification value, iodine value, peroxide value, rancidity, moisture, ash, volatile matter, heavy metals, fineness of powder, density, viscosity of cosmetic raw materials and finished products. Study of quality of raw materials and general methods of analysis of raw material used in cosmetic manufacture as per BIS. Indian Standard specification laid down for sampling and testing of various cosmetics in finished forms such as baby care products, skin care products, dental products, personal hygiene preparations and perfumes, lips sticks. Hair products and skin creams by Bureau Indian Standards. **12 Hrs**

## REFERENCES:

1. Pharmacognosy by Trease and Evans
2. Pharmacognosy by Kokate, Purohit and Gokhale
3. Quality Control Methods for Medicinal Plant, WHO, Geneva
4. Pharmacognosy & Pharmacobiotechnology by Ashutosh Kar
5. Essential of Pharmacognosy by Dr.S.H.Ansari 12 Hrs 12 Hrs
6. Cosmetics - Formulation, Manufacturing and Quality Control, P.P. Sharma, 4th edition, Vandana Publications Pvt. Ltd., Delhi
7. Indian Standard specification, for raw materials, BIS, New Delhi.
8. Indian Standard specification for 28 finished cosmetics BIS, New Delhi
9. Harry's Cosmeticology 8th edition
10. Suppliers catalogue on specialized cosmetic excipients
11. Wilkinson, Moore, seventh edition, George Godwin. Poucher's Perfumes, Cosmetics and Soaps
12. Hilda Butler, 10th Edition, Kluwer Academic Publishers. Handbook of Cosmetic Science and Technology, 3rd Edition.

## PHARMACEUTICAL ANALYSIS PRACTICALS -II (MPA 205P)

1. Comparison of absorption spectra by UV and Wood ward - Fiesure rule
2. Interpretation of organic compounds by FT-IR
3. Interpretation of organic compounds by NMR
4. Interpretation of organic compounds by MS
5. Determination of purity by DSC in pharmaceuticals
6. Identification of organic compounds using FT-IR, NMR, CNMR and Mass spectra
7. Bio molecules separation utilizing various sample preparation techniques and Quantitative analysis of components by gel electrophoresis.
8. Bio molecules separation utilizing various sample preparation techniques and Quantitative analysis of components by HPLC techniques.
9. Isolation of analgesics from biological fluids (Blood serum and urine).
10. Protocol preparation and performance of analytical/Bioanalytical method validation. 11. Protocol preparation for the conduct of BA/BE studies according to guidelines.
12. In process and finished product quality control tests for tablets, capsules, parenterals and creams
13. Quality control tests for Primary and secondary packing materials
14. Assay of raw materials as per official monographs
15. Testing of related and foreign substances in drugs and raw materials
16. Preparation of Master Formula Record.
17. Preparation of Batch Manufacturing Record.
18. Quantitative analysis of rancidity in lipsticks and hair oil
19. Determination of aryl amine content and Developer in hair dye

20. Determination of foam height and SLS content of Shampoo.
21. Determination of total fatty matter in creams (Soap, skin and hair creams)
22. Determination of acid value and saponification value.
23. Determination of calcium thioglycolate in depilatories.

## Semester III

### MRM 301T - Research Methodology & Biostatistics

#### UNIT - I

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

#### UNIT - II

**Biostatistics:** Definition, application, sample size, importance of sample size, factors influencing sample size, dropouts, statistical tests of significance, 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.

#### UNIT - III

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

#### UNIT - IV

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

#### UNIT - V

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