



ರಾಜೀವ್ ಗಾಂಧಿ ಆರೋಗ್ಯ ವಿಜ್ಞಾನಗಳ ವಿಶ್ವವಿದ್ಯಾಲಯ, ಕರ್ನಾಟಕ, ಬೆಂಗಳೂರು  
RAJIV GANDHI UNIVERSITY OF HEALTH SCIENCES, KARNATAKA, BENGALURU  
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RGU/AUTH/MPHARM/147/2017-18

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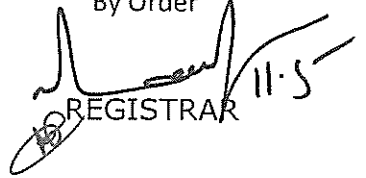
## NOTIFICATION

- Sub:** Revised ordinance relating to Master of Pharmacy (M.Pharm) course (Semester System)
- Ref:** (1) PCI Notification ref.No.14-136-2016-PCI,14-154/2015-PCI (53095-55431) dated 21.12.2016  
(2) Proceedings of meeting of BOS in Pharmacy (PG) held on 05.12.2016  
(3) Proceedings of meeting of Faculty of Pharmacy held on 05.12.2016  
(4) Proceedings of meeting of Academic Council held on 22.12.2016  
(5) Approval of Syndicate in its 125<sup>th</sup> meeting held on 06.01.2017.

In exercise of the powers conferred under section 35 of RGUHS Act, 1994, Syndicate is pleased to notify the revised ordinance relating to Master of Pharmacy (M.Pharm) course (Semester System) as shown in annexure appended herewith.

The revised ordinance shall come into force from the academic year 2017-18 and onwards.

By Order

  
REGISTRAR 11.5

To

1. All the Principals of Pharmacy Colleges affiliated to RGUHS
2. The Registrar (Evaluation), RGUHS
3. The Director, Dept. of Curriculum Development, RGUHS

Copy to:

1. The Secretary to Governor, Governor's Secretariat, Raj Bhavan, Bangalore-560 001.
2. The Secretary to Government, Health & Family Welfare Department (Medical Education).Vikasa Soudha, Bangalore-560 001.
3. The PA to Vice-Chancellor/Registrar/Registrar(Evaluation), RGUHS, Bangalore
4. The System Analyst, RGUHS to host the notification on RGUHS website.
5. Guard File/Office Copy

**Revised Regulations for the  
Master of Pharmacy Degree Program  
(w.e.f. June 2016)**

***Credit Based Semester System***

**Pharmacy Council of India**  
**Combined Council's Building, Kotla Road,**  
**Aiwan-E-Ghalib Marg,**  
**New Delhi-110 002**

## 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

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 V**. 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 I.

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

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

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

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

<b>Course Code</b>	<b>Course</b>	<b>Credit Hours</b>	<b>Credit Points</b>	<b>Hrs./wk</b>	<b>Marks</b>
<b>Semester I</b>					
MCC101T	Cosmeceuticals – Biology	4	4	4	100
MCC102T	Cosmetics - Formulation Science	4	4	4	100
MCC103T	Quality Assurance	4	4	4	100
MCC104T	Cellular and Molecular Pharmacology	4	4	4	100
MCC105P	Cosmeceutics 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>					
MCC201T	Cosmeceuticals	4	4	4	100
MCC202T	Cosmetic Analysis and Evaluation	4	4	4	100
MCC203T	Cosmetics- Industry and Regulatory	4	4	4	100
MCC204T	Computer Aided Drug Delivery System	4	4	4	100
MCC205P	Cosmeceutics 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. (Industrial Pharmacy)**

<b>Course Code</b>	<b>Course</b>	<b>Credit Hours</b>	<b>Credit Points</b>	<b>Hrs./wk</b>	<b>Marks</b>
<b>Semester I</b>					
MPA101T	Modern Pharmaceutical Analytical Techniques	4	4	4	100
MIP101T	Pharmaceutical Formulation Development	4	4	4	100
MIP102T	Customized drug Delivery System	4	4	4	100
MIP103T	Drug Regulations and Intellectual Property Rights	4	4	4	100
MIP104P	Industrial Pharmacy 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>					
MIP201T	Advanced Biopharmaceutics and Pharmacokinetics	4	4	4	100
MIP202T	Scale up and Technology Transfer	4	4	4	100
MIP203T	Pharmaceutical Production Technology	4	4	4	100
MIP204T	Entrepreneurship Management	4	4	4	100
MIP205P	Industrial Pharmacy 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 Analysis)**

<b>Course Code</b>	<b>Course</b>	<b>Credit Hours</b>	<b>Credit Points</b>	<b>Hrs./wk</b>	<b>Marks</b>
<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	Cosmetic Analysis and Evaluation	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 – 5: Course of study for M. Pharm. (Pharmaceutical Biotechnology)**

Course Code	Course	Credit Hours	Credit Points	Hrs./wk	Marks
<b>Semester I</b>					
MPA101T	Modern Pharmaceutical Analytical Techniques	4	4	4	100
MPB101T	Microbial And Cellular Biology	4	4	4	100
MPB102T	Bioprocess Engineering and Technology	4	4	4	100
MPB103T	Advanced Pharmaceutical Biotechnology	4	4	4	100
MPB104P	Pharmaceutical Biotechnology 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>					
MPB201T	Proteins and protein Formulation	4	4	4	100
MPB202T	Immunotechnology	4	4	4	100
MPB203T	Bioinformatics and Computer Technology	4	4	4	100
MPB204T	Biological Evaluation of Drug Therapy	4	4	4	100
MPB205P	Pharmaceutical Biotechnology 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. (Pharmaceutical Chemistry)**

<b>Course Code</b>	<b>Course</b>	<b>Credit Hours</b>	<b>Credit Points</b>	<b>Hrs./wk</b>	<b>Marks</b>
<b>Semester I</b>					
MPA101T	Modern Pharmaceutical Analytical Techniques	4	4	4	100
MPC101T	Advanced Organic Chemistry -I	4	4	4	100
MPC102T	Advanced Medicinal chemistry	4	4	4	100
MPC103T	Chemistry of Natural Products	4	4	4	100
MPC104P	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 – 7: Course of study for M. Pharm. (Pharmaceutics)**

Course Code	Course	Credit Hours	Credit Points	Hrs./wk	Marks
<b>Semester I</b>					
MPA101T	Modern Pharmaceutical Analytical Techniques	4	4	4	100
MPH101T	Modified Release Drug Delivery System	4	4	4	100
MPH102T	Modern Pharmaceutics	4	4	4	100
MPH103T	Pharmaceutical Regulatory Affair	4	4	4	100
MPH104P	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>
<b>Semester II</b>					
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 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>

**Table – 8: Course of study for M. Pharm. (Pharmacognosy)**

Course Code	Course	Credit Hours	Credit Points	Hrs./wk	Marks
<b>Semester I</b>					
MPA101T	Modern Pharmaceutical Analytical Techniques	4	4	4	100
MPG101T	Advanced Pharmacognosy-1	4	4	4	100
MPG102T	Phytochemistry	4	4	4	100
MPG103T	Industrial Herbal drug technology	4	4	4	100
MPG104P	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
MPG102T	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 – 9: Course of study for (Pharmacology)**

Course Code	Course	Credit Hours	Credit Points	Hrs./wk	Marks
<b>Semester I</b>					
MPA101T	Modern Pharmaceutical Analytical Techniques	4	4	4	100
MPL101T	Advanced Pharmacology-I	4	4	4	100
MPL102T	Pharmacological and Toxicological Screening Methods-I	4	4	4	100
MPL103T	Cellular and Molecular Pharmacology	4	4	4	100
MPL104P	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
MPL102T	Pharmacological and Toxicological Screening Methods-II	4	4	4	100
MPL203T	Principles of Drug Discovery	4	4	4	100
MPL204T	Experimental Pharmacology practical- II	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 – 10: 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
MPP102T	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 – 11: Course of study for M. Pharm. (Pharmaceutical Quality Assurance)**

Course Code	Course	Credit Hours	Credit Points	Hrs./wk	Marks
<b>Semester I</b>					
MPA101T	Modern Pharmaceutical Analytical Techniques	4	4	4	100
MQA101T	Quality Management System	4	4	4	100
MQA102T	Quality Control and Quality Assurance	4	4	4	100
MQA103T	Product Development and Technology Transfer	4	4	4	100
MQA104P	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 – 12: Course of study for M. Pharm. (Pharmaceutical Regulatory Affairs)**

Course Code	Course	Credit Hours	Credit Points	Hrs./wk	Marks
<b>Semester I</b>					
MRA101T	Good Pharmaceutical Practices	4	4	4	100
MRA102T	Pharmaceutical Regulations in India	4	4	4	100
MRA103T	International Pharmaceutical Regulations I	4	4	4	100
MRA104T	Clinical Research Regulations	4	4	4	100
MRA105T	Pharmaceutical Regulatory Affairs 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>					
MRA201T	Documentation and Regulatory Writing	4	4	4	100
MRA202T	Biologicals Regulations	4	4	4	100
MRA203T	International Pharmaceutical Regulations II	4	4	4	100
MRA204T	Medical Device Regulations	4	4	4	100
MRA205P	Pharmaceutical Regulatory Affairs 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 – 13: Course of study for M. Pharm. III Semester  
(Common for All Specializations)**

<b>Course Code</b>	<b>Course</b>	<b>Credit Hours</b>	<b>Credit Points</b>
MRM101T	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 – 14: Course of study for M. Pharm. IV Semester  
(Common for All Specializations)**

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

**Table – 15: Semester wise credits distribution**

<b>Semester</b>	<b>Credit Points</b>
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 – 16: 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 – XVII.

### **11.1. End semester examinations**

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

**Tables – 17: Schemes for internal assessments and end semester examinations (Cosmeceutics)**

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
<b>SEMESTER I</b>								
MCC101T	Cosmeceuticals – Biology	10	15	1 Hr	25	75	3 Hrs	100
MCC102T	Cosmetics - Formulation Science	10	15	1 Hr	25	75	3 Hrs	100
MCC103T	Quality Assurance	10	15	1 Hr	25	75	3 Hrs	100
MCC104T	Cellular and Molecular Pharmacology	10	15	1 Hr	25	75	3 Hrs	100
MCC105P	Cosmeceutics Practical I	20	30	6 Hrs	50	100	6 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
<b>Total</b>								<b>650</b>
<b>SEMESTER II</b>								
MCC201T	Cosmeceuticals	10	15	1 Hr	25	75	3 Hrs	100
MCC202T	Cosmetic Analysis and Evaluation	10	15	1 Hr	25	75	3 Hrs	100
MCC203T	Cosmetics- Industry and Regulatory	10	15	1 Hr	25	75	3 Hrs	100
MCC204T	Computer Aided Drug Delivery System	10	15	1 Hr	25	75	3 Hrs	100
MCC201T	Cosmeceuticals	20	30	6 Hrs	50	100	6 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
<b>Total</b>								<b>650</b>

**Tables – 18: Schemes for internal assessments and end semester examinations (Industrial Pharmacy)**

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 Analytical Techniques	10	15	1 Hr	25	75	3 Hrs	100
MIP101T	Pharmaceutical Formulation Development	10	15	1 Hr	25	75	3 Hrs	100
MIP102T	Customized drug Delivery System	10	15	1 Hr	25	75	3 Hrs	100
MIP103T	Drug Regulations and Intellectual Property Rights	10	15	1 Hr	25	75	3 Hrs	100
MIP104P	Industrial Pharmacy Practical I	20	30	6 Hrs	50	100	6 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
<b>Total</b>								<b>650</b>
<b>SEMESTER II</b>								
MIP201T	Advanced Biopharmaceutics and Pharmacokinetics	10	15	1 Hr	25	75	3 Hrs	100
MIP202T	Scale up and Technology Transfer	10	15	1 Hr	25	75	3 Hrs	100
MIP203T	Pharmaceutical Production Technology	10	15	1 Hr	25	75	3 Hrs	100
MIP204T	Entrepreneurship Management	10	15	1 Hr	25	75	3 Hrs	100
MIP205P	Industrial Pharmacy Practical II	20	30	6 Hrs	50	100	6 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
<b>Total</b>								<b>650</b>

**Tables – 19: Schemes for internal assessments and end semester examinations (Pharmaceutical Analysis)**

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	1 Hr	25	75	3 Hrs	100
MPA102T	Advanced Pharmaceutical Analysis	10	15	1 Hr	25	75	3 Hrs	100
MPA103T	Pharmaceutical Validation	10	15	1 Hr	25	75	3 Hrs	100
MPA104T	Food Analysis	10	15	1 Hr	25	75	3 Hrs	100
MPA105P	Pharmaceutical Analysis-I	20	30	6 Hrs	50	100	6 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
<b>Total</b>								<b>650</b>
<b>SEMESTER II</b>								
MPA201T	Advanced Instrumental Analysis	10	15	1 Hr	25	75	3 Hrs	100
MPA202T	Modern Bio-Analytical Techniques	10	15	1 Hr	25	75	3 Hrs	100
MPA203T	Quality Control and Quality Assurance	10	15	1 Hr	25	75	3 Hrs	100
MPA204T	Cosmetic Analysis and Evaluation	10	15	1 Hr	25	75	3 Hrs	100
MPA205P	Pharmaceutical Analysis-II	20	30	6 Hrs	50	100	6 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
<b>Total</b>								<b>650</b>

**Tables – 20: Schemes for internal assessments and end semester examinations (Pharmaceutical Biotechnology)**

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 Analytical Techniques	10	15	1 Hr	25	75	3 Hrs	100
MPB101T	Microbial And Cellular Biology	10	15	1 Hr	25	75	3 Hrs	100
MPB102T	Bioprocess Engineering and Technology	10	15	1 Hr	25	75	3 Hrs	100
MPB103T	Advanced Pharmaceutical Biotechnology	10	15	1 Hr	25	75	3 Hrs	100
MPB104P	Pharmaceutical Biotechnology Practical I	20	30	6 Hrs	50	100	6 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
<b>Total</b>								<b>650</b>
<b>SEMESTER II</b>								
MPB201T	Proteins and protein Formulation	10	15	1 Hr	25	75	3 Hrs	100
MPB202T	Immunotechnology	10	15	1 Hr	25	75	3 Hrs	100
MPB203T	Bioinformatics and Computer Technology	10	15	1 Hr	25	75	3 Hrs	100
MPB204T	Biological Evaluation of Drug Therapy	10	15	1 Hr	25	75	3 Hrs	100
MPB205P	Pharmaceutical Biotechnology Practical II	20	30	6 Hrs	50	100	6 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
<b>Total</b>								<b>650</b>

**Tables – 21: Schemes for internal assessments and end semester examinations (Pharmaceutical Chemistry)**

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 Analytical Techniques	10	15	1 Hr	25	75	3 Hrs	100
MPC101T	Advanced Organic Chemistry -I	10	15	1 Hr	25	75	3 Hrs	100
MPC102T	Advanced Medicinal chemistry	10	15	1 Hr	25	75	3 Hrs	100
MPC103T	Chemistry of Natural Products	10	15	1 Hr	25	75	3 Hrs	100
MPC104P	Pharmaceutical Chemistry Practical I	20	30	6 Hrs	50	100	6 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
<b>Total</b>								<b>650</b>
<b>SEMESTER II</b>								
MPC201T	Advanced Spectral Analysis	10	15	1 Hr	25	75	3 Hrs	100
MPC202T	Advanced Organic Chemistry -II	10	15	1 Hr	25	75	3 Hrs	100
MPC203T	Computer Aided Drug Design	10	15	1 Hr	25	75	3 Hrs	100
MPC204T	Pharmaceutical Process Chemistry	10	15	1 Hr	25	75	3 Hrs	100
MPC205P	Pharmaceutical Chemistry Practical II	20	30	6 Hrs	50	100	6 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
<b>Total</b>								<b>650</b>



**Tables – 22: Schemes for internal assessments and end semester examinations (Pharmaceutics)**

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 Analytical Techniques	10	15	1 Hr	25	75	3 Hrs	100
MPH101T	Modified Release Drug Delivery System	10	15	1 Hr	25	75	3 Hrs	100
MPH102T	Modern Pharmaceutics	10	15	1 Hr	25	75	3 Hrs	100
MPH103T	Pharmaceutical Regulatory Affair	10	15	1 Hr	25	75	3 Hrs	100
MPH104P	Pharmaceutics Practical I	20	30	6 Hrs	50	100	6 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
<b>Total</b>								<b>650</b>
<b>SEMESTER II</b>								
MPH201T	Molecular Pharmaceutics(Nano Tech and Targeted DDS)	10	15	1 Hr	25	75	3 Hrs	100
MPH202T	Advanced Biopharmaceutics & Pharmacokinetics	10	15	1 Hr	25	75	3 Hrs	100
MPH203T	Computer Aided Drug Delivery System	10	15	1 Hr	25	75	3 Hrs	100
MPH204T	Cosmetic and Cosmeceuticals	10	15	1 Hr	25	75	3 Hrs	100
MPH205P	Pharmaceutics Practical I	20	30	6 Hrs	50	100	6 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
<b>Total</b>								<b>650</b>

**Tables – 23: 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>								
MPA101T	Modern Pharmaceutical Analytical Techniques	10	15	1 Hr	25	75	3 Hrs	100
MPG101T	Advanced Pharmacognosy-1	10	15	1 Hr	25	75	3 Hrs	100
MPG102T	Phytochemistry	10	15	1 Hr	25	75	3 Hrs	100
MPG103T	Industrial Herbal drug technology	10	15	1 Hr	25	75	3 Hrs	100
MPG104P	Pharmacognosy Practical I	20	30	6 Hrs	50	100	6 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
<b>Total</b>								<b>650</b>
<b>SEMESTER II</b>								
MPG201T	Medicinal Plant biotechnology	10	15	1 Hr	25	75	3 Hrs	100
MPG102T	Advanced Pharmacognosy-II	10	15	1 Hr	25	75	3 Hrs	100
MPG203T	Indian system of medicine	10	15	1 Hr	25	75	3 Hrs	100
MPG204T	Herbal cosmetics	10	15	1 Hr	25	75	3 Hrs	100
MPG205P	Pharmacognosy Practical II	20	30	6 Hrs	50	100	6 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
<b>Total</b>								<b>650</b>

**Tables – 24: 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>								
MPA101T	Modern Pharmaceutical Analytical Techniques	10	15	1 Hr	25	75	3 Hrs	100
MPL101T	Advanced Pharmacology-I	10	15	1 Hr	25	75	3 Hrs	100
MPL102T	Pharmacological and Toxicological Screening Methods-I	10	15	1 Hr	25	75	3 Hrs	100
MPL103T	Cellular and Molecular Pharmacology	10	15	1 Hr	25	75	3 Hrs	100
MPL104P	Pharmacology Practical I	20	30	6 Hrs	50	100	6 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
<b>Total</b>								<b>650</b>
<b>SEMESTER II</b>								
MPL201T	Advanced Pharmacology II	10	15	1 Hr	25	75	3 Hrs	100
MPL102T	Pharmacological and Toxicological Screening Methods-II	10	15	1 Hr	25	75	3 Hrs	100
MPL203T	Principles of Drug Discovery	10	15	1 Hr	25	75	3 Hrs	100
MPL204T	Experimental Pharmacology practical- II	10	15	1 Hr	25	75	3 Hrs	100
MPL205P	Pharmacology Practical II	20	30	6 Hrs	50	100	6 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
<b>Total</b>								<b>650</b>

**Tables – 25: 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	1 Hr	25	75	3 Hrs	100
MPP102T	Pharmacotherapeutics-I	10	15	1 Hr	25	75	3 Hrs	100
MPP103T	Hospital & Community Pharmacy	10	15	1 Hr	25	75	3 Hrs	100
MPP104T	Clinical Research	10	15	1 Hr	25	75	3 Hrs	100
MPP105P	Pharmacy Practice Practical I	20	30	6 Hrs	50	100	6 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
<b>Total</b>								<b>650</b>
<b>SEMESTER II</b>								
MPP201T	Principles of Quality Use of Medicines	10	15	1 Hr	25	75	3 Hrs	100
MPP102T	Pharmacotherapeutics II	10	15	1 Hr	25	75	3 Hrs	100
MPP203T	Clinical Pharmacokinetics and Therapeutic Drug Monitoring	10	15	1 Hr	25	75	3 Hrs	100
MPP204T	Pharmacoepidemiology & Pharmacoeconomics	10	15	1 Hr	25	75	3 Hrs	100
MPP205P	Pharmacy Practice Practical II	20	30	6 Hrs	50	100	6 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
<b>Total</b>								<b>650</b>

**Tables – 26: Schemes for internal assessments and end semester examinations (Pharmaceutical Quality Assurance)**

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 Analytical Techniques	10	15	1 Hr	25	75	3 Hrs	100
MQA101T	Quality Management System	10	15	1 Hr	25	75	3 Hrs	100
MQA102T	Quality Control and Quality Assurance	10	15	1 Hr	25	75	3 Hrs	100
MQA103T	Product Development and Technology Transfer	10	15	1 Hr	25	75	3 Hrs	100
MQA104P	Pharmaceutical Quality Assurance Practical I	20	30	6 Hrs	50	100	6 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
<b>Total</b>								<b>650</b>
<b>SEMESTER II</b>								
MQA201T	Hazards and Safety Management	10	15	1 Hr	25	75	3 Hrs	100
MQA202T	Pharmaceutical Validation	10	15	1 Hr	25	75	3 Hrs	100
MQA203T	Audits and Regulatory Compliance	10	15	1 Hr	25	75	3 Hrs	100
MQA204T	Pharmaceutical Manufacturing Technology	10	15	1 Hr	25	75	3 Hrs	100
MQA205P	Pharmaceutical Quality Assurance Practical II	20	30	6 Hrs	50	100	6 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
<b>Total</b>								<b>650</b>

**Tables – 27: Schemes for internal assessments and end semester examinations (Pharmaceutical Regulatory Affairs)**

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
<b>SEMESTER I</b>								
MRA101T	Good Pharmaceutical Practices	10	15	1 Hr	25	75	3 Hrs	100
MRA102T	Pharmaceutical Regulations in India	10	15	1 Hr	25	75	3 Hrs	100
MRA103T	International Pharmaceutical Regulations I	10	15	1 Hr	25	75	3 Hrs	100
MRA104T	Clinical Research Regulations	10	15	1 Hr	25	75	3 Hrs	100
MRA105T	Pharmaceutical Regulatory Affairs Practical I	20	30	6 Hrs	50	100	6 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
<b>Total</b>								<b>650</b>
<b>SEMESTER II</b>								
MRA201T	Documentation and Regulatory Writing	10	15	1 Hr	25	75	3 Hrs	100
MRA202T	Biologicals Regulations	10	15	1 Hr	25	75	3 Hrs	100
MRA203T	International Pharmaceutical Regulations II	10	15	1 Hr	25	75	3 Hrs	100
MRA204T	Medical Device Regulations	10	15	1 Hr	25	75	3 Hrs	100
MRA205P	Pharmaceutical Regulatory Affairs Practical II	20	30	6 Hrs	50	100	6 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
<b>Total</b>								<b>650</b>

**Tables – 28: 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>								
MRM101T	Research Methodology and Biostatistics*	10	15	1 Hr	25	75	3 Hrs	100
-	Journal club	-	-	-	25	-	-	25
-	Discussion / Presentation (Proposal Presentation)	-	-	-	50	-	-	50
-	Research work*	-	-	-	-	350	1 Hr	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	1 Hr	400
<b>Total</b>								<b>500</b>

\*Non University Examination

### 11.2. Internal assessment: Continuous mode

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

**Table – 29: Scheme for awarding internal assessment: Continuous mode**

Theory	
Criteria	Maximum Marks
Attendance (Refer Table – 30)	8
Student – Teacher interaction	2
<b>Total</b>	<b>10</b>
Practical	
Attendance (Refer Table – 30)	10
Based on Practical Records, Regular viva voce, etc.	10
<b>Total</b>	<b>20</b>

**Table – 30: Guidelines for the allotment of marks for attendance**

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

#### 11.2.1. Sessional Exams

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

### 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 XIII. The exact dates of examinations shall be notified from time to time.

**Table – 31: Tentative schedule of end semester examinations**

<b>Semester</b>	<b>For Regular Candidates</b>	<b>For Failed Candidates</b>
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 – 32:**

**Table – 32: Letter grades and grade points equivalent to Percentage of marks and performances**

<b>Percentage of Marks Obtained</b>	<b>Letter Grade</b>	<b>Grade Point</b>	<b>Performance</b>
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<sub>1</sub>, C<sub>2</sub>, C<sub>3</sub> and C<sub>4</sub> and the student’s grade points in these courses are G<sub>1</sub>, G<sub>2</sub>, G<sub>3</sub> and G<sub>4</sub>, respectively, and then students’ SGPA is equal to:

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

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:

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

**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,  $\dots$  and  $S_1, S_2, S_3, \dots$  is the SGPA of semester I, II, III,  $\dots$ .

## 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

**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.

**M. PHARM. PHARMACEUTICS (MPH)**

## MODERN PHARMACEUTICAL ANALYSIS (MPA101T)

### 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,

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

### THEORY

60 HOURS

1. **UV-Visible spectroscopy:** Introduction, Theory, Laws, Instrumentation **11 Hrs**  
associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV-Visible spectroscopy.  
**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  
**Spectrofluorimetry:** Theory of Fluorescence, Factors affecting fluorescence, Quenchers, Instrumentation and Applications of fluorescence spectrophotometer.  
**Flame emission spectroscopy and Atomic absorption spectroscopy:** Principle, Instrumentation, Interferences and Applications.
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. **11 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 **11 Hrs**

- 4 Chromatography:** Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution and applications of the following: **11 Hrs**  
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
- 5 Electrophoresis:** Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following: **11 Hrs**  
a) Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresis d) Zone electrophoresis e) Moving boundary electrophoresis f) Iso electric focusing  
**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.
- 6 Immunological assays :** RIA (Radio immuno assay), ELISA, Bioluminescence assays. **5 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. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4<sup>th</sup> edition, CBS Publishers, New Delhi, 1997.
5. Organic Spectroscopy - William Kemp, 3<sup>rd</sup> edition, ELBS, 1991.
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

## DRUG DELIVERY SYSTEM (MPH101T)

### 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
- The formulation and evaluation of Novel drug delivery systems..

### THEORY

**60 Hrs**

**10 Hrs**

- 1. SR/CR formulation:** 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.

**10 Hrs**

- 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

- 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.

**6 Hrs**

- 5. Trans Dermal 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.



- 8 Hrs**
7. **Vaccine delivery systems:** Vaccines, uptake of antigens, single shot vaccines, mucosal and transdermal delivery of vaccines.

**6 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 (MPH102T)

### 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

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

### THEORY

#### 60 HRS

##### 10 hrs

1. **Preformation Concepts** – 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

2. **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

3. **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

4. **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**

- 5. Compression and compaction:** Physics of tablet compression, compression, consolidation, effect of friction, distribution of forces, compaction profiles. Solubility enhancement techniques.

**10 Hrs**

- 6. Study of consolidation parameters;** Diffusion parameters, Dissolution parameters and Pharmacokinetic parameters, Heckal plots, Similarity factors –  $f_2$  and  $f_1$ , Higuchi and Peppas plot, Linearity Concept of significance, Standard deviation, chi square test, student T-test, Anova test.

## 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 – Rawbins.
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.

## REGULATORY AFFAIRS (MPH103T)

### 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
- To know the chemistry, manufacturing controls and their regulatory importance
- To learn the documentation requirements for
- To learn the importance and

### 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 Hr

1. **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  

**1  
2 hrs**
2. **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**

3. 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**

4. **Non clinical drug development:** Global submission of IND,NDA,ANDA.Investigation medicinal products dossier, dossier (IMPD) and investigator brochure (IB)

**12 hrs**

5. **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 Mantis.
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>

## **PRACTICALS (MPH104P)**

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)(MPH201T)**

### **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**

**12 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, preparation and application of Niosomes, Aquasomes, Phytosomes, Electrosomes.

**12hrs**

- 4. Pulmonary Drug Delivery Systems :** Aerosols, propellents, ContainersTypes, preparation and evaluation, Intra Nasal Route Delivery systems; Types, preparation and evaluation

**12hrs**

- 5. Veterinary Drug Delivery Systems:** Tablets and bolus, Feed additives, Drinking water medication, Oral paste and gels, Drenchers and Tubing product

### **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).

### **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

## **ADVANCED BIOPHARMACEUTICS & PHARMACOKINETICS (MPH202T)**

### **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**

At 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 evaluate dosage regimens of the drugs using pharmacokinetic and biopharmaceutic parameters.
- The potential clinical pharmacokinetic problems and apply basic pharmacokinetic
- The principles to solve them

### **THEORY**

**60 Hrs**

**12hrs**

1. **Drug Absorption From The Gastrointestinal Tract:** Gastrointestinal tract, Mechanism of drug absorption, Factors affecting passive drug absorption, pH-partition theory of drug absorption. Factors affecting drug absorption: 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, Correlation of in vivo data with in vitro dissolution data. 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, Structure of Octanol, Biopharmaceutics Classification System. Solubility: Experimental methods. Permeability: In-vitro, in-situ and In-vivo methods.

**12Hrs**

- 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, 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, Drug Product Considerations.

**12Hrs**

- 3. Pharmacokinetics:** Basic considerations, Pharmacokinetic models, Compartment modeling: One compartment model- IV bolus, IV infusion, Extravascular. Multi Compartment model: Two compartment - model in brief, Non-Linear Pharmacokinetics: Cause of non-linearity, Michaelis – Menten equation, Estimation  $K_{max}$  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.

**12Hrs**

- 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, Generic Biologics (Biosimilar Drug Products), Clinical Significance of Bioequivalence Studies, Special Concerns in Bioavailability and Bioequivalence Studies, Generic Substitution.

**12Hrs**

- 5. Application of Pharmacokinetics:** Modified-Release Drug Products, Targeted Drug Delivery Systems and Biotechnological Products. pharmacokinetic and pharmacodynamic, drug interactions. Pharmacokinetics and pharmacodynamics of biotechnology drugs. Introduction, Proteins and peptides, Monoclonal antibodies, Oligonucleotides, Vaccines (immunotherapy), Gene therapies.

## 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.J aiswal., 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, Leaand Febiger, Philadelphia, 1970
7. Clinical Pharmacokinetics, Concepts and Applications 3rd edition by MalcolmRowland and Thom~ N. Tozer, Lea and Febiger, Philadelphia, 1995
8. Dissolution, Bioavailability and Bioequivalence, Abdou. H.M, Mack PublishingCompany, 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.Pemarowski, 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, 1<sup>st</sup> 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 (MPH203T)

### 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

At 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

**60Hrs**

1. **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 Parameter Estimation, Confidence Regions, Nonlinearity at the Optimum, Sensitivity Analysis, Optimal Design, Population Modeling

**Quality-by-Design In Pharmaceutical Development:** Introduction, ICH Q8 guideline, Regulatory and industry views on QbD, Scientifically based QbD - examples of application

**12Hrs**

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.

**12Hrs**

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

**12Hrs**

4. **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

**Computer Simulations in Pharmacokinetics and Pharmacodynamics:** Introduction, Computer Simulation: Whole Organism, Isolated Tissues, Organs, Cell, Proteins and Genes.

**Computers in Clinical Development:** Clinical Data Collection and Management, Regulation of Computer Systems

**12Hrs**

5. **Artificial Intelligence (AI), Robotics and Computational fluid dynamics:** General overview, Pharmaceutical Automation, Pharmaceutical applications, Advantages and Disadvantages. Current Challenges and Future Directions.

**12Hrs**

**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 (MPH204T)

### 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 will be able to understand

- The key ingredients used in cosmetics and cosmeceuticals.
- The key building blocks for various formulations.
- The current technologies in the market
- The various key ingredients and basic science to develop cosmetics and cosmeceuticals
- The scientific knowledge to develop cosmetics and cosmeceuticals with desired Safety, sensory, stability, and efficacy.

### THEORY

60Hrs

12Hrs

#### 1. Formulations approaches and Requirements

Definition of cosmetic products as per EU guidelines .Structure of skin relating to problems like dry skin, acne, pigmentation, prickly heat, wrinkles and body odor. Structure of hair and hair growth cycle. Common problems associated with oral cavity. Cleansing and care needs for face, eye lids, lips, hands, feet, nail, scalp, neck, body and under-arms. Formulation requirements for ethnic needs.

12Hrs

#### 2. Plant Lay out, factory requirements and commonly used cosmetics raw materials

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 cream, shampoo and toothpaste.

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

**Controversial ingredients:** Parabens, formaldehyde liberators, dioxane.

12Hrs

#### 3. Design of special purpose 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.

**12Hrs**

### **3. 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, emulsifiers and rheology modifiers. Challenges in formulating herbal cosmetics.

**12Hrs**

### **4. Formulation of Lip care products and Cosmetic Safety .**

Chemistry and formulation of paraphylene diamine based hair colorants. Soaps and syndet bars Labelling requirements for cosmetics Study of salient features of cosmetic safety data base developed by private body, and International Nomenclature of Cosmetic Ingredients (INCI). Review of the list of ingredients on the labels of cosmetics, cosmeceuticals, baby care and men's range of the products in the market and conduct comparative study of the formulations.

### **RECOMMENDED BOOKS:**

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.

## **PRACTICAL (MPH205P)**

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
5. Formulation and evaluation of niosomes
6. Formulation and evaluation of spheruls
7. Improvement of dissolution characteristics of slightly soluble drug by Solid dispersion technique.
8. Comparison of dissolution of two different marketed products /brands
9. Protein binding studies of a highly protein bound drug & poorly protein bound drug
10. Bioavailability studies of Paracetamol.
11. Pharmacokinetic and IVIVC data analysis by Winnoline<sup>R</sup> software
12. *In vitro* cell studies for permeability and metabolism
13. DoE Using Design Expert<sup>®</sup> Software
14. Formulation data analysis Using Design Expert<sup>®</sup> Software
15. Quality-by-Design in Pharmaceutical Development
16. Computer Simulations in Pharmacokinetics
17. Computer Simulations Pharmacodynamics
18. Computational Modeling Of Drug Disposition
19. To develop Clinical Data Collection manual
20. To carry out Sensitivity Analysis, and Population Modeling.
21. Development and evaluation of Creams
22. Development and evaluation of Shampoo and Toothpaste base
23. To Incorporate herbal and chemical actives to develop products
24. To address Dry skin, acne, blemish, Wrinkles, bleeding gums and dandruff

**M. PHARM. PHARMACEUTICAL CHEMISTRY  
(MPC)**



## MODERN PHARMACEUTICAL ANALYSIS (MPA101T)

### 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,

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

### THEORY HOURS

60

- 1. UV-Visible spectroscopy:** Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV-Visible spectroscopy. **12 Hrs**  
**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  
**Spectrofluorimetry:** Theory of Fluorescence, Factors affecting fluorescence, Quenchers, Instrumentation and Applications of fluorescence spectrophotometer.  
**Flame emission spectroscopy and Atomic absorption spectroscopy:** Principle, Instrumentation, Interferences and Applications.
- 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. **12 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 **12 Hrs**

- 4 Chromatography:** Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution and applications of the following: **12 Hrs**  
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
- 5 Electrophoresis:** Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following: **12 Hrs**  
a) Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresis d) Zone electrophoresis e) Moving boundary electrophoresis f) Iso electric focusing  
**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.
- 6 Medical device and applications:** Introduction, Historical and current prospectus( specific division to be included)

## 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. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4<sup>th</sup> edition, CBS Publishers, New Delhi, 1997.
5. Organic Spectroscopy - William Kemp, 3<sup>rd</sup> edition, ELBS, 1991.
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-1 (MPC101T)

### 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

- a. Organic intermediates: Carbocations, carbanions, free radicals, carbenes and nitrenes. Their method of formation, stability and synthetic applications.
- b. Types of reaction mechanisms and methods of determining them,
- c. Detailed knowledge regarding the reactions, mechanisms and their relative reactivity and orientations.
  - i. Aliphatic and aromatic compounds,
  - ii. Nucleophilic uni- and bimolecular reactions (SN1 and SN2)
  - iii. Elimination reactions (E1 & E2; Hoffman & Saytzeff's rule)
  - iv. Rearrangement reaction

12Hrs

#### 2. Study of mechanism synthetic applications of following named Reactions:

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

12 Hrs

#### 3. Synthetic Reagents & Applications

Aluminiumisopropoxide, N-bromosuccinamide, diazomethane, dicyclohexylcarbodiimide, Wilkinson reagent, Witting 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-and1,3-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

**12Hrs**

#### **4. Heterocyclic Chemistry**

General methods of synthesis and applications of drugs of five, six membered and fused heterocycles such as imidazole, pyrazole, triazole, pyrimidine, quinoline, acridine, phenothiazine and purine. Synthesis of few representative drugs containing these heterocyclic nucleus

**12Hrs**

#### **5. Synthons approach and retrosynthesis applications**

- 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

**12Hrs**

#### **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, NewYork.
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. A guide to mechanisms in Organic Chemistry – Peter Skyes (Orient Longman, New Delhi).
6. Reactive intermediates in organic chemistry – Tandom and Gowel.

7. Combinational Chemistry – Synthesis and applications – Stephen R Wilson & Anthony W Czarnik.
8. Carey, Organic chemistry, 5th edition (Viva Books Pvt. Ltd.)
9. Organic synthesis-The disconnection approach, S. Warren, Wiley India
10. Principles of organic synthesis, ROC Norman and JM Coxan, Nelson thorns
11. Organic synthesis- Special techniques VK Ahluwalia and R Agarwal, Narosa Publishers
12. Organic reaction mechanisms IV edtn, VK Ahluwalia and RK Parashar, Narosa Publishers

## ADVANCED MEDICINAL CHEMISTRY (MPC102T)

### 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. Chemistry of prostaglandins, leukotrienes and thromboxones.

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

12

Hrs

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

- **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.
- **Combating drug resistance:** Causes for drug resistance, strategies to combat drug resistance in antibiotics and anticancer therapy, Genetic principles of drug resistance.

**Hrs**

- **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 Chemistry of Synthetic drugs:** Systematic study, SAR, Mechanism of action and synthesis of

new generation molecules of following class of drugs: Anti-hypertensive drugs, Psychoactive

drugs, Anticonvulsant drugs, H1 & H2 receptor antagonist, COX1 & COX2 inhibitors,

Adrenergic & Cholinergic agents, Antineoplastic and Antiviral agents.

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

**12 Hrs**

**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.

**Combinatorial chemistry and High throughput screening:** Different techniques, Solid phase synthesis, Solution phase synthesis, Parallel synthesis, applications of combinatorial chemistry. High Throughput Screening- general outline, importance and application.

**12**

**Hrs**

#### **REFERENCES:**

1. Medicinal Chemistry by Burger.
2. Wilson and Gisvold's Text book of Organic Medicinal and Pharmaceutical Chemistry.
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.
6. Principles of Medicinal Chemistry by William Foye.
7. Drug Design Volumes by Arienes.
8. Principles of Drug Design by Smith.
9. The Organic Chemistry of the Drug Design and Drug action by Richard B.Silverman.
10. An Introduction to Medicinal Chemistry –Graham L.Patrick, (III Edition.)
11. Biopharmaceutics and pharmacokinetics by DM.Brahmankar, Sunil B .Jaiswal.
12. Peptidomimetics in Organic and Medicinal Chemistry by Antonio Guarna and Andrea Trabocchi, First edition, Wiley publishers.



## CHEMISTRY OF NATURAL PRODUCTS (MPC103T)

### 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. Chemistry of macrolid antibiotics: Erythromycine, Azithromycine, Cephalosporins(New generation)

12Hrs

#### 2. Alkaloids- General introduction, classification, isolation, purification, stereochemistry, molecular modification and biological activity of alkaloids, general methods of structural determination of alkaloids, structural elucidation of ephedrine, morphine, ergot, emetine and reserpine.

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

12Hrs

#### 3. Steroids- General introduction, chemistry of sterols, sapogenin and cardiac glycosides. Stereochemistry and nomenclature of steroids, Structure elucidation of

male & female sex hormones( testosterone, Estradiol, progesterone), Adrenocortcoids (carsisone) and contraceptive agents.

**Terpenoids** – Classification, isolation, isoprene rule and general methods of structural elucidation of Terpenoids; Structural elucidation of drugs belonging to mono, di and tri terpenoids, carotinoids.

12Hrs

**4. 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

**Active constituent of certain crude drugs used in Indigenous system.**

Diabetic therapy – *Gymnema sylvestre*, *Salacia reticulate*, *Pterocarpus marsupiam*, *Swertia chirata*, *Trigonella foenum graccum*; Liver dysfunction – *Phyllanthus niruri*; Antitumor – *Curcuma longa* Linn.

12Hrs

**5. Structural Characterization of natural Products**

Structural characterization of natural compounds using IR, <sup>1</sup>HNMR, <sup>13</sup>CNMR and MS Spectroscopy

12Hrs

**REFERENCES**

1. Modern methods of plant analysis – Peech and M.V.Tracey.
2. Phytochemistry Vol. I and II by Miller, Jan Nostrant Rein Hld.
3. Recent advances in Phytochemistry Vol. I to IV – Scikel Runeckles.
4. Chemistry of natural products Vol I onwards IWPAC.
5. Natural Product Chemistry Nakanishi Gggolo.
6. Natural Product Chemistry “A laboratory guide” – Rapheal Khan.
7. The Alkaloid Chemistry and Physiology by THF Manske.
8. Introduction to molecular Phytochemistry – CHJ Wells, Chapmannstall.
9. Organic Chemistry of Natural Products Vol I and II by Gurdeep and Chatwall.
10. Organic Chemistry of Natural Products Vol I and II by O.P. Agarwal.
11. Organic Chemistry Vol I and II by I.L. Finar
12. Elements of Biotechnology by P.K. Gupta.
13. Pharmaceutical Biotechnology by S.P.Vyas and V.K.Dixit.
14. Biotechnology by Purohit and Mathoor.
15. Phytochemical methods of Harborne.
16. Burger’s Medicinal Chemistry.

## **PRACTICALS (MPC104P)**

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 HPLC
4. Experiments based on Gas Chromatography
5. Estimation of riboflavin/quinine sulphate by fluorimetry
6. Estimation of sodium/potassium by flame photometry

### **To perform the following reactions of synthetic importance**

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

## ADVANCED SPECTRAL ANALYSIS (MPC201T)

### 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

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

- 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

#### 60Hrs

1. **UV and IR spectroscopy:** Wood ward – Fiesure rule for 1,3- butadienes, cyclic dienes and  $\alpha$ ,  $\beta$ -carbonyl compounds and interpretation compounds of enones. ATR-IR, IR Interpretation of organic compounds.

1

#### 2Hrs

2. **NMR spectroscopy:** 1-D and 2-D NMR, NOESY and COSY, HECTOR, INADEQUATE techniques, Interpretation of organic compounds.

#### 12Hrs

3. **Mass Spectroscopy:** Mass fragmentation and its rules, Fragmentation of important functional groups like alcohols, amines, carbonyl groups and alkanes, Meta stable ions, Mc Lafferty rearrangement, Ring rule, Isotopic peaks, Interpretation of organic compounds.

#### 12Hrs

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) CE-MS g) High Performance Thin Layer chromatography h) Super critical fluid chromatography i) Ion Chromatography j) I-EC (Ion-Exclusion Chromatography)

k)

Flash

chromatography.

**12Hrs**

5. **Thermal methods of analysis** – Introduction, principle, instrumentation and application of DSC, DTA and TGA.

**Raman Spectroscopy:** Introduction, Principle, Instrumentation and Applications.

**Radio immuno assay:** Biological standardization , bioassay, ELISA,  
Radioimmuno assay of digitalis and insulin

**12Hrs**

**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(MPC202T)

### 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.

12Hrs

#### 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, over-activation 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

**12Hrs**

### 4. Catalysis

- a. Types of catalysis, heterogeneous and homogeneous 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. Homogeneous catalysis, hydrogenation, hydroformylation, hydrocyanation, Wilkinson catalysts, chiral ligands and chiral induction, Ziegler-Natta catalysts, some examples of homogeneous 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

**12Hrs**

### 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, Fischer's 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.

**12Hrs**

## 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, Wiley India
7. Principles of organic synthesis, R.C. Norman and J.M. Coxon, Nelson Thornes
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 (MPC203T)

### 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

60 Hrs

1. **Introduction to Computer Aided Drug Design (CADD):** 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.

12 Hrs

2. **Quantitative Structure Activity Relationships: Applications**

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.

12 Hrs

3. **Molecular Modeling and Docking**

a. Molecular and Quantum Mechanics in drug design

b. Energy Minimization Methods: comparison between global minimum conformation and bioactive conformation

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)

12 Hrs

4. **Molecular Properties and Drug Design**

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.

**12 Hrs**

#### **5. Pharmacophore Mapping and Virtual Screening**

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.

**12 Hrs**

#### **REFERENCES:**

1. Computational and structural approaches to drug design edited by Robert M Stroud and Janet. F Moore
2. Introduction to Quantitative Drug Design by Y.C. Martin.
3. Drug Design by Ariens Volume 1 to 10, Academic Press, 1975.
4. Principles of Drug Design by Smith and Williams.
5. The Organic Chemistry of the Drug Design and Drug action by Richard B. Silverman.
6. Medicinal Chemistry by Burger.
7. An Introduction to Medicinal Chemistry –Graham L. Patrick, (III Edition.)
8. Wilson and Gisvold's Text book of Organic Medicinal and Pharmaceutical Chemistry.
9. Comprehensive Medicinal Chemistry – Corwin and Hansch.
10. Computational and structural approaches to drug design edited by Robert M Stroud and Janet. F Moore

## PHARMACEUTICAL PROCESS CHEMISTRY (MPC204T)

### 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

- 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

**12 Hrs**

#### 2. Unit operations

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

**12 Hrs**

### 3. Unit Processes

- 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.

12 Hrs

### 4. Unit Processes

- 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
  - i. Antibiotics; Penicillin and Streptomycin,
  - ii. Vitamins: B2 and B12
  - iii. Statins: lovastatin, simvastatin

#### Reaction progress kinetic analysis

- a. Streamlining reaction steps, route selection,
- b. Characteristics of expedient routes, characteristics of cost-effective routes, reagent selection, families of reagents useful for scale-up.

12 Hrs

### 5. Industrial Safety

- 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

12 Hrs

### REFERENCES:

1. Process Chemistry in the Pharmaceutical Industry: Challenges in an Ever-Changing Climate-An Overview; K. Gadamasetti
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
11. Clausen, Mattson: Principle of Industrial Chemistry
12. Lowenheim & M.K. Moran: Industrial Chemicals
13. S.D. Shukla & G.N. Pandey: A text book of Chemical Technology Vol. II
14. J.K. Stille: Industrial Organic Chemistry (PH)
15. Srreva: Chemical Proccess
16. B.K.Sharma: Industrial Chemistry
17. ICH Guidelines
18. United States Food and Drug Administration official website [www.fda.gov](http://www.fda.gov)

## PRACTICALS (MPC205P)

1. Synthesis of organic compounds by adapting different approaches involving (3 experiments)
  - a. Oxidation
  - b. Reduction/hydrogenation
  - c. 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 – Fiesure 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-iodotolene 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
- 22.** Virtual screening based experiment



**PHARMACOLOGY**  
**(MPC)**



## **SEMISTER I**

1. MODERN PHARMACEUTICAL ANALYSIS
2. ADVANCED PHARMACOLOGY-I
3. PHARMACOLOGICAL AND TOXICOLOGICAL SCREENING METHODS-I
4. CELLULAR AND MOLECULAR PHARMACOLOGY

Practicals

## **SEMISTER I**

1. ADVANCED PHARMACOLOGY-II
2. TOXICOLOGICAL SCREENING METHODS
3. PRINCIPLES OF DRUG DISCOVERY
4. CLINICAL RESEARCH AND PHARMACOVIGILANCE
5. EXPERIMENTAL PHARMACOLOGY-II

Practicals

\*Soft skills should be added in research methodology and biostatistics paper in semester III

\*Practical in Modern pharmaceutical with emphasis on analysis case study

## MODERN PHARMACEUTICAL ANALYSIS (MPA101T)

### 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,

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

### THEORY HOURS

60

1. **UV-Visible spectroscopy:** Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV-Visible spectroscopy. **12 Hrs**  
**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  
**Spectrofluorimetry:** Theory of Fluorescence, Factors affecting fluorescence, Quenchers, Instrumentation and Applications of fluorescence spectrophotometer.  
**Flame emission spectroscopy and Atomic absorption spectroscopy:** Principle, Instrumentation, Interferences and Applications.
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. **12 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 **12 Hrs**

- 4 Chromatography:** Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution and applications of the following: **12 Hrs**  
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
- 5 Electrophoresis:** Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following: **12 Hrs**  
a) Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresis d) Zone electrophoresis e) Moving boundary electrophoresis f) Iso electric focusing
- 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.

#### 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. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4<sup>th</sup> edition, CBS Publishers, New Delhi, 1997.
5. Organic Spectroscopy - William Kemp, 3<sup>rd</sup> edition, ELBS, 1991.
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

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## ADVANCED PHARMACOLOGY-I (MPL101T)

### 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

### HOURS

#### UNIT-I

##### General Pharmacology

12 Hrs

- a. Pharmacokinetics: The dynamics of drug absorption, distribution, biotransformation and elimination. Concepts of linear and non-linear compartment models. Significance of Protein binding. 06 hrs
- 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. 06 hrs

#### UNIT-II

12 Hrs

##### Neurotransmission

06 Hrs

- 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). Co-transmission

##### Systemic Pharmacology

06 Hrs

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

**a. Autonomic Pharmacology**

Parasympathomimetics and lytics, sympathomimetics and lytics, agents affecting neuromuscular junction

**UNIT-III****12 Hrs****Central nervous system Pharmacology**

General and local anesthetics	02 hrs
Sedatives and hypnotics, drugs used to treat anxiety.	02 hrs
Depression, psychosis, mania, epilepsy, neurodegenerative diseases.	05 hrs
Narcotic and non-narcotic analgesics.	03 hrs

**UNIT-IV****Cardiovascular Pharmacology****12 Hrs**

Diuretics, antihypertensives, antiischemics, anti-arrhythmics, drugs for heart failure and hyperlipidemia.	07 hrs
Hematinics, coagulants, anticoagulants, fibrinolytics and anti-platelet drugs	05 hrs

**UNIT- V****Autocoid Pharmacology****12 Hrs**

The physiological and pathological role of Histamine, Serotonin, Kinins Prostaglandins Opioid autocoids.	08 hrs
Pharmacology of antihistamines, 5HT antagonists.	04 hrs

**REFEERENCES**

1. The Pharmacological basis of therapeutics- Goodman and Gill man'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.
6. 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

## PHARMACOLOGICAL AND TOXICOLOGICAL SCREENING METHODS-I (MPL102T)

### 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  
HOURS**

**60**

### Unit-I

**12 Hrs**

#### Laboratory Animals

Common lab animals: Description, handling and applications of different species and strains of animals. 02 hrs

Transgenic animals: Production, maintenance and applications 02 hrs

Anaesthesia and euthanasia of experimental animals. 03 hrs

Maintenance and breeding of laboratory animals. 02 hrs

CPCSEA guidelines to conduct experiments on animals 02 hrs

Good laboratory practice. 01 hrs

### Unit-II

**12 Hrs**

#### 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 coordination, 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.

### **Unit-III**

**12 Hrs**

**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.

### **Unit-IV**

**12 hrs**

**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, antihyperlipidemic, and agents. Anti cancer agents

### **Unit V**

**12 hrs**

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

Immunosuppressants and immunomodulators 02 hrs

**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

08 hrs

Limitations of animal experimentation and alternate animal experiments. 01 hr

Extrapolation of *in vitro* data to preclinical and preclinical to humans. 01 hr

### **REFERENCES**

1. Biological standardization by J.H. Burn D.J. Finney and I.G. Goodwin
2. Indian Pharmacopeia and other Pharmacopeias
3. Screening methods in Pharmacology by Robert Turner. A
4. Evaluation of drugs activities by Laurence and Bachrach

5. Methods in Pharmacology by Arnold Schwartz.
6. Fundamentals of experimental Pharmacology by M.N.Ghosh
7. Pharmacological experiment on intact preparations by Churchill Livingstone
8. Drug discovery and Evaluation by Vogel H.G.
9. Experimental Pharmacology by R.K.Goyal.
10. Preclinical evaluation of new drugs by S.K. Gupta



## CELLULAR AND MOLECULAR PHARMACOLOGY (MPL103T)

### 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

### Unit I

12 Hrs

#### 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.

### Unit II

12Hrs

#### 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.

### Unit III

12Hrs

Principles and applications of genomic and proteomic tools

06 hrs

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** **06 hrs**

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

**Unit IV**

**12Hrs**

**Pharmacogenomics** **08 hrs**

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** **04 hrs**

Types of immunotherapeutics, humanisation antibody therapy, Immunotherapeutics in clinical practice

**Unit V**

**12Hrs**

**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

**Unit VI**

Biosimilars

**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.Ausuvel et la.

### **Experimental Pharmacology- I (MPL104P)**

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,  $\alpha$  amylase,  $\alpha$  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 - Douglas 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)

## ADVANCED PHARMACOLOGY-II (MPL201T)

### 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

### UNIT-I

#### Endocrine Pharmacology

**12 Hrs**

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

### UNIT-II

#### Chemotherapy

**12 Hrs**

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.

### UNIT-III

**12 Hrs**

#### Chemotherapy

**06 Hrs**

Drugs used in Protozoal Infections  
Drugs used in the treatment of Helminthiasis  
Chemotherapy of cancer

#### Immunopharmacology

**06 Hrs**

Cellular and biochemical mediators of inflammation and immune response. Allergic or hypersensitivity reactions. Pharmacotherapy of asthma and COPD.

Immunosuppressants and Immunostimulants

#### **UNIT-IV**

##### **GIT Pharmacology**

**08 Hrs**

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

##### **Chronopharmacology**

**04 Hrs**

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

#### **UNIT-V**

##### **Free radicals Pharmacology**

**04 Hrs**

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:**

**08 Hrs**

Alzheimer's disease, Parkinson's disease, Cancer, Diabetes mellitus

##### **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

## TOXICOLOGICAL SCREENING METHODS (MPL202T)

### Scope:

The 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.

### Unit I

12 Hrs

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

### Unit II

12 Hrs

Acute, sub-acute and chronic- oral, dermal and inhalational studies as per OECD guidelines.  
Acute eye irritation, skin sensitization, dermal irritation & dermal toxicity studies.  
Test item characterization- importance and methods in regulatory toxicology studies

### Unit III

12 Hrs

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

### Unit IV

12 Hrs

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 safety pharmacology.  
Tier1- CVS, CNS and respiratory safety pharmacology, HERG assay. Tier2- GI, renal and other studies

**Unit V****12 Hrs**

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

**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/guidancecomplianceregulatoryinformation/guidances/ucm073246.pdf>)



## PRINCIPLES OF DRUG DISCOVERY (MPL203T)

### 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

### Unit-I

12 Hrs

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.

### Unit-II

12 Hrs

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

### Unit-III

12 Hrs

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,

**Unit-IV****12 Hrs**

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.

**Unit-V****12 Hrs**

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

## References

1. MouldySioud. Target Discovery and Validation Reviews and Protocols: Volume 2 Emerging Molecular Targetsand Treatment Options. 2007 Humana Press Inc.
2. Darryl León. Scott MarkellIn. 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., Hoboken, New Jeney.

## **CLINICAL RESEARCH AND PHARMACOVIGILANCE (MPL204T)**

### **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

### **UNIT-I hours**

**12**

#### **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

### **UNIT- II hours**

**12**

#### **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

### **UNIT- III hours**

**12**

**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.

### **UNIT-IV hours**

**12**

#### **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

### **UNIT-V**

**12 hours**

#### **Methods, ADR reporting and tools used in Pharmacovigilance**

International classification of diseases, International Non-proprietary 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.

### **UNIT-VI**

Pharmacoeconomics, Dermatology, pharmacoeconomics, safety pharmacology

### **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.

### **Experimental Pharmacology-II (MPL205P)**

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  $PA_2$  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.
17. Protocol design for clinical trial.
18. Protocol design for clinical trial.
19. Design of ADR monitoring protocol.

20. In silico docking studies.
21. In silico pharmacophore based screening.
22. In silico QSAR studies.
23. ADR reporting
24. In silico docking studies.

### **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.

**M. PHARM. PHARMACOGNOSY (MPG)**

## ADVANCED PHARMACOGNOSY-1 (MPG101 T)

### 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

1. Know the advances in the cultivation and production of drugs
2. Know the various phyto-pharmaceuticals and their source & utilization and medicinal value.
3. Know the various nutraceuticals/herbs and their health benefits

### Course Description

#### THEORY

60

#### Hours

**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 *In-situ* conservation of medicinal plants.

**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.

**12 Hrs**

**3. Nutraceuticals:** Current trends and future scope, Inorganic mineral supplements, Vitamin supplements, Digestive enzymes, Dietary fibres, Cereals and grains, Health drinks from natural origin, Antioxidants, Polyunsaturated fatty acids, Herbs as functional foods, Formulation and standardization of nutraceuticals, 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) Tocotrienols and Tocopherols
- g) Andrographolide, glycolipids, guggulipids, withanolides, vascine, taxol      **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:**

- 1) Cultivation of medicinal and aromatic crops, 1st edition, by AA Farooqui and B.S. Sreeramu. University Press, 2001.
- 2) Medicinal natural products (a biosynthetic approach), 1st edition, by Paul M. Dewick, John Wiley & Sons Ltd., England, 1998.
- 3) Natural Products from Plants, 1st edition, by Peter B. Kaufman, CRC Press, New York, 1998
- 4) Glimpses of Indian Ethano Pharmacology by P. Pushpangadam. Ulf Nyman. V.George Tropical Botanic Garden & Research Institute, 1995.
- 5) Natural products: A lab guide by Raphael Ikan , 2nd Edition, Academic Press 1991.
- 6) Pharmacognosy - G. E. Trease and W.C. Evans. 15th Edition W.B. Saunders Edinburgh, New York.
- 7) Pharmacognosy-Tyler, Brady, Robbers
- 8) Modern Methods of Plant Analysis- Peach & M.V. Tracey, Vol. I&II
- 9) Recent Advances in Phytochemistry- Vol. 1&4: Scikel Runeckles- Appleton Century crofts.
- 10) Chemistry of Marine Natural Products- Paul J. Schewer 1973.
- 11) Marine Natural Products-Vol.I to IV.
- 12) Cultivation of Medicinal Plants by C.K. Atal & B.M. Kapoor.
- 13) Cultivation and Utilization of Aromatic Plants By C.K. Atal & B.M. Kapoor

- 14) Herbal Drug Industry by RD. Choudhary, 1st edition, Eastern Publisher, New Delhi, 1996.
- 15) Text book of Pharmacognosy by C.K.Kokate, Purohit, Ghokhale, 4th edition, Nirali Prakasshan, 1996.
- 16) Pharmacognosy and Pharmacobiotechnology by Ashutoskar, New Age Publications, New Delhi.
- 17) Text Book of Pharmacognosy by T.E. Wallis

## PHYTOCHEMISTRY (MPG102T)

### Scope:

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

### Objectives:

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

1. know the different classes of phytoconstituents and their properties and general process of natural product drug discovery
2. know the process isolation, purification and identification of phytoconstituents

### THEORY

**60 Hrs**

1. **Biosynthetic pathways and Radio tracing techniques:** Constituents & their Biosynthesis, 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, Vincaalkaloids.
- b) Glycosides: Digitoxin, Glycyrrhizin, Sennosides, Bacosides, Ginsenosides, Quercetin, Rutin.
- c) Steroids: Hecogenin, guggulosterone and withanolides
- d) Coumarin: Umbelliferone.
- e) Terpenoids: Cucurbitacins
- f) Carotenoids: Lycopene,  $\beta$ -carotene.
- g) Camphor, Menthol, Eugenol.

**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 anticancer, CNS cardiovascular drugs, antitubercular drugs and immunomodulators, Clinical studies emphasis on phase 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, and method of fractionation. Detection of different classes of phytoconstituents by latest CCCET, SCFE techniques including preparative HPLC and Flash column chromatography, AAS.

**12 Hrs**

- 4. Phytochemical finger printing:** HPTLC and LCMS/GCMS characterization of extracts containing alkaloids, saponins, glycosides and flavanoids.

**12 Hrs**

- 5. Pharmacological screening:** In vitro, In vivo screening techniques with reference to antiglycomerate, analgesics, antidiabetic, antilipidemic, anticancer, antiulcer, antiviral, antipsychotic, antilithiatic, Toxicity studies as per OECD guidelines, acute, chronic and clinical toxicity.

**12 Hrs**

#### **REFERENCES:**

- 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 & Bladt.
- 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

## INDUSTRIAL PHARMACOGNOSTICAL TECHNOLOGY (MPG103T)

### Scope:

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

### Objective:

By the end of the course the student shall be able to:-

1. Know the requirements for setting up the herbal/natural drug industry.
2. To know and understand the guidelines for quality of herbal/natural medicines and regulatory issues.
3. To know patenting/IPR of herbals/natural drugs and trade of raw and finished materials.

### THEORY

**60Hrs**

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 production management.

**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, IPR.  
Quality assurance in herbal/natural drug products.  
Concepts of TDM, GMP, GLP, ISO-9000.

**12Hrs**

3. **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. **Testing of natural products and drugs:** Effect of herbal medicines on clinical laboratory testing. Regulation and dispensing of herbal drugs. Stability testing of

natural  
**12 Hrs**

products,

protocols.

- 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:**

1. Herbal drug industry by R.D. Choudhary (1996), 1st Edn, 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. Herbal Cosmetics by H.Pande, Asia Pacific Business press, Inc, New Delhi.
4. The complete technology book on herbal perfumes and cosmetics, by H.Pande, National Institute of Industrial Research, Delhi.
5. Quality control of herbal drugs by Pulok K Mukarjee (2002), 1st Edition, Business Horizons Pharmaceutical Publisher, New Delhi.
6. PDR for Herbal Medicines (2000), 2nd Edition, Medicinal Economic Company, New Jersey.
7. Indian Herbal Pharmacopoeia (2002), Revised Edition, 1DMA, Mumbai.
8. Text book of Pharmacognosy by C.K. Kokate, Purohit, Gokhlae (1996), 4th Edition, Nirali Prakashan, New Delhi.
9. Text book of Pharmacognosy and Phytochemistry by Vinod D. RangarI (2002), Part I & II, Career Publication, Nasik, India.
10. Plant drug analysis by H.Wagner and S.Bladt, 2nd edition, Springer, Berlin.
11. Standardization of Botanicals. Testing and extraction methods of medicinal herbs by V. Rajpal (2004), Vol.I, Eastern Publisher, New Delhi.
12. Phytochemical Dictionary. Handbook of Bioactive Compounds from Plants by J.B.Harborne, (1999), IInd Edition, Taylor and Francis Ltd, UK.
13. Herbal Medicine. Expanded Commission E Monographs by M.Blumenthal, (2004), 1ST Edition,
14. Drug Formulation Manual by D.P.S.Kohli and D.H.Shah (1998), II Edition, Eastern Publisher, New Delhi.

## **PRACTICALS (MPGI04P)**

1. Analysis of pharmacopoeial compounds of natural origin and their formulations by UV Vis spectrophotometer
2. Simultaneous estimation of multi component containing formulations by UV spectrophotometry
3. Analysis of recorded spectra of simple phytoconstituents
4. Experiments based on Gas Chromatography
5. Estimation of sodium/potassium by flame photometry
6. Development of fingerprint of selected medicinal plant extracts commonly used in herbal drug industry viz. ashwagandha, tulsi, bael, amla, ginger, aloe, vidang, senna, lawronia by HPTLC method
7. Method of extraction
8. Phytochemical screening
9. Thin layer chromatography
10. Demonstration of HPLC- estimation of glycyzeizin
11. Monograph analysis of clove oil
12. Monograph analysis of castor oil.
13. Identification of bioactive constituents from plant extracts
14. Formulation using qualitative and quantitative methods.

## MEDICINAL PLANT BIOTECHNOLOGY (MPG201T)

### 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

60Hrs

- 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.  

1  
2 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.  

12 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.  

12 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.

**12 Hrs**

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

**12 Hrs**

**REFERENCES:**

1. Plant tissue culture – Bhagwani, Vol 5. ( Elsevier)
2. Plant cell and Tissue Culture ( Lab. Manual ) – J.R.M.M. Yeoman.
3. Elements in biotechnology by P. K. Gupta.
4. An introduction to plant tissue culture by M. K. Razdan.
5. Experiments in plant tissue culture by John H. D and Lorin W. R.
6. Pharmaceutical biotechnology by S. P. Vyas and V. K. Dixit.
7. Plant cell and tissue culture by Jeffrey W. Pollard and John M Walker.
8. Plant tissue culture by Dixon, Oxford Washington DC, 1985
9. Plant tissue culture by Street.
10. Pharmacognosy by G. E. Trease and W. C. Evans.
11. Biotechnology by Purohit and Mathur.
12. Biotechnological applications to tissue culture by Shargool.
13. Pharmacognosy by Virroo E. Tyler, Lynn R. Brady and James E. Robberrt.

## ADVANCED PHARMACOGNOSY-II (MPG202T)

### 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
- Know the methods of detection of adulteration and evaluation techniques for the herbal drugs
- To know the methods of screening of herbals for various biological properties

### THEORY

60Hrs

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, heavy metals, pesticide residues, phytotoxin, microbial contamination in herbs fruital formulation.

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.

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 and Anticancer drugs. *In vivo* evaluation techniques for Anti-inflammatory, Antiulcer, Anticancer,

Wound healing, Antidiabetic, Hepatoprotective, Cardio protective, Diuretics and Antifertility.  
**12 Hrs**

#### **REFERENCES:**

1. Glimpses of Indian Ethano Pharmacology by P. Pushpangadam. Ulf Nyman. V.George Tropical Botanic Garden & Research Institute, 1995.
2. Natural products: A lab guide by Raphael Ikan , 2nd Edition, Academic Press 1991.
3. Pharmacognosy - G. E. Trease and W.C. Evans. 15th Edition W.B. Saunders Edinburgh, New York.
4. Pharmacognosy-Tyler, Brady, Robbers
5. Modem Methods of Plant Analysis- Peach & M.V. Tracey, Vol. I&II
6. Herbal Drug Industry by RD. Choudhary, 1st edition, Eastern Publisher, New Delhi, 1996.
7. Text book of Pharmacognosy by C.K.Kokate, Purohit, Ghokhale, 4th edition, Nirali Prakasshan, 1996.
8. Text Book of Pharmacognosy by T.E. Wallis
9. Quality control of herbal drugs by Pulok K Mukarjee (2002), Ist Edition, Business Horizons Pharmaceutical Publisher, New Delhi.
10. Indian Herbal Pharmacopoeia (2002), Revised Edition, IDMA, Mumbai.
11. Text book of Pharmacognosy and Phytochemistry by Vinod D. RangarI (2002), 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 Publisher, New Delhi.
14. Herbal Medicine. Expanded Commission E Monographs by M.Blumenthal, (2004), IST Edition,

## INDIAN SYSTEMS OF MEDICINE (MPG203T)

### Scope

To make the students understand thoroughly on 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.

### Objective

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 formulation.

### THEORY

60Hrs

#### 1. Fundamental concepts of Ayurveda, Siddha, Unani, and Homoeopathy systems of medicine:

Different dosage forms of the ISM-

**Ayurveda:** Chronological development of Charak Samhita, Sushrut Samhita and Kashyapa Samhita. Ayurvedic Pharmacopoeia Analysis of Ayurvedic Formulations and crude drugs with references to: Identity, purity and quality of crude drugs.

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

12Hrs

#### 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 herbal drug industry of GAP, GMP and GLP in traditional system of medicine. 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 skill, Government skills in AYUSH, ISM, CCRAS, CCRS, CCRH, CCRU.**

**12 Hrs**

**REFERENCES:**

1. Ayurvedic Pharmacopoeia (2004), The Controller of Publications, Civil Lines, Govt. of India, New Delhi.
2. Hand Book on Ayurvedic Medicines by H.Panda National Institute of Industrial Research, New Delhi.
3. Ayurvedic System of Medicine by Kaviraj Nagendranath Sengupata (1998), 2<sup>nd</sup> Revised Edition, Sri Satguru Publications, New Delhi.
4. Ayurvedic Pharmacopoeia. Formulary of Ayurvedic Medicines (2000), IMCOPS, Chennai.
5. Homeopathic Pharmacopoeia. Formulary of Homeopathic Medicines (2004), IMCOPS, Chennai.
6. Homeopathic Pharmacy An introduction & Hand book by Steven B. Kayne (1997), Churchill Livingstone, New York.
7. Indian Herbal Pharmacopoeia (2002), Revised Edition, IDMA, Mumbai.
8. British Herbal Pharmacopoeia British (1990), Herbal Medicine Association, UK.
9. GMP for Botanicals - Regulatory and Quality issues on Phytomedicine by Pulok K Mukharjee (2003), First edition, Business Horizons, New Delhi.
10. Indian System of Medicine and Homeopathy in India (2001), Planning and Evaluation Cell, Govt.of India, New Delhi.
11. Essential of Food and Nutrition by Swaminathan (1999), Bappco, Bangalore.
12. Clinical Dietitics and Nutrition by F.P. Antia (1997), 4<sup>th</sup> Edi, Oxford Universith Press, Delhi.
13. Yoga- The Science of Holistic Living by V.K.Yoga (2005), Vivekananda Yoga Prakashna Publishing, Bangalore.

## HERBAL COSMETICS (MPG204T)

### 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 Drug and cosmetic act.

### Objective

After completion of the course, student is 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

**60Hrs**

1. **Introduction:** Herbal/natural cosmetics, Classification & Economic aspects.  
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. **Herbal Cosmetics for the skin:** Physiology and chemistry of skin and pigmentation, hairs, scalp, oral and nail, Cleansing cream, Lotions, Vanishing and Foundation creams, Anti- sun burn preparations, Moisturizing cream, deodorants, Face powders, Face packs, Lipsticks, Bath products, soaps and baby product, Preparation and standardisation of the following :  
Shampoos, Conditioners, Tonic, Bleaches, Colorants, Depilatories and Hair oils, Dentifrices and Mouth washes & Tooth Pastes, Cosmetics for Nails.

**12 Hrs**

3. **Cosmeceuticals of herbal and natural origin:** Hair growth formulations, Fairness formulations.

**12 Hrs**

4. Commonly used herbal cosmetics, raw materials, preservatives, surfactants, humectants, oils, colours, and some functional herbs, preformulation studies, compatibility studies, possible interactions between chemicals and herbs, design of herbal cosmetic formulation.

**12 Hrs**

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

**REFERENCES:**

- ❖ Panda H. 2007. Herbal Cosmetics (Hand book), Edition I, Asia Pacific Business Press Inc, New Delhi.
- ❖ Thomson EG. 2006. Modern Cosmetics, Edition I, Universal Publishing Corporation, Mumbai.
- ❖ P.P.Sharma. 2008. Cosmetics- Formulation, Manufacturing & Quality Control, Edition 4, Vandana Publications, New Delhi.
- ❖ Supriya K B. 2005. Handbook of Aromatic Plants, Edition II(Revised and Enlarged), Pointer Publishers, Jaipur.
- ❖ Skaria P. 2007. Aromatic Plants (Horticulture Science Series Vol. 1) , Edition I, New India Publishing Agency, New Delhi.
- ❖ Kathi Keville and Mindy Green.1995. Aromatherapy ( A Complete Guide to the Healing Art), Edition I, Sri Satguru Publications, New Delhi.
- ❖ Chattopadhyay PK. 2000. Herbal Cosmetics & Ayurvedic Medicines (EOU), Edition I, National Institute of Industrial Research, Delhi.
- ❖ Balsam MS & Edward Sagarin. 2008. Cosmetics Science and Technology, Edition II (Vol-II), Wiley Interscience, New York.

## **PRACTICALS (MPG205P)**

1. Isolation of nucleic acid from cauliflower heads
2. Isolation of RNA from yeast
3. Quantitative estimation of DNA
4. Immobilization of whole cell
5. Establishment of callus culture
6. Establishment of suspension culture
7. Estimation of aldehyde
8. Estimation of phenolic content in herbal raw materials
9. Estimation of alkaloid content in herbal raw materials
10. Estimation of 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. Herbal cosmetic formulation such as lip balm, lipstick, facial cream, herbal hair and nail care products
14. Evaluation of herbal tablets and capsules
15. Dermatological preparation like sunscreen, UV protection cream, skin care formulations for fungal and dermato reaction
16. Formulation of cough syrup



**M. PHARM. COSMECEUTICS (MCC)**

## COSMECEUTICALS-BIOLOGY (MCC101T)

### Scope:

- To impart knowledge on the biological aspects of – skin and hair, nails, eyes.
- To understand basic problems associated with skin and hair.
- To understand the mechanism of Skin irritation, allergy and allergic reactions that are major causes for skin problems.

### Objectives:

- To have stronger scientific basis in developing cosmeceutical products.

### Theory

60 Hours

#### 1. Skin

Structure and functions of skin, baby's skin and problems unique to baby's skin, Age-associated morphological and histological changes in human skin. Difference between baby's skin and adult skin, Ethnic and gender differences in skin properties. Etiology and current treatment for psoriasis and wound healing process.

1

2Hrs

#### 2. Immunology

Types of skin allergic reaction, immunological mechanism of skin allergy.

Terminologies used: Contact dermatitis, Irritant Contact Dermatitis, allergic Contact dermatitis, photo-irritant contact dermatitis, phototoxicity, contact urticaria syndrome

General concepts of skin irritancy: Principles and molecular mechanisms of skin irritation,

evaluation, factors predisposing to cutaneous irritation. Cosmetic and occupational Irritants.

12Hrs

#### 3. Irritation study models

Artificial skin modeling – Human reconstituted epidermis and skin, Skin organ culture models and other new types of skin equivalents

Cosmetic safety testing as per BIS (Bureau of Indian Standards), alternate safety testing methods: Cell line techniques for safety studies (including mutagenicity studies) and toxicity studies, toxicity studies models.

12Hrs

#### **4. Nail :**

Anatomy of nail. Common problems associated with nail- Brittleness striations, splitting, pitting and fungal infections.

**12Hrs**

#### **5. Hair:**

The Structure and Properties of Hair, hair growth cycle. Hair-fall aetiology and current treatment. Racial differences in hair structure.

#### **Microbiology:**

Pharmacopeial methods of evaluation of preservative efficacy.

**12Hrs**

#### **REFERENCES**

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

## **COSMETICS – FORMULATION SCIENCE (MCC102T)**

### **SCOPE:**

- To impart knowledge on the fundamental principles of cosmetic product development.
- To understand key ingredients used in cosmetics and cosmeceuticals
- To understand the building blocks in the formulation of cosmetic products.

### **OBJECTIVES:**

- Upon completion of the course, the students will be able to:
- Know various key ingredients used to develop cosmetics.
- Combine the ingredients together to develop cosmetics with desired sensory.

### **THEORY**

**60 HOURS**

#### **1. Formulation Principles:**

- a. Definition of Cosmetics as per EU and Indian Guidelines
- b. Cleansing and care needs for face, eye lids, lips, hands, feet, nail, scalp, neck, body and underarms. Examples of marketed product.
- c. Formulation requirements for ethnic needs.
- d. Cosmetic product development process

**12 Hrs**

#### **2. Formulation Building blocks:**

Building blocks for different product formulations of cosmetics/cosmeceuticals:

- e. Surfactants- Classification and application.
- f. Emollients and rheological additives: classification and application.
- g. Antimicrobial used as preservatives, their merits and demerits. Factors affecting microbial preservative efficacy.
- h. Perfumes; Classification of perfumes. Perfume ingredients listed as allergens.
- i. Application of various product forms in cosmetics: Solution, creams, lotion, ointment, paste, gels, stick, tablets, capsules, powders and aerosol. Examples from marketed product.

**12 Hrs**

#### **3. Skin cleansing and care**

Dry skin, skin moisturisation,

**Skin Cleansing:** Building blocks and formulation of Soap, syndet bars, face wash, body wash, face mask. Their relative advantages and disadvantages

**Skin Care:** Classification, requirement of an Ideal skin cream.

Building blocks and formulation of cold cream, vanishing cream, moisturizing cream, moisturizing gel, body lotion, petroleum Jelly.

**12 Hrs**

#### **4. Hair**

Hair Care: Ideal requirements of a shampoo.

Formulation of shampoos, Hair conditioners, Hair oil, hair cream. and hair styling gels

Chemistry and formulation of Paraphenylene diamine based Hair dyes.

**12**

**Hrs**

#### **5. Oral care, color cosmetics, deodorants and baby care**

Oral Care: Ideal requirement of a toothpaste. Building blocks and formulation of tooth paste and mouth wash.

Color Cosmetics: Building blocks and formulation of Lipstick, Mascara, nail polish and Face Powder.

Deodorants and antiperspirants: Ingredients and mechanism of action

Baby Care: Approach to baby care formulations.

**12 Hrs**

#### **REFERENCES:**

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

## PRODUCTION TECHNOLOGY & QUALITY ASSURANCE (MCC103T)

### SCOPE:

This course deals with the various quality assurance aspects of pharmaceutical industries. It covers the important aspects like cGMP, documentation, to understand about validation types, methodology application and how it can be applied to industry and thus to improve the quality of the products. Impart fundamental knowledge about quality management System. This knowledge can be applied in QA of cosmetics.

### Objectives:

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

- The cGMP aspects in a pharmaceutical industry
- To appreciate the importance of documentation.
- Explain the aspect of validation
- Apply the knowledge of validation to manufacturing, instruments and equipments
- To understand the quality evaluation of products
- Need of Quality management system in Industry
- This knowledge can be used to evolve stringent QA systems for cosmeceuticals

### THEORY

60 HOURS

#### 1. Introduction to Quality

**Definition** - Quality assurance and Quality control, concept of TQM, GMP, ICH, Brief study of ICH common technical documents – Q1-Q11, Quality by design, six sigma concept, ISO 9000 & 14000.

**Document maintenance in pharmaceutical industry:** Batch Formula Record, Master Formula Record, Quality audit reports and documents, quality reports, distribution records, Common Technical Document and Drug Master Files, Medical Devices, Electronic Common Technical Documentation, complaints and evaluation of complaints, Handling of return goods, recalling and waste disposal.

12Hrs

#### 2. cGMP of Pharmaceutical manufacturing:

Evolution and Principles of cGMP, Schedule-M, WHO-GMP requirements, European Union (EU) and United States Food and Drug Administration (USFDA) guidelines on Pharmaceutical manufacturing. URS, FAT, DQ, SAT, IQ, OQ, PQ of machines and equipment. Clean room standards for different countries and names.

12Hrs

### **3. Introduction to Pharmaceutical Validation:**

Definition, Manufacturing Process Model, scope of Validation, Advantage of Validation, Organization for Validation, Validation Master plan, Types of validation, Design Qualification, Installation Qualification, Operational Qualification & Performance Qualification of facilities. A Review of Prospective, Concurrent, Retrospective Validation & Revalidation including the use of Statistical Process Control (SPC).

**12Hrs**

### **4. Quality Management System :**

Quality risk management: Introduction, risk assessment, risk control, risk review, risk Management tools, HACCP, risk ranking and filtering. Change Control, Deviation-(planned and unplanned), Corrective Action and Preventive Action (CAPA), Handling of nonconformance, Vendor evaluation process, Out of specification (OOS), Annual Product Review, batch reconciliation and finished goods release, Market recalls & Market complaints.

**12Hrs**

### **5. Quality Control Process**

In process quality control and finished products quality control for following formulation in pharma industry: Liquids – Suspension, Emulsion, solutions, Ointments, creams, Jelly's, Parenterals , ophthalmic. Quality control test for containers, closures and secondary packing materials.

**12Hrs**

### **REFERENCES**

1. Quality Assurance of Pharmaceuticals- A compedium of Guide lines and Related materials Vol I & II, 2nd edition, WHO Publications, 1999.
2. The International Pharmacopoeia – vol I, II, III, IV & V - General Methods of Analysis and Quality specification for Pharmaceutical Substances, Excipients and Dosage forms, 3rd edition, WHO, Geneva, 2005.
3. Good laboratory Practice Regulations – Allen F. Hirsch, Volume 38, Marcel Dekker Series, 1989.
4. ICH guidelines
5. ISO 9000 and total quality management
6. The drugs and cosmetics act 1940 – Deshpande, Nilesh Gandhi, 4th edition, Susmit Publishers, 2006.

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. B. T. Loftus & R. A. Nash, "Pharmaceutical Process Validation", Drugs and Pharm Sci. Series, Vol. 129, 3rd Ed., Marcel Dekker Inc., N.Y.
9. The Theory & Practice of Industrial Pharmacy, 3rd edition, Leon Lachman, Herbert A. Lieberman, Joseph. L. Karig, Varghese Publishing House, Bombay.
10. Michael Levin, "Pharmaceutical Process Scale-Up", Drugs and Pharm. Sci. Series, Vol. 157, 2nd Ed., Marcel Dekker Inc., N.Y.
11. Pharmaceutical Equipment Validation: The Ultimate Qualification Handbook, Phillip A. Cloud, Interpharm Press
12. Lachman L Liberman Theory and practice of industrial pharmacy by 3rd edition
13. 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.



## CELLULAR AND MOLECULAR PHARMACOLOGY (MCC104T)

### 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.

This subject is important since animal experimentation is restricted and cell biology knowledge is critical for alternate preclinical studies on safety and efficacy.

### 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
- Apply the knowledge in developing cell line safety studies.

### THEORY

60 HOURS

#### 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 rs

#### 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,

**12Hrs**

### **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 application.

Principles and applications of cell viability assays, glucose uptake assay, Calcium influx assays .

Principles and applications of flow cytometry

### **5. Chapter to be identified**

**12Hrs**

#### **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.Ausuvel et la.

## PRACTICALS (MCC105P)

- A) Visit to dermatology and dental wards. Submitting case report on common skin and oral cavity problems observed.
- B) Analysis in detail selecting a specific skin or oral cavity problem.

### Lab Practicals

- 1) Cytotoxicity studies using cell lines,
- 2) Preservative efficacy test
- 3) *In vitro* assay for antibacterial efficacy.

### Design and Development of following products:

- 4) Moisturizing cream
- 5) Tooth Paste
- 6) Shampoo
- 7) Hair oil
- 8) Lip Balm
- 9) Petroleum jelly
- 10) Isolation and identification of DNA from various sources (Bacteria, Cauliflower, onion, Goat liver).
- 11) Isolation of RNA from yeast
- 12) Estimation of RNA/DNA by UV Spectroscopy
- 13) Gene amplification by PCR.
- 14) Enzyme based *in-vitro* assays (MPO, AChEs,  $\alpha$  amylase,  $\alpha$  glucosidase).
- 15) Cell viability assays (MTT/Trypan blue/SRB).
- 16) DNA damage study by Comet assay.

## COSMECEUTICALS (MCC201T)

### SCOPE:

- To impart knowledge on the fundamental principles of cosmeceuticals product development.
- To understand the building blocks in the formulation of cosmeceutical products.
- To develop knowledge in design and development of cosmeceuticals- focusing on safety, stability, sensory and delivery of actives.

### OBJECTIVES:

Upon completion of the course, the students will be able to Know

- Various key ingredients used to develop cosmeceuticals.
- Combine the ingredients together to develop cosmeceuticals with desired sensory and efficacy.

### THEORY

**60 HOURS**

#### **1. Sun protection, pigmentation and wrinkles**

Sun Protection: Solar spectrum, UV A and UV B rays of the sun. Skin damages caused by over exposure to sunlight, organic and in-organic sunscreens, SPF and Tan protection. Challenges in developing sunscreen formulations. Global regulatory aspects of sunscreen products. Case study on sunscreen products in the market.

Skin Pigmentation and Wrinkles: Melanogenesis and ethnic differences. Ways to control skin pigmentation. Actives and mechanism of action. Building blocks and formulation of a skin anti-blemish cream. Skin bleaches and skin lightening. Case study on skin lightening products in the market.

Skin wrinkles: Factors that leads to skin wrinkles. Role of anti-oxidants in reducing skin wrinkles. Building block and formulation of an anti-wrinkle product. Case study on anti-aging/antiwrinkle product in the market.

**12Hrs**

#### **2. Acne, Prickly heat, Dandruff and oral care**

Causes for acne, prickly heat and dandruff and current treatment.

Building blocks and formulation of products for treatment of acne, prickly heat and dandruff.

Case study of marketed products.

#### **Oral care:**

Basic understating of the cause of Bleeding gums, sensitive teeth, plague, halitosis.

Role of antimicrobial agents, anti oxidants and astringents for oral care.  
Denture cleansers. Building blocks and formulation of anti-cavity, tooth sensitivity relief and teeth-whitening tooth paste. Case study on the marketed products

**12Hrs**

### **3. Herbal Cosmetics**

Herbal ingredients used in Hair care, skin care and oral care and nail.

Guidelines for herbal cosmetics by private bodies like cosmos with respect to preservatives, emollients, foaming agents, emulsifiers and rheology modifiers.

Formulation and development of herbal cosmetics.

**12Hrs**

### **4. Dermal Drug Delivery**

Factors affecting dermal drug delivery. Role of penetration enhancers in dermal delivery.

Dermal drug delivery systems: Nano particles, Liposomes, patches, Iontophoresis, sonophoresis, electroporation, micro-needles.

**12Hrs**

### **5. To be identified**

## **REFERNECES**

1. Harry's Cosmeticology. 8<sup>th</sup> edition.
2. Poucher's perfume cosmetics and Soaps, 10th edition
3. Cosmetics - Formulation, manufacture and quality control PP.Sharma, 4th edition
4. Handbook of cosmetic science and Technology A.O.Barel, M.Paye and H.I.Maibach. 3rdedition
5. S.P.Vyas and Roop K.Khar Controlled Drug Delivery system, Concepts and Advances
6. Cosmetic and Toiletries recent suppliers catalogue.
7. CTFA directory.

## **COSMETIC ANALYSIS & EVALUATION (MCC202T)**

### **SCOPE**

This course is designed to impart knowledge on analysis of cosmetic raw materials and finished products. 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 physical constants of cosmetic raw materials
- Cosmetic raw materials, additives and their analysis
- Analysis of finished cosmetic products
- Principles of performance evaluation of cosmetic products.

### **THEORY**

**60Hrs**

1. Determination of acid value, ester value, Saponification value, iodine value, peroxide value, rancidity, moisture, ash, volatile matter, heavy metals, fineness of powders, density, viscosity of cosmetics raw materials.  

**12 hrs**
2. Study on the quality of raw materials and general methods of analysis of raw material used in cosmetic manufacture as per BIS.  

**12 hrs**
3. Indian standard specifications laid down for sampling and testing of various cosmetics in finished forms such as baby care powders, skin care products, dental products, personal hygiene preparations, lips sticks, hair products and skin creams by the Bureau Indian Standards.  

**12 hrs**
4. Principles of equipment used to measure product performance of skin and hair care products - Sebumeter, corneometer, trans-epidermal water loss, Skin color, hair tensile properties, hair combing properties.  
Performance evaluation of shampoos, antiperspirants, deodorants, sunscreens, foam baths and abrasiveness of dentifrices.  

**12 hrs**
5. Study of specialized additives- quality parameters and analysis of rheology modifiers, preservatives, emollients, hair conditioners and fragrances  

**12 hrs**

**REFERENCES:**

1. Cosmetics – Formulation, Manufacturing and Quality Control, P.P. Sharma, 4<sup>th</sup> edition, Vandana Publications Pvt. Ltd., Delhi
2. Indian Standard specification, for raw materials, BIS, New Delhi.
3. Indian Standard specification for 28 finished cosmetics BIS, New Delhi
4. Harry's Cosmeticology 8th edition
5. Suppliers catalogue on specialized cosmetic excipients
6. Wilkinson, Moore, seventh edition, George Godwin. Poucher's Perfumes, Cosmetics and Soaps
7. Hilda Butler, 10th Edition, Kluwer Academic Publishers. Handbook of Cosmetic Science and Technology, 3rd Edition,
8. Dry skin syndrome: Taylor and Francis.

## COSMETICS- INDUSTRY AND REGULATORY (MCC203T)

### SCOPE:

- To impart knowledge on the basic regulatory aspects relating to cosmetics
- To understand the manufacturing equipments and GMP as per regulatory guidelines
- To understand the aspects of technology transfer from R&D to manufacturing.

**Objectives:** Upon completion of the course, the students will be able to:

- Effectively design products and documentation that meets regulatory requirements
- Implement smooth transfer of technology from design stage to factory production.

**Theory  
Hours**

**60**

### 1. Indian Regulations

Indian Regulation for cosmetics:

Regulatory provisions relating to import and manufacturing of cosmetics – conditions for obtaining license, prohibition of manufacture and sale of certain cosmetics, loan license, offences and penalties.

Misbranded and spurious cosmetics.

Indian regulatory requirement for factory premises, location and surrounding, designing of plant layout, building, light, ventilation, water supply, disposal of waste, first aid, packaging facilities, sanitation in manufacturing premises and health clothing and sanitary requirement of staff.

**12Hrs**

### 2. Manufacturing & ASEAN standards

Equipments used in the manufacturing of creams, shampoo and toothpaste. GMP guidelines as per ASEAN standards for cosmetics

**12Hrs**

### 3. European Union Guidelines

Summary of features of EU guidelines for cosmetics: Ingredients, safety assessment, labeling, the product information package, GMP, animal testing and efficacy testing. Cosmeceuticals as OTC and quasi drugs.



**12Hrs**

**4. Technology transfer**

Significance of pilot plant scale up studies.

Stability studies: Change in parameter to be observed, Photostability, accelerated stability testing- Temperature humidity, freest thaw and stress test. Aerosol product stability studies. Technology transfer of formulations from R&D to factory- Documentations.

**1**

**2Hrs**

**5. Private Regulatory bodies:**

a) Environmental and safety concerns of certain cosmetic ingredients that are debated and discussed. – Nano sized sunscreens, triclosan, formaldehyde liberators, Polythene beads, Sodium and ammonium laureth sulfates, phthalates.

b) Study of salient features of cosmetic safety data base developed by private body, and International Nomenclature of Cosmetic Ingredients (INCI).

c) Principles of cosmetovigilance.

d) Product claim development and advertisement; Role of ASCI.

**12Hrs**

**REFERENCES**

7. Harry's Cosmeticology. 8th edition
8. Cosmetics - Formulation, manufacture and quality control PP.Sharma, 4<sup>th</sup> edition
9. ASEAN definition of Cosmetics and illustrative list by category of Cosmetic products.
10. EU regulation (EC) no. 1223/2009 of the European parliament and of the council of 30<sup>th</sup> November 2009, on cosmetic products.
11. Theory and Practice of Industrial Pharmacy by Lachmann and Libermann

## **COMPUTER AIDED DRUG DELIVERY SYSTEM (MCC204T)** **(This should be an Elective)**

### **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**

At 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**

**60Hrs**

6. **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 Parameter Estimation, Confidence Regions, Nonlinearity at the Optimum, Sensitivity Analysis, Optimal Design, Population Modeling  
**Quality-by-Design In Pharmaceutical Development:** Introduction, ICH Q8 guideline, Regulatory and industry views on QbD, Scientifically based QbD - examples of application

**12Hrs**

7. **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

8. **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

### 12 Hrs

9. **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  
**Computer Simulations in Pharmacokinetics and Pharmacodynamics:** Introduction, Computer Simulation: Whole Organism, Isolated Tissues, Organs, Cell, Proteins and Genes.  
**Computers in Clinical Development:** Clinical Data Collection and Management, Regulation of Computer Systems

### 12 Hrs

#### 10. To be identified

#### REFERENCES

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

### **PRACTICALS (MCC205P):**

1. Design and formulate unique Cream, shampoo, toothpaste, moisturizing gel, and lip balm. Study private body guidelines for green/premium cosmetics of Ecocert/Cosmos, and suggest changes in the formulations.
2. Design and Development of cosmeceutical product for the treatment of dry skin, wrinkles, acne, blemishes, dandruff, and bleeding gums.
3. Case study report of products in the market- Sun-protection, aging, acne, pigmentation, prickly heat, dandruff, hair-fall, teeth cavities, bleeding gums, teeth whitening, Comparing labeled formulation ingredients.
4. Quantitative analysis of rancidity in hair oils and Lipsticks
5. Determination of aryl amine content and Developer in hair dye
6. Determination of foam height and SLS content of Shampoo.
7. Determination of total fatty matter in creams (Soap, Skin and hair Creams)
9. Comparative Study of marketed cosmetic product claims
10. DoE Using Design Expert<sup>®</sup> Software
10. Formulation data analysis Using Design Expert<sup>®</sup> Software
11. Quality-by-Design in Pharmaceutical Development

**M. PHARM. INDUSTRIAL PHARMACY  
(MIP)**

## MODERN PHARMACEUTICAL ANALYSIS (MPA101T)

### 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,

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

### THEORY

60 HOURS

1. **UV-Visible spectroscopy:** Introduction, Theory, Laws, Instrumentation **11 Hrs**  
associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV-Visible spectroscopy.  
**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  
**Spectrofluorimetry:** Theory of Fluorescence, Factors affecting fluorescence, Quenchers, Instrumentation and Applications of fluorescence spectrophotometer.  
**Flame emission spectroscopy and Atomic absorption spectroscopy:** Principle, Instrumentation, Interferences and Applications.
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. **11 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 **11 Hrs**
- 4 Chromatography:** Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution and applications of the following: **11 Hrs**  
 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
- 5 Electrophoresis:** Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following: **11 Hrs**  
 a) Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresis  
 d) Zone electrophoresis e) Moving boundary electrophoresis f) Iso electric focusing  
**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.
- 6. Immunological Assays:** Radioimmunity assay (RIA), ELISA (Theory & practical) and knowledge on Bioluminescence assays. **5 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

## PHARMACEUTICAL FORMULATION DEVELOPMENT (MIP101T)

### Scope

This course is designed to impart knowledge and skills necessary to train the students on par with the routine of Industrial activities in R&D and F&D

### Objectives

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

- The scheduled activities in a Pharmaceutical firm.
- The pre formulation studies of pilot batches of pharmaceutical industry.
- The significance of dissolution and product stability

### THEORY

60Hrs

12 Hrs

1. **Preformulation Studies:** Molecular optimization of APIs (drug substances), crystal morphology and variations, powder flow, structure modification, drug-excipient compatibility studies, methods of determination.

12 Hrs

2. **Formulation Additives:** Study of different formulation additives, factors influencing their incorporation, role of formulation development and processing, new developments in excipient science, determination methods, drug excipient interactions. Design of experiments – factorial design for product and process development.

12 Hrs

3. **Solubility:** Importance, experimental determination, phase-solubility analysis, pH-solubility profile, solubility techniques to improve solubility and utilization of analytical methods – cosolvency, salt formation, complexation, solid dispersion, micellar solubilization and hydrotropy.

12 Hrs

4. **Dissolution:** Theories, mechanisms of dissolution, *in-vitro* dissolution testing models – sink and non-sink. Factors influencing dissolution and intrinsic dissolution studies. Dissolution test apparatus – designs, dissolution testing for conventional and controlled release products. Data handling and correction factor. Biorelevant media, *in-vitro* and *in-vivo* correlations, levels of correlations.



- 5. Product Stability:** Degradation kinetics, mechanisms, stability testing of drugs and pharmaceuticals, factors influencing-media effects and pH effects, accelerated stability studies, interpretation of kinetic data (API & tablets). Solid state stability and shelf life assignment. Stability protocols, reports and ICH guidelines.

**REFERENCES:**

1. Lachman L, Lieberman HA, Kanig JL. The theory and practice of industrial pharmacy, 3<sup>rd</sup> ed., Varghese Publishers, Mumbai 1991.
2. Sinko PJ. Martin's physical pharmacy and pharmaceutical sciences, 5<sup>th</sup> ed., B.I. Publications Pvt. Ltd, Noida, 2006.
3. Lieberman HA, Lachman L, Schwartz JB. Pharmaceutical dosage forms: tablets Vol. I-III, 2<sup>nd</sup> ed., CBS Publishers & distributors, New Delhi, 2005.
4. Connors KA. A Text book of pharmaceutical analysis Wells JI. Pharmaceutical preformulation: The physicochemical properties of drug substances. Ellis Horwood Ltd., England, 1998.
5. Yalkowsky SH. Techniques of solubilization of drugs. Vol-12. Marcel Dekker Inc., New York, 1981
6. Dressman J, Kramer J. Pharmaceutical dissolution testing. Saurah printer pvt. Ltd., New Delhi, 2005.
7. Sethi PD. Quantitative analysis of drugs in pharmaceutical formulations, 3<sup>rd</sup> ed., CBS publications, New Delhi, 2008.
8. Carstensen JT, Rhodes CT. Drug stability principles and practices, 3<sup>rd</sup> ed., CBS Publishers & distributors, New Delhi, 2005.
9. Yoshioka S, Stella VJ. Stability of drugs and dosage forms, Springer (India) Pvt. Ltd., New Delhi, 2006.
10. Banker GS, Rhodes CT. Modern Pharmaceutics, 4<sup>th</sup> ed., Marcel Dekker Inc, New York, 2005.
11. W. Grimm - Stability testing of drug products.
12. Mazzo DJ. International stability testing. Eastern Press Pvt. Ltd., Bangalore, 1999.
13. Beckett AH, Stenlake JB. Practical pharmaceutical chemistry, Part I & II., 4<sup>th</sup> ed., CBS Publishers & distributors, New Delhi, 2004.
14. Indian Pharmacopoeia. Controller of Publication. Delhi, 1996.
15. British Pharmacopoeia. British Pharmacopoeia Commission Office, London, 2008.
16. United States Pharmacopoeia. United States Pharmacopoeial Convention, Inc, USA, 2003.

## CUSTOMIZED DRUG DELIVERY SYSTEMS (MIP102T)

### Scope

This course is designed to impart knowledge and skills necessary to train the students in the area of customized drug delivery systems.

### Objective

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

- The need, concept, design and evaluation of various customized, sustained and controlled release dosage forms.
- To formulate and evaluate various customized/novel drug delivery systems

### THEORY

**60Hrs**

**12 Hrs**

- 1. Concept & Models for NDDS:** Classification of rate controlled drug delivery systems (DDS), rate programmed release, activation modulated & feedback regulated DDS, effect of system parameters in controlled drug delivery, computation of desired release rate and dose for controlled release DDS, pharmacokinetic design for DDS – intermittent, zero order & first order release.

**Carriers for Drug Delivery:** Polymers / co-polymers-introduction, classification, characterization, polymerization techniques, application in CDDS / NDDS, biodegradable & natural polymers.

**12 Hrs**

- 2. Study of Various DDS:** Concepts, design, formulation & evaluation of controlled release oral DDS, Mucoadhesive DDS (buccal, nasal, pulmonary) Pulsatile, colon specific, liquid sustained release systems.

**12 Hrs**

- 3. Transdermal Drug Delivery Systems:** Theory, design, formulation & evaluation including iontophoresis and other latest developments in skin delivery systems.

**Sub Micron Cosmeceuticals:** Biology, formulation science and evaluation of various cosmetics for skin, hair, nail, oral cavity, eye etc and it's regulatory aspects.

**12 Hrs**

- 4. Targeted Drug Delivery Systems:** Importance, concept, biological process and events involved in drug targeting, design, formulation & evaluation, methods in drug targeting – nanoparticles, liposomes, niosomes, pharmacosomes, resealed erythrocytes, microspheres, magnetic microspheres. Specialized pharmaceutical

emulsions – multiple emulsions, micro-emulsions. **Protein / Peptide Drug Delivery Systems:** Concepts, delivery techniques, formulation, stability testing, causes of protein destabilization, stability and destabilization.

**Biotechnology in Drug Delivery Systems:** Brief review of major areas-recombinant DNA technology, monoclonal antibodies, gene therapy.

**12 Hrs**

- 5. 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.

**REFERENCES:**

1. Novel Drug Delivery System, Y.W. Chein, Vol 50, Marcel Dekker, NY.
2. Controlled Drug Delivery Systems, Robinson, Vol 29, Marcel Dekker, NY.
3. Transdermal Controlled Systemic Medications, YW Chein, Vol 31, Marcel Dekker, NY.
4. Bioadhesive DDS, E. Mathiowitz, Vol 98, Marcel Dekker, NY.
5. Nasal System Drug Delivery, K.S.E. Su, Vol 39, Marcel Dekker, NY.
6. Drug Delivery Devices, Vol 32, P Tyle Marcel Dekker, NY.
7. Polymers for Controlled Drug Delivery, P.J. Tarcha, CRC Press.
8. Pharmaceutical Biotechnology, Vyas, CBS, Delhi.
9. Biotechnology of Industrial Antibiotics, E.J. Vandamme, Marcel Dekker, NY.
10. Protein Formulation & Delivery, E.J. McNally, Vol 99, Marcel Dekker, NY.
11. Drug Targeting, M.H. Rubinstein, John Wiley, NY.

## INTELLECTUAL PROPERTY RIGHTS (MIP103T)

### Scope

This course is designed to impart knowledge and skills necessary to train the students to be on par with the routine of Industrial activities in drug regulatory affairs

### Objectives

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

- Assist in Regulatory Audit process.
- Establish regulatory guidelines for drug and drug products
- The Regulatory requirements for contract research organization

### THEORY

**60Hrs**

**12 Hrs**

1. Definition, Need for patenting, Types of Patents, Conditions to be satisfied by an invention to be patentable, Introduction to patent search. Parts of patents. Filing of patents. The essential elements of patent; Guidelines for preparation of laboratory note book, Non-obviousness in Patent.

**12 Hrs**

2. Role of GATT, TRIPS, and WIPO.

**12 Hrs**

3. Brief introduction to Trademark protection and WHO Patents. IPR's and its types, Major bodies regulating Indian Pharmaceutical sector,

**12 Hrs**

4. Brief introduction to CDSCO. WHO, USFDA, EMEA, TGA, MHRA, MCC, ANVISA

**12 Hrs**

5. Regulatory requirements for contract research organization. Regulations for Biosimilars.

### REFERENCES:

1. Pharmaceutical Process Validation: By Fra R. Berry and Robert A. Nash, Vol 57, 2<sup>nd</sup> Edition
2. Applied Production and Operation Management By Evans, Anderson and Williams
3. GMP for pharmaceuticals Material Management by K.K. Ahuja Published by CBS publishers
4. ISO 9000-Norms and explanations

## **PRACTICALS**

### **SEMESTER-1(MIP104P)**

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. Effect of surfactants on the solubility of drugs.
8. Effect of pH on the solubility of drugs.
9. Dissolution methods of transdermal drug delivery systems.
10. Stability testing of solution and solid dosage forms for photo degradation..
11. Stability studies of drugs in dosage forms at 25 °C, 60% RH and 40 °C, 75% RH.
12. Compatibility evaluation of drugs and excipients.
13. Preparation and evaluation of different polymeric membranes.
14. Formulation and evaluation of sustained release oral matrix tablet.
15. Formulation and evaluation of sustained release oral reservoir system.
16. Formulation and evaluation of microspheres / microcapsules.
17. Formulation and evaluation of transdermal films.
18. Design and evaluation of face wash, body- wash, creams, lotions, shampoo, toothpaste, lipstick.

## ADVANCED BIOPHARMACEUTICS & PHARMACOKINETICS (MIP201T)

### 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.

### Objectives

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

- The basic concepts in Biopharmaceutics and pharmacokinetics.
- The use of raw data and derive the pharmacokinetic models and parameters the best describe the process of drug absorption, distribution, metabolism and elimination.
- To critically evaluate Biopharmaceutics studies involving drug product equivalency.
- To design and evaluate dosage regimens of the drugs using pharmacokinetic and biopharmaceutic parameters.

### THEORY

60Hrs

12Hrs

- 1. Drug Absorption From The Gastrointestinal Tract:** Gastrointestinal tract, Mechanism of drug absorption, Factors affecting passive drug absorption, pH-partition theory of drug absorption. Factors affecting drug absorption: 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, Correlation of in vivo data with in vitro dissolution data. 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, Structure of Octanol, Biopharmaceutics Classification System. Solubility: Experimental methods. Permeability: In-vitro, in-situ and In-vivo methods.

12Hrs

- 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, 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, Drug Product Considerations.

**12Hrs**

- 3. Pharmacokinetics:** Basic considerations, Pharmacokinetic models, 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  $K_{max}$  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.

**12Hrs**

- 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, The Biopharmaceutics Classification System, Generic Biologics (Biosimilar Drug Products), Clinical Significance of Bioequivalence Studies, Special Concerns in Bioavailability and Bioequivalence Studies, Generic Substitution.

**12Hrs**

- 5. Application of Pharmacokinetics:** Modified-Release Drug Products, Targeted Drug Delivery Systems and Biotechnological Products. Relationship between Pharmacokinetics and Pharmacodynamics: Generation of a pharmacokinetic–pharmacodynamic (PKPD) equation, Pharmacokinetic and pharmacodynamic, drug interactions. Pharmacokinetics and pharmacodynamics of biotechnology

drugs: Introduction, Proteins and peptides ,Monoclonal antibodies, Oligonucleotides, Vaccines (immunotherapy),Gene therapies.

#### **REFERENCES:**

1. Biopharmaceutics and Clinical Pharmacokinetics by Milo Gibaldi, 4<sup>th</sup> edition, Philadelphia, Lea and Febiger, 1991
2. Biopharmaceutics and Pharmacokinetics, A. Treatise, D .M. Brahmkar and Sunil B.J aiswal., Vallab Prakashan, 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.Pemarowski, 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, 1 st 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.



## SCALE UP AND TECHNOLOGY TRANSFER (MIP202T)

### Scope

This course is designed to impart knowledge and skills necessary to train the students to be on scale up, technology transfer process and industrial safety issues.

### Objectives:

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

- Manage the scale up process in pharmaceutical industry.
- Assist in technology transfer.
- To establish safety guidelines, which prevent industrial hazards.

### THEORY

**60Hrs**

**12Hrs**

**1. Pilot plant design:** Basic requirements for design, facility, equipment selection, for tablets, capsules, liquid orals, parenterals and semisolid preparations.

**Scale up:** Importance, Technology transfer from R & D to pilot plant to plant scale, process scale up for tablets, capsules, liquid orals, semisolids, parenterals, NDDS products – stress on formula, equipments, product uniformity, stability, raw materials, physical layout, input, in-process and finished product specifications, problems encountered during transfer of technology.

**12Hrs**

**2. Validation:** General concepts, types, procedures & protocols, documentation, VMF. Analytical method validation, cleaning validation and vendor qualification.

**12Hrs**

**3. Equipment Qualification:** Importance, IQ, OQ, PQ for equipments – autoclave, DHS, membrane filter, rapid mixer granulator, cone blender, FBD, tablet compression machine, liquid filling and sealing machine.

**12Hrs**

**4.Process validation:** importance, validation of mixing, granulation, drying, compression, tablet coating, liquid filling and sealing, sterilization, water process systems, environmental control.

**12Hrs**

**6. Industrial safety:** Hazards – fire, mechanical, electrical, chemical and pharmaceutical, Monitoring & prevention systems, industrial effluent testing & treatment. Control of environmental pollution.

**REFERENCES:**

1. Pharmaceutical process validation, JR Berry, Nash, Vol 57, Marcel Dekker, NY.
2. Pharmaceutical Production facilities, design and applications, by GC Cole, Taylor and Francis.
3. Pharmaceutical project management, T.Kennedy, Vol 86, Marcel Dekker, NY.
4. The theory & Practice of Industrial Pharmacy, L.Lachman, H.A.Lieberman, Varghese Publ. Bombay.
5. Tablet machine instruments in pharmaceuticals, PR Watt, John Wiloy.
6. Pharmaceutical dosage forms, Tablets, Vol 1, 2, 3 by Lachman, Lieberman, Marcel Dekker, NY.
7. Pharmaceutical dosage forms, Parenteral medications, Vol 1, 2 by K.E. Avis, Marcel Dekker, NY.
8. Dispersed system Vol 1, 2, 3 by Lachman, Lieberman, Marcel Dekker, NY.
9. Subrahmanyam, CVS, Pharmaceutical production and Management,2007,Vallabh Prakashan,Dehli.

## PHARMACEUTICAL PRODUCTION TECHNOLOGY (MIP203T)

### Scope

This course is designed to impart knowledge and skills necessary to train the students to be on par with the routine of Industrial activities in Production

### Objectives

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

- Handle the scheduled activities in a Pharmaceutical firm.
- Manage the production of large batches of pharmaceutical formulations.

### THEORY

**60Hrs**

**12Hrs**

- 1. Improved Tablet Production:** Tablet production process, unit operation improvements, granulation and pelletization equipments, continuous and batch mixing, rapid mixing granulators, rota granulators, spongers and marumerisers, and other specialized granulation and drying equipments. Problems encountered.  
**Coating Technology:** Process, equipments, particle coating, fluidized bed coating, application techniques. Problems encountered.

**12Hrs**

- 2. Parenteral Production:** Area planning & environmental control, wall and floor treatment, fixtures and machineries, change rooms, personnel flow, utilities & utilities equipment location, engineering and maintenance.

**12Hrs**

- 3. Lyophilization Technology:** Principles, process, freeze-drying equipments.

**12Hrs**

- 4. Capsule Production:** Production process, improved capsule manufacturing and filling machines for hard and soft gelatin capsules. Layout and problems encountered.  
**Disperse Systems Production:** Production processes, applications of mixers, mills, disperse equipments including fine solids dispersion, problems encountered.

**Packaging Technology:** Types of packaging materials, machinery, labeling, package printin for different dosage forms.

**12Hrs**

- 5. Air Handling Systems:** Study of AHUs, humidity & temperature control, air filtration systems, dust collectors. **Water Treatment Process:** Techniques and maintenance – RO, DM, ultra – filtration, WFI.

**REFERENCES:**

1. The theory & Practice of Industrial Pharmacy, L. Lachman, Varghese Publ, Bombay.
2. Modern Pharmaceutics by Banker, Vol 72, Marcel Dekker, NY.
3. Pharmaceutical Dosage Forms, Vol 1, 2, 3 by Lachman, Lieberman, Marcel Dekker, NY.
4. Pharmaceutical Dosage Forms, Parental medications, Vol 1, 2 by K.E. Avis, Marcel Dekker, NY.
5. Pharmaceutical Production Facilities, design and applications, by G.C. Cole, Taylor and Francis.
6. Dispersed System Vol 1, 2, 3 by Lachman, Lieberman, Marcel Dekker, NY.
7. Product design and testing of polymeric materials by N.P. Chezerisionoff.
8. Pharmaceutical Project Management, T.Kennedy, Vol 86, Marcel Dekker, NY.
9. Packaging Pharmaceutical and Health Care, H.Lockhard.
10. Quality Control of Packaging Materials in Pharmaceutical Industy, .Kharburn, Marcel Dekker, NY.
11. Freeze drying / Lyophilization of Pharmaceuticals & Biological Products, L. Ray, Vol 96, Marcel Dekker, NY.
12. Tablet Machine instrumentation in pharmaceuticals, PR Watt, Ellis Horwoods, UK.

## **ENTREPRENEURSHIP MANAGEMENT (MIP204T)**

### **Scope**

This course is designed to impart knowledge and skills necessary to train the students on entrepreneurship management.

### **Objectives:**

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

- The Role of enterprise in national and global economy
- Dynamics of motivation and concepts of entrepreneurship
- Demands and challenges of Growth Strategies And Networking

### **THEORY**

#### **60Hrs**

**12Hrs**

#### **1. Conceptual Frame Work**

Concept need and process in entrepreneurship development. Role of enterprise in national and global economy. Types of enterprise – Merits and Demerits. Government policies and schemes for enterprise development. Institutional support in enterprise development and management

**12Hrs**

#### **2. Entrepreneur**

Entrepreneurial motivation – dynamics of motivation. Entrepreneurial competency – Concepts.

Developing Entrepreneurial competencies - requirements and understanding the process of entrepreneurship development, self awareness, interpersonal skills, creativity, assertiveness, achievement, factors affecting entrepreneur role.

**12Hrs**

#### **3. Launching And Organising An Enterprise**

Environment scanning – Information, sources, schemes of assistance, problems. Enterprise selection, market assessment, enterprise feasibility study, SWOT Analysis. Resource mobilisation - finance, technology, raw material, site and manpower. Costing and marketing management and quality control. Feedback, monitoring and evaluation.

**12Hrs**

#### **4. Growth Strategies And Networking**

Performance appraisal and assessment. Profitability and control measures, demands and challenges. Need for diversification. Future Growth – Techniques of

expansion and diversification, vision strategies. Concept and dynamics. Methods, Joint venture, co-ordination and feasibility study.

**12Hrs**

**5. Preparing Project Proposal To Start On New Enterprise**

Project work – Feasibility report; Planning, resource mobilisation and implementation.

**REFERENCES:**

1. Akhauri, M.M.P.(1990): Entrepreneurship for Women in India, NIESBUD, New Delhi.
2. Hisrich, R.D & Brush, C.G.(1996) The Women Entrepreneurs, D.C. Health & Co., Toronto.
3. Hisrich, R.D. and Peters, M.P. (1995): Entrepreneurship – Starting, Developing and Managing a New Enterprise, Richard D., Inwin, INC, USA.
4. Meredith, G.G. etal (1982): Practice of Entrepreneurship, ILO, Geneva.
5. Patel, V.C.(1987): Women Entrepreneurship – Developing New Entrepreneurs, Ahmedabad EDII.

## **PRACTICALS**

### **SEMESTER-2(MIP205P)**

- 1.** Improvement of dissolution characteristics of slightly soluble drug by Solid dispersion technique.
- 2.** Comparison of dissolution of two different marketed products /brands
- 3.** Protein binding studies of a highly protein bound drug & poorly protein bound drug
- 4.** Bioavailability studies of Paracetamol.
- 5.** Pharmacokinetic and IVIVC data analysis by Winnoline<sup>R</sup> software
- 6.** *In vitro* cell studies for permeability and metabolism
- 7.** Formulation and evaluation of tablets
- 8.** Formulation and evaluation of capsules
- 9.** Formulation and evaluation of injections
- 10.** Formulation and evaluation of emulsion
- 11.** Formulation and evaluation of suspension.
- 12.** Formulation and evaluation of enteric coating tablets.

**M. PHARM. PHARMACEUTICAL ANALYSIS (MPA)**



## MODERN PHARMACEUTICAL ANALYSIS (MPA101T)

### 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,

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

### THEORY

60 HOURS

- 1. UV-Visible spectroscopy:** Introduction, Theory, Laws, Instrumentation **11 Hrs**  
associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV-Visible spectroscopy.  
**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  
**Spectrofluorimetry:** Theory of Fluorescence, Factors affecting fluorescence, Quenchers, Instrumentation and Applications of fluorescence spectrophotometer.  
**Flame emission spectroscopy and Atomic absorption spectroscopy:** Principle, Instrumentation, Interferences and Applications.
- 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. **11 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, **11 Hrs**

Isotopic peaks and Applications of Mass spectroscopy.

- 4 Chromatography:** Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution and applications of the following: **11 Hrs**  
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
- 5 Electrophoresis:** Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following: **11 Hrs**  
a) Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresis  
d) Zone electrophoresis e) Moving boundary electrophoresis f) Iso electric focusing  
**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.
- 6. Immunological Assays:** Radioimmunity assay (RIA), ELISA (Theory & practical) and knowledge on Bioluminescence assays. **5 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

## ADVANCED PHARMACEUTICAL ANALYSIS (MPA102T)

### Scope

This subject deals with the various aspects of reagents, quantitative analysis of functional group used in the analytical method development. It also covers the biological testing of various vaccines and impurities

### Objectives

After the completion of the course, it is expected that the student shall be 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 HOURS

1. **Analytical principle and procedure involved in the assay of following methods with special emphasize on official drugs in IP:** 12 Hrs
  - a) Complexometric titration b) Non aqueous titration c) Redox titration d) Diazotization titration e) UV – Visible method f) HPLC g) Potentiometric titrations h) pKa and log p determination
  
2. **Analytical principle, procedure and applications of the following reagents:** 12 Hrs
  - a) Ninhydrin b) 3-Methyl-2- benzthiazolinone hydrazone [MBTH] c) Folin – Ciocaltau [FC] d) Para-dimethyl-amino benzaldehyde [PDAB] e) Para-dimethyl- amino cinnamaldehyde [PDAC] f) 2, 6- Dichloroquinone chlorimide g) 1,2- naphthaquinone-4-sulfonate h) 2,3,5-Triphenyltetrazolium i) 2,4-Dinitro Phenyl hydrazine [DNPH] j) Bratton – Marshall reagent k) 3,5- Dinitro salicylic acid [DNSA]
  
3. **Principles and procedure involved in quantitative estimation of following functional groups in drugs and elements:** 12 Hrs
  - a) Hydroxyl b) Amine c) Carboxyl d) Carbonyl f) Ester g) Methoxyl

a) Sodium b) Potassium c) Calcium d) Halogens e) Phosphorus e) Sulphur

**4. Biological tests and assays of the following: 12 Hrs**

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 (Principles and procedures).

**5. Impurities and stability studies 12 Hrs**

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

**Elemental Impurities**

Element classification, control of elemental impurities, Potential Sources of elemental Impurities, Identification of Potential Elemental Impurities, analytical procedures, instrumentation & C, H, N, S analysis.

**Method development, Stability studies and concepts of validation**

Accelerated stability testing & shelf life calculation, WHO and ICH stability testing guideline, Stability zones, Photostability testing guidelines, ICH stability guidelines for biological products

**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.
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 2006, 2010.
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.

## PHARMACEUTICAL VALIDATION (MPA103T)

### 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 HOURS**

- 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, Disintegration and Dissolution

**Qualification of Glassware:** Volumetric flask, pipette, 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).

**12 Hrs**

- 4. History of various phases of drug development and drug approval, IND, NDA (Phase I - IV), Content and Formal ANDA**

**Analytical method validation:** General principles, Validation of analytical method as per ICH guidelines

**12 Hrs**

### **5. Regulatory scenario in India:**

Regulatory aspects of pharmaceutical and bulk drug manufacture and drug analysis, loan license (contract manufacture) auditing, recent amendments to drugs and cosmetics act, provisions of consumer protection act, environment protection act.

**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 Interscience.

## **FOOD ANALYSIS (MPA104T)**

### **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
- Student shall have the knowledge on food regulations and legislations.

### **THEORY**

**60Hrs**

1. a. Carbohydrates – Chemistry & 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  
  
b. 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

**12Hrs**

2. a. 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.



b. Vitamins – classification of vitamins, methods of analysis of vitamins, Principles of microbial assay and physiological significance of vitamins of B-series.

**12Hrs**

3. a. Food additives – Introduction, analysis of Preservatives, antioxidants, artificial sweeteners, flavors, flavor enhancers, stabilizers, thickening and jelling agents

b. 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

**12Hrs**

4. a. General Analytical methods for milk, milk constituents and milk products like ice cream, milk powder, butter, margarine, cheese including adulterants and contaminants of milk.

b. Analysis of fermentation products like wine, spirits, beer and vinegar.

**12Hrs**

5. a. Pesticide analysis - Effects of pest and insects on various food, use of pesticides in agriculture, pesticide cycle, organophosphorous and organo chlorine pesticides analysis, determination of pesticide residues in grain, fruits, vegetables, milk and milk products.

b. Legislation regulations of food products with special emphasis on BIS, Agmark and US-FDA.

**12Hrs**

## **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.

### **PRACTICAL (MPL101P)**

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 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 (MPA201T)

### 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

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. **UV and IR spectroscopy:** Wood ward – Fiesure rule for 1,3- butadienes, cyclic dienes and  $\alpha$ ,  $\beta$ -carbonyl compounds and interpretation compounds of enones. ATR-IR, IR Interpretation of organic compounds **12Hrs**
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, Mc Lafferty rearrangement, Ring rule, Isotopic peaks, Interpretation of organic compounds **12 Hrs**
4. **Hyphenated analytical techniques :** Principle, Instrumentation and Applications of the following: **12 Hrs**
  - a) GC-MS b) LC-MS c) ICP-MS d) LC-NMR e) EC-MS f) High Performance Thin Layer chromatography h) Super critical fluid chromatography i) Ion Chromatography j) I-EC (Ion-Exclusion Chromatography) k) Flash chromatography
5. **Thermal methods of analysis** – Introduction, principle, instrumentation and application of DSC, DTA and TGA. **12 Hrs**

**Radio Immuno Assay:** Importance, various components, Principle, Different methods, Limitation & Applications of RIA.

**Optical Rotatory Dispersion:** Principle, Plain curves, Cotton effect, Circular Dichroism, Measurement of rotation angle in ORD and applications

### References

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

## MODERN BIO-ANALYTICAL TECHNIQUES (MPA202T)

### 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
- Bioanalytical method validation
- Guidelines for BA/BE studies.
- GCP

### THEORY

60 HOURS

#### 1. Analysis of drugs in biological matrices:

Analysis of drugs in use and drugs in Research and Development

#### Biological matrix and Problems with analysis of biological matrices:

Properties of the biological media, small organic molecules, peptides and protein drugs, prodrugs, formulations, drug metabolites, other drugs, safety considerations.

#### 2. Good Clinical Practice (GCP):

12 Hrs

Origin of GCP, Requirements of GCP compliance, Guidelines for GCP, guidelines of ICH, guidelines of ICMR, Ensuring GCP, Documentation of GCP practice, Audit of GCP compliance

#### 3. USFDA & UDSCO Guidelines for BA/BE studies for orally administered drug products:

12 Hrs

Introduction, Design and conduct of studies, Facilities to conduct BA/BE studies, SPE sorbents, Retention of BA/BE samples, Maintenance of records of BA/BE studies

**4.Extraction of drugs and metabolites from biological matrices: 12 Hrs**

General principle and procedure involved in the bio-analytical methods such as Protein precipitation, Liquid - Liquid extraction and Solid phase extraction and membrane filtration.

**5.Separation techniques 12 Hrs**

Bio molecules separation by HPLC, LC MS/MS and Gel electrophoresis

**REFERENCES:**

1. Analysis of drugs in Biological fluids - Joseph Chamberlain, 2<sup>nd</sup> Edition. CRC Press, Newyork. 1995.
2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5<sup>th</sup> edition, Eastern press, Bangalore, 1998.
3. Pharmaceutical Analysis - Higuchi, Brochmman and Hassen, 2<sup>nd</sup> 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, 2<sup>nd</sup> Edition, John Wiley & Sons, New Jercey. USA.
6. Chromatographic Analysis of Pharmaceuticals – John A Adamovics, 2<sup>nd</sup> Edition, Marcel Dekker, Newyork, USA. 1997.
7. Chromatographic methods in clinical chemistry & Toxicology – Roger L Bertholf, Ruth E Winecker, John Wiley & Sons, New Jercey, USA. 2007.
8. Good Laboratory Practice Regulations, 2<sup>nd</sup> 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 guidelines

## QUALITY CONTROL AND QUALITY ASSURANCE (MPA203T)

### 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 will 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 HOURS**

1. Concept and evolution of Quality Control and Quality Assurance, **12 Hrs**  
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.
2. **cGMP guidelines according to schedule M, USFDA (inclusive of CDER and CBER) Pharmaceutical Inspection Convention(PIC), WHO and EMEA covering:** **12 Hrs**  
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.
3. **Analysis of raw materials, finished products, packaging materials, in process quality control (IPQC), Developing specification (ICH Q6 and Q3)** **12 Hrs**  
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.

- 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**
- b. NABL certification & accreditation procedure    c. Patent Regime and IPR

## 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, Excepients 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.

## **COSMETIC ANALYSIS & EVALUATION (MPA204T)**

### **Scope**

This course is designed to impart knowledge on analysis of cosmetic raw materials and finished products. Performance analysis 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 Food constituents

- Determination of physical constants of cosmetic raw materials
- Cosmetic raw materials, additives and their analysis
- Analysis of finished cosmetic products
- Principles of performance evaluation of cosmetic products.

### **THEORY**

**60Hrs**

1. Determination of acid value, ester value, Saponification value, iodine value, peroxide value, rancidity, moisture, ash, volatile matter, heavy metals, fineness of powders, density, viscosity of cosmetics raw materials and finished products  

**12 Hrs**
2. Study on the quality of raw materials and general methods of analysis of raw material used in cosmetic manufacture as per BIS.  

**12 Hrs**
3. Indian standard specifications laid down for sampling and testing of various cosmetics in finished forms such as baby care powders, skin care products, dental products, personal hygiene preparations, lips sticks, hair products and skin creams by the Bureau Indian Standards.  

**12 Hrs**
4. Principles of equipment used to measure product performance of skin and hair care products - Sebumeter, corneometer, trans-epidermal water loss, Skin color, hair tensile properties, hair combing properties.  
Performance evaluation of shampoos, antiperspirants, deodorants, sunscreens, foam baths and abrasiveness of dentifrices.  

**12 Hrs**
5. Study of specialized additives- quality parameters and analysis of rheology modifiers, preservatives, emollients, hair conditioners and fragrances  

**12 Hrs**

### **References**

1. Cosmetics – Formulation, Manufacturing and Quality Control, P.P. Sharma, 4<sup>th</sup> edition, Vandana Publications Pvt. Ltd., Delhi
2. Indian Standard specification, for raw materials, BIS, New Delhi.
3. Indian Standard specification for 28 finished cosmetics BIS, New Delhi
4. Harry's Cosmeticology
5. Wilkinson, Moore, seventh edition, George Godwin. Poucher's Perfumes, Cosmetics and Soaps
6. Hilda Butler, 10<sup>th</sup> Edition, Kluwer Academic Publishers. Handbook of Cosmetic Science and Technology, 3<sup>rd</sup> Edition,

**PRACTICAL (MPL205P):**

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
17. Preparation of Master Formula Record.
18. Preparation of Batch Manufacturing Record.
19. Quantitative analysis of rancidity in lipsticks and hair oil
20. Determination of aryl amine content and Developer in hair dye
21. Determination of foam height and SLS content of Shampoo.
22. Determination of total fatty matter in creams (Soap, skin and hair creams)
23. Determination of acid value and saponification value.
24. Determination of calcium thioglycolate in depilatories

**M. PHARM. PHARMACEUTICAL QUALITY  
ASSURANCE (MQA)**

## MODERN PHARMACEUTICAL ANALYSIS (MPA101T)

### 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 HOURS

60

- 1. 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. **14 Hrs**  
**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.  
**Spectrofluorimetry:** Theory of Fluorescence, Factors affecting fluorescence (Characteristics of drugs that can be analysed by fluorimetry), Quenchers, Instrumentation and Applications of fluorescence spectrophotometer.  
**Flame emission spectroscopy and Atomic absorption spectroscopy:** Principle, Instrumentation, Interferences and Applications.
- 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: **12 Hrs**
- 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
- 5 Electrophoresis:** Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following: **8 Hrs**
- Paper electrophoresis
  - Gel electrophoresis
  - Capillary electrophoresis
  - Zone electrophoresis
  - Moving boundary electrophoresis
  - Iso electric focusing
- 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.
- 6 Potentiometry:** Principle, working, Ion selective Electrodes and Application of potentiometry. **4 Hrs**
- Thermal Analysis:** Polymer behavior, factors affecting and instrumentation, and working, application of TGA

**REFERENCES** (Latest edition to be recommended)

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



## QUALITY MANAGEMENT SYSTEMS (MQA101T)

### 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.

8Hrs

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 (MQA102T)

### 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 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. 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).

**10 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. 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, 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 (MQA103T)**

### **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. Preformulation 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. Preformulation 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.

**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. Patrevala. John I. Disouza. Maharukh T.Rustomji. CRC Press, Group of Taylor and Francis.
7. Dissolution, Bioavailability and Bio-Equivalence by Abdou H.M, Mack Publishing company, Eastern Pennsylvania.
8. Remingtons Pharmaceutical Sciences, by Alfonso & Gennaro, 19th Edn.(1995)OO2C Lippincott;Williams and Wilkins A Wolters Kluwer Company, Philadelphia.
9. The Pharmaceutical Sciences; the Pharma Path way 'Pure and applied Pharmacy' by D. A Sawant, Pragathi Books Pvt. Ltd.
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 (MQA104P)

### 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
11. In process and finished product quality control tests for tablets, capsules, parenterals and semisolid dosage forms.
12. Assay of raw materials as per official monographs
13. Testing of related and foreign substances in drugs and raw materials
14. To carry out pre formulation study for tablets, parenterals (2 experiment).
15. To study the effect of pH on the solubility of drugs, (1 experiment)
16. Quality control tests for Primary and secondary packaging materials
17. Accelerated stability studies (1 experiment)
18. Improved solubility of drugs using surfactant systems (1 experiment)
19. Improved solubility of drugs using co-solvency method (1 experiment)
20. Determination of Pka and Log p of drugs.

## HAZARDS AND SAFETY MANAGEMENT (MPA201T)

### 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: Fire prevention, types of fire extinguishers and critical Hazard management 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 (MQA202T)

### 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).

**12 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.

**12 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.

**12 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 (Q2) and USP.

**12 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 5.

**12 Hrs**

#### **REFERENCES:**

1. B. T. Loftus & R. A. Nash, "Pharmaceutical Process Validation", Drugs and Pharm Sci. Series, Vol. 129, 3rd Ed., Marcel Dekker Inc., N.Y.
2. The Theory & Practice of Industrial Pharmacy, 3rd edition, Leon Lachman, Herbert A. Lieberman, Joseph. L. Karig, Varghese Publishing House, Bombay.
3. Validation Master plan by Terveeks or Deeks, Davis Harwood International publishing.
4. Validation of Aseptic Pharmaceutical Processes, 2nd Edition, by Carleton & Agalloco, (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
9. Analytical Method validation and Instrument Performance Verification by Churg Chan, Heiman Lam, Y.C. Lee, Yue. Zhang, Wiley Interscience.
10. Huber L. Validation and Qualification in Analytical Laboratories. Informa Healthcare
11. Wingate G. Validating Corporate Computer Systems: Good IT Practice for Pharmaceutical Manufacturers. Interpharm Press
12. LeBlanc DA. Validated Cleaning Technologies for Pharmaceutical Manufacturing. Interpharm Press

## AUDITS AND REGULATORY COMPLIANCE (MPA203T)

### 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.

**1**

**2**

**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.

**1**

**2**

**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.

**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 (MPA204T)

### 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

60Hrs

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

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

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

1

2H

rs

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.

**12Hrs**

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.

**12Hrs**

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.

1

2H

rs

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.

## REFERENCES

1. Lachman L, Lieberman HA, Kanig JL. The theory and practice of industrial pharmacy, 3<sup>rd</sup> ed., Varghese Publishers, Mumbai 1991.
2. Sinko PJ. Martin's physical pharmacy and pharmaceutical sciences, 5<sup>th</sup> ed., B.I. Publications Pvt. Ltd, Noida, 2006.
3. Lieberman HA, Lachman L, Schwartz JB. Pharmaceutical dosage forms: tablets Vol. I-III, 2<sup>nd</sup> ed., CBS Publishers & distributors, New Delhi, 2005.
4. Banker GS, Rhodes CT. Modern Pharmaceutics, 4<sup>th</sup> 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, 1<sup>st</sup> 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(MQA204P)**

#### **PRACTICALS**

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

**M.PHARM. PHARMACEUTICAL REGULATORY AFFAIRS  
(MRA)**

## GOOD REGULATORY PRACTICES (MRA 101T)

### Scope

This course is designed to impart fundamental knowledge biological and medical devices on various Good Regulatory Practices viz., cGMP, GLP, GALP and GDP pharmaceutical industries and understand the rationale behind these requirements and will propose ways and means of complying them.

### Objectives

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

- The key elements of current Good Manufacturing Practices, Good Laboratory Practices, Good Automated Laboratory Practices, Good Documentation Practices
- The check lists for various Good Regulatory Practices and
- Prepare SOPs for Good Pharmaceutical Practices
- Implement Good Regulatory Practices in the Health care Industries and
- Prepare for the Audit of the Pharmaceutical Industries.
- Prepare for the rediness and conduct of the audit/inspections

### THEORY

60Hrs

1. **Current Good Manufacturing Practices:** Introduction, US cGMP Part 210 and Part 211.EC Principles of GMP (Directive 91/356/EEC) Article 6 to Article 14 and WHO cGMP guidelines GAMP-5; Medical devices, GHTF guidance docts

12Hrs

2. **Good Laboratory Practices:** Introduction,USFDA GLP Regulations (Subpart A to Subpart K),Controlling the GLP inspection process,GLP Documentation,Audit, goals of Laboratory Quality Audit, Audit tools, Future of GLP regulations, ISO

12Hrs

3. **Good Automated Laboratory Practices:** Introduction to GALP, Principles of GALP, GALP Requirements, SOPs of GALP, Training Documentation,21 CFR Part 11,General check list of 21CFR Part 11, Software Evaluation checklist, ISO.

12Hrs

4. **Good Distribution Practices:** Introduction to GDP, Legal GDP requirements put worldwide, Principles, Personnel, Documentation, Premises and Equipment, Deliveries to Customers, Returns, Self Inspection, Provision of information, Stability testing principles, WHO GDP, USP GDP( Supply chain integrity), GHTF guidance/IMDRF/CDSCO

12Hrs

5. **Quality management systems:** Concept of Quality, Total Quality Management, Quality by design, Six Sigma concept, Out of Specifications (OOS), Change control. Validation: Types of Validation, Types of Qualification, Validation master plan (VMP), Analytical Method Validation. Validation of utilities, [Compressed air, steam, water systems, Heat Ventilation and Air conditioning (HVAC)]and Cleaning Validation. The International Conference on Harmonization (ICH) process, ICH guidelines to establish quality, safety and efficacy of drug substances and

products, ISO 13485, Schedule M III

**12Hrs**

|

**REFERENCES**

1. Good Laboratory Practice Regulations, by Sandy Weinberg, Fourth Edition, Drugs and the Pharmaceutical Sciences, Vol.168
2. Good Pharmaceutical Manufacturing practice, Rational and compliance by John Sharp, CRC Press
3. Establishing a cGMP Laboratory Audit System, A practical Guide by David M.Bleisner, Wiley Publication.
4. How to practice GLP by PP Sharma, Vandana Publications.
5. Laboratory Auditing for Quality and Regulatory compliance bu Donald C.Singer, Drugs and the Pharmaceutical Sciences, Vol.150.

## **REGULATIONS LEGISLATIONS FOR FOOD PMBC IN INDIA (MRA 102T)**

### **Scope:**

This course is designed to impart fundamental knowledge on regulations and legislations in India with respect to PMBC. It prepares the students for basic regulatory requirements in India of PMB for manufacture, import, registration, export, sale, marketing authorization, clinical trials and intellectual property rights.

### **Objectives:**

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

- Know different Acts and guidelines that regulate PMBC industry in India.
- Understand the approval process and regulatory requirements for drugs and medical devices

### **THEORY**

**60 HOURS**

#### **UNIT I**

##### ➤ **Study of Relevant provisions of FPMBC**

##### ➤ **Acts and Rules (with latest amendments):**

- Drugs and Cosmetics Act 1940 and other Relevant provisions (Rules, Schedules and Guidelines) for approval of FPMBC , Rules 1945: DPCO and NPPA
- Legal definitions of schedules to the Act and Rules, Import of drugs, Manufacture of drugs, Sale of Drugs& Packing of drugs & other related Acts-Narcotic etc

Central Drug Standard Control Organization and State Licensing Authority:

1. Rules, Regulations, Guidelines For Regulatory filling of FPMB to Relevant Regulations
2. Fomat and contents of Regulatory dossier filling
3. Clinical trials /Investigations
  - Clinical Trials
    - New Drugs
  - Medical Devices
  - Fixed Dose Combinations

|

**12 Hrs**



## UNIT II

**Regulatory requirements FNPCMB and approval procedures for:**

**12 Hrs**

## UNIT III

**Indian Pharmacopoeial standards**

- **BIS Standards & ISO and other relevant standards**

## UNIT IV

**BA/ BE:** Bioavailability and Bioequivalence data, BCS Classification of Drugs, Regulatory Requirements for Bioequivalence study

Stability requirements: ICH and WHO

**Guidelines for drug testing in animals/Preclinical studies**

- Animal testing: Rationale for conducting studies, CPCSEA Guidelines
- ethical guidelines for human participants
- ICMR-DBT Guidelines for Stem Cell Research

**12 Hrs**

## UNIT V

**Intellectual Property Rights:** Patent, Trademark, Copyright, Industrial Designs and Geographical Indications, Indian Patent Scenario. IPR vs Regulatory Affairs

**12 Hrs**

## REFERENCES

1. Manual of Patent Practice & Procedure, 3rd Edition, by The Patent Office of India
2. Patent Failure How Judges, Bureaucrats, and Lawyers put innovators at risk by James Bessen and Michael J. Meurer
3. Principles and Practice of Clinical Trial Medicine by Richard Chin and Bruce Y. Lee
4. Ethical Guidelines for Biomedical Research on Human Participants by Indian Council of Medical Research New delhi 2006.
5. CPCSEA Guidelines for Laboratory Animal Facility by Committee for the purpose of control and supervision on experiments on animals (CPCSEA)
6. ICH E6 Guideline — Good Clinical Practice|| by ICH Harmonised Tripartite
7. Guidance for Industry on Submission of Clinical Trial Application for Evaluating Safety and Efficacy by CDSCO (Central Drug Standard Control Organisation)
8. Guidance for Industry on Requirement of Chemical & Pharmaceutical Information including Stability Study Data before approval of clinical trials / BE studies by CDSCO
9. Guidelines for Import and Manufacture of Medical Devices by CDSCO
10. Guidelines from official website of CDSCO

## INTERNATIONAL REGULATORY ASPECTS OF FNPCMB (MRA103T)

### Scope:

This course is designed to impart the fundamental knowledge on the drug development general regulatory requirements for approval of FNPCMB Japan. It prepares the students to have elementary knowledge on the regulatory requirements, documentation requirements, and registration procedures for marketing the products in above countries.

**Objectives:** Upon completion of the course, the student shall be able to understand the Regulatory registration and landscape

### THEORY

**60 Hours**

#### Unit-I

**12 Hours**

**USA and CANADA:** Organization structure and functions of FDA. Federal register and Code of Federal Regulations (CFR), History and evolution of United States Federal, Food, Drug and Cosmetic Act (FFDCA), Hatch Waxman act and Orange book, Purple book, Drug Master Files (DMF) system in US, Regulatory Approval Process for Investigational New Drug (IND), New Drug Application (NDA), Abbreviated New Drug Application (ANDA), Supplemental New Drug Application (SNDA); Regulatory requirements for Orphan drugs and Combination Products, Changes to an approved NDA / ANDA. Regulatory considerations for manufacturing, packaging and labeling of pharmaceuticals in USA

#### Unit-II

**12 Hours**

**EUROPEAN UNION and AUSTRALIA:** Organization and structure of EMA & EDQM, General guidelines, Active Substance Master Files (ASMF) system in EU, Content and approval process of IMPD, Marketing Authorization procedures in EU (Centralized procedure, Decentralized procedure, Mutual recognition procedure and National Procedure). Regulatory considerations for manufacturing, packaging and labeling of pharmaceuticals in EU, Eudralex directives for human medicines, Variations & extensions, Compliance of European Pharmacopoeia (CEP)/ Certificate of Suitability (CoS), Marketing Authorization (MA) transfers, Qualified Person (QP) in EU

#### Unit-III

**12**

#### Hours

**Japan:** Organization of the PMDA, Pharmaceutical Laws and regulations, types of registration applications, DMF system in Japan, drug regulatory approval process, Regulatory considerations

for manufacturing, packaging and labeling of pharmaceuticals in Japan, Post marketing surveillance in Japan

#### **UNIT IV**

#### **BRAZIL and CHINA**

#### **UNIT V**

#### **ASEAN and SOUTH ASIA**

#### **REFERENCES:**

Generic Drug Product Development, Solid Oral Dosage forms, Leon Shargel and Isader Kaufer, Marcel Dekker series, Vol.143  
Pharmaceutical Regulatory Process, Edited by Ira R. Berry Marcel Dekker Series, Vol.144

1. 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.
2. New Drug Approval Process: Accelerating Global Registrations By Richard A Guarino, MD, 5<sup>th</sup> edition, Drugs and the Pharmaceutical Sciences, Vol.190.
3. Guidebook for drug regulatory submissions / Sandy Weinberg. By John Wiley & Sons. Inc.
4. Drugs: From Discovery to Approval, Second Edition By Rick Ng
5. New Drug Development: A Regulatory Overview, Eighth Edition By Mark Mathieu
6. Pharmaceutical Risk Management By Jeffrey E. Fetterman, Wayne L. Pines and Gary H. Slatko
7. Preparation and Maintenance of the IND Application in eCTD Format By William K. Sietsema
8. Country Specific Guidelines from official websites.

## CLINICAL RESEARCH REGULATIONS (MRA 104T)

### Scope:

This course is designed to impart the fundamental knowledge on the clinical development process of FNPCMB, phases and conduct of clinical trials and research, regulations and guidance governing the conduct of clinical research in INDIA. It prepares the students to learn in detail on various laws, legislations and guidance related to safety, efficacy, ethical conduct and regulatory approval of clinical trials and investigations

**Objectives:** Upon completion of the course, the student shall be able to (know, do and appreciate)

- Clinical drug development process and different phases of clinical trials, investigations
- History, origin and ethics of clinical research
- regulatory requirements for conducting clinical trials investigations and research
- regulations and guidance governing the conduct of clinical research,

### **THEORY**

**60 Hours**

#### **Unit-I**

**12 Hours**

#### **Basics for Clinical trials for drug development process**

- Phases of clinical trials, Clinical Trial protocol
- Phase 0 studies
- Phase I and subtype studies (single ascending, multiple ascending, dose escalation, methods, food effect studies, drug – drug interaction, PK end points)
- Phase II studies (proof of concept or principle studies to establish efficacy)
- Phase III studies (Multi ethnicity, global clinical trial, registration studies)
- Phase IV studies (Post marketing authorization studies; pits and practices)
- Ethical principles governing informed consent process
- Patient Information Sheet and Informed Consent Form
- The informed consent process and documentation

#### **Unit-II**

**12 Hours**

#### **Basic CT for MD Ethics in Clinical Research:**

- Historical Perspectives: Nuremberg Code, Thalidomide study , Nazis Trials, Tuskegee Syphilis Study, The Belmont Report, The declaration of Helsinki
- Origin of International Conference on Harmonization - Good Clinical Practice (ICH-GCP) guidelines.
- The ethics of randomized clinical trials
- The role of placebo in clinical trials
- Ethics of clinical research in special population
- Institutional Review Board/Independent Ethics Committee/Ethics Committee – composition, roles, responsibilities, review and approval process and ongoing monitoring of safety data

- Data safety monitoring boards.
- Responsibilities of sponsor, CRO, and investigator in ethical conduct of clinical research

### **Unit-III**

**12 Hours**

#### **Regulations governing Clinical Trials**

**USA:** Regulations to conduct drug studies in USA (FDA)

- NDA 505(b)(1) of the FD&C Act (Application for approval of a new drug)
- NDA 505(b)(2) of the FD&C Act (Application for approval of a new drug that relies, at least in part, on data not developed by the applicant)
- ANDA 505(j) of the FD&C Act (Application for approval of a generic drug product)
- FDA Guidance for Industry - Acceptance of Foreign Clinical Studies
- FDA Clinical Trials Guidance Document: Good Clinical Practice

**EU:** Clinical Research regulations in European Union (EMA)

**India:** Clinical Research regulations in India – Schedule Y

### **Unit-IV**

#### **Clinical Research Related Guidelines**

**12 Hours**

- Good Clinical Practice Guidelines (ICH GCP E6)
- Indian GCP Guidelines
- ICMR Ethical Guidelines for Biomedical Research
- CDSCO guidelines

#### **Regulatory Guidance on Efficacy and Safety**

##### **ICH Guidance's**

- E4 – Dose Response Information to support Drug Registration
- E7 – Studies in support of General Population: Geriatrics
- E8 – General Considerations of Clinical Trials
- E10 – Choice of Control Groups and Related Issues in Clinical Trials,
- E 11 – Clinical Investigation of Medicinal Products in the Pediatric Population

### **Unit-V**

**12 Hours**

#### **USA & EU Guidance**

##### **USA: FDA Guidance**

- CFR 21Part 50: Protection of Human Subjects
- CFR 21Part 54: Financial Disclosure by Clinical Investigators
- CFR 21Part 312: IND Application
- CFR 21Part 314: Application for FDA Approval to Market a New Drug
- CFR 21Part 320: Bioavailability and bioequivalence requirements
- CFR 21Part 812: Investigational Device Exemptions

- CFR 21Part 822: Post-market surveillance
- FDA Safety Reporting Requirements for INDs and BA/BE Studies
- FDA Med Watch
- Guidance for Industry: Good Pharmacovigilance Practices and Pharmacoepidemiologic Assessment

***European Union: EMA Guidance***

- EU Directives 2001
- EudraLex (EMA) Volume 3 – Scientific guidelines for medicinal products for human use
- EU Annual Safety Report (ASR)
- Volume 9A – Pharmacovigilance for Medicinal Products for Human Use

**REFERENCES:**

1. Clinical Trials and Human Research: A Practical Guide to Regulatory Compliance By Fay A. Rozovsky and Rodney K. Adams
2. HIPAA and Human Subjects Research: A Question and Answer Reference Guide By Mark Barnes, JD, LLM and Jennifer Kulynych, JD, PhD
3. Principles and Practices of Clinical Research, Second Edition Edited by John I. Gallin and Frederick P. Ognibene
4. Reviewing Clinical Trials: A Guide for the Ethics Committee; Johan PE Karlberg and Marjorie A Speers; Karlberg, Johan Petter Einar, Hong Kong.
5. International Pharmaceutical Product Registration: Aspects of Quality, Safety and Efficacy; Anthony C. Cartwright; Taylor & Francis Inc., USA.
6. New Drug Approval Process: The Global Challenge; Guarino, Richard A; Marcel Dekker Inc., NY.
7. FDA regulatory affairs: a guide for prescription drugs, medical devices, and biologics; Douglas J. Pisano, David Mantus; CRC Press, USA
8. Country Specific Guidelines from official websites.

**RECOMMENDED WEBSITES:**

1. 1. EU Clinical Research Directive 2001: <http://www.eortc.be/services/doc/clinical-eudirective-04-april-01.pdf>
2. Code of Federal Regulations,  
FDA:<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm>
3. Guidelines of International Conference on Harmonization:  
<http://www.ich.org/products/guidelines.html>
4. Eudralex Guidelines: <http://www.gmpcompliance.info/euguide.htm>
5. FDA New Drug Application:  
<http://www.fda.gov/regulatoryinformation/legislation/FederalFoodDrugandCosmeticActFDCAct/FDCActChapterVDrugsandDevices/ucm108125.htm>
6. Medicines and Healthcare products Regulatory Agency: <http://www.mhra.gov.uk>

7. Central Drugs Standard Control Organization Guidance for Industry: <http://cdsco.nic.in/CDSCO-GuidanceForIndustry.pdf>
8. ICMR Ethical Guidelines for Biomedical Research: [http://icmr.nic.in/ethical\\_guidelines.pdf](http://icmr.nic.in/ethical_guidelines.pdf)

### **PRACTICALS (MRA105P)**

1. Case studies (4 Nos.) of each of Good Pharmaceutical Practices.
2. Documentation for in process and finished products Quality control tests for Solid, liquid, Semisolid and Sterile preparations.
3. Preparation of SOPs, Analytical reports (Stability and validation)
4. Protocol preparation for documentation of various types of records (BMR, MFR, DR)
5. Labeling comparison between brand & generics.
6. Preparation of clinical trial protocol for registering trial in India
7. Registration for conducting BA/ BE studies in India
8. Import of drugs for research and developmental activities
9. Preparation of regulatory dossier as per Indian CTD format
10. Registering for different Intellectual Property Rights in India
11. GMP Audit Requirements as per CDSCO
12. Preparation and documentation for Indian Patent application.
13. Preparation of checklist for registration of IND as per ICH CTD format.
14. Preparation of checklist for registration of NDA as per ICH CTD format.
15. Preparation of checklist for registration of ANDA as per ICH CTD format.
16. Case studies on response with scientific rationale to USFDA Warning Letter
17. Preparation of submission checklist of IMPD for EU submission.
18. Comparison study of marketing authorization procedures in EU.
19. Comparative study of DMF system in US, EU and Japan
20. Preparation of regulatory submission using eCTD software
21. Preparation of Clinical Trial Application (CTA) for US submission
22. Preparation of Clinical Trial Application (CTA) for EU submission
23. Comparison of Clinical Trial Application requirements of US, EU and Japan of a dosage form.
24. Regulatory requirements checklist for conducting clinical trials in India.
25. Regulatory requirements checklist for conducting clinical trials in Europe.
26. Regulatory requirements checklist for conducting clinical trials in USA



## DOCUMENTATION AND REGULATORY WRITING (MRA 201T)

### Scope

This course is designed to impart fundamental knowledge on documentation and general principles involved in regulatory writing and submission to agencies.

### Objectives

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

1. Know the various documents pertaining to drugs in pharmaceutical industry
  2. Understand the basics of regulatory compilation
  3. Create and assemble the regulation submission as per the requirements of agencies
  4. Follow up the submissions and post approval document requirements
- 
1. **Documentation in pharmaceutical industry:** Exploratory Product Development Brief (EPDB) for Drug substance and Drug product, Product Development Plan (PDP), Product Development Report (PDR), Master Formula Record, Batch Manufacturing Record and its calculations, Batch Reconciliation, Batch Packaging Records, Print pack specifications, Distribution records, Certificate of Analysis (CoA), Site Master File and Drug Master Files (DMF).
  2. **Dossier preparation and submission:** Introduction and overview of dossiers, contents and organization of dossier, binders and sections, compilation and review of dossier. Paper submissions, overview and modules of CTD, electronic CTD submissions  
**Electronic submission:** Planning electronic submission, requirements for submission, regulatory bindings and requirements, Tool and Technologies, electronic dossier submission process and validating the submission, Electronic Submission Gateway (ESG). Non eCTD electronic submissions (NeeS), Asian CTD formats (ACTD) submission. Organizing, process and validation of submission
  3. **Audits:** Introduction, Definition, Summary, Types of audits, GMP compliance audit, Audit policy, Internal and External Audits, Second Party Audits, External third party audits, Auditing strategies, Preparation and conducting audit, Auditing strategies, audit analysis, audit report, audit follow up. Auditing/inspection of manufacturing facilities by regulatory agencies. Timelines for audits/inspection
  4. **Inspections:** Pre-approval inspections, Inspection of pharmaceutical manufacturers, Inspection of drug distribution channels, Quality systems requirements for national good manufacturing practice inspectorates, inspection report, model certificate of good manufacturing practices, Root cause analysis, Corrective and Preventive action (CAPA)
  5. **Product life cycle management:** Prior Approval Supplement (PAS), Post Approval Changes [SUPAC], Changes Being Effectuated in 30 Days (CBE-30), Annual Report, Post marketing

Reporting Requirements, Post approval Labeling Changes, Lifecycle Management, FDA Inspection and Enforcement, Establishment Inspection Report (EIR), Warning Letters, Recalls, Seizure and Injunctions

## 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).
5. Implementing Juran's Road Map for Quality Leadership: Benchmarks and Results, By Al Endres, Wiley, 2000
6. Understanding, Managing and Implementing Quality: Frameworks, Techniques and Cases, By Jiju Antony; David Preece, Routledge, 2002
7. 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
8. Corporate Culture and the Quality Organization By James W. Fairfield-Sonn, Quorum Books, 2001
9. The Quality Management Sourcebook: An International Guide to Materials and Resources By Christine Avery; Diane Zabel, Routledge, 1997
10. The Quality Toolbox, Second Edition, Nancy R. Tague, ASQ Publications
11. Juran's Quality Handbook, Sixth Edition, Joseph M. Juran and Joseph A. De Feo, ASQ Publications
12. Root Cause Analysis, The Core of Problem Solving and Corrective Action, Duke Okes, 2009, ASQ Publications

## **BIOLOGICS REGULATIONS (MRA 203T)**

### **Scope**

This course is designed to impart fundamental knowledge on Regulatory Requirements, Licensing and Registration, Regulation on Labelling of Biologics in India, USA and Europe

It prepares the students to learn in detail on Regulatory Requirements for biologics, Vaccines and Blood Products

### **Objectives**

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

- Know the regulatory Requirements for Biologics and Vaccines
- Understand the regulation for newly developed biologics and biosimilars
- Know the pre-clinical and clinical development considerations of biologics
- Understand the Regulatory Requirements of Blood and/or Its Components Including Blood Products and label requirements

### **Theory**

**60 Hrs**

#### **Unit I**

**1.India :** Introduction, Applicable Regulations and Guidelines , Principles for Development of Similar Biologics, Data Requirements for Preclinical Studies, Data Requirements for Clinical Trial Application, Data Requirements for Market Authorization Application, Post-Market Data for Similar Biologics, Pharmacovigilance. GMP and GDP.

**12 Hrs**

#### **Unit II**

**2.USA:** Introduction to Biologics; biologics, biological and biosimilars, different biological products, difference between generic drug and biosimilars, laws, regulations and guidance on biologics/ biosimilars, development and approval of biologics and biosimilars (IND, PMA, BLA, NDA, 510(k), pre-clinical and clinical development considerations, advertising, labelling and packing of biologics

**12 Hrs**

#### **Unit III**

**3. European Union:** Introduction to Biologics; directives, scientific guidelines and guidance related to biologics in EU, comparability/ biosimilarity assessment, Plasma master file, TSE/ BSE evaluation, development and regulatory approval of biologics (Investigational medicinal products and biosimilars), pre-clinical and clinical development considerations; stability, safety, advertising, labelling and packing of biologics in EU

**12 Hrs**

## Unit IV

4. **Vaccine regulations in India, US and European Union:** Clinical evaluation, Marketing authorisation, Registration or licensing, Quality assessment, Pharmacovigilance, Additional requirements

**12 Hrs**

## Unit V

5. **Blood and Blood Products Regulations in India, US and European Union:** Regulatory Requirements of Blood and/or Its Components Including Blood Products, Label Requirements, ISBT (International Society of Blood Transfusion) and IHN (International Haemovigilance Network)

**12 Hrs**

## REFERENCES

1. FDA Regulatory Affairs: A Guide for Prescription Drugs, Medical Devices, and Biologics, Douglas J. Pisano , David S. Mantus ; Informa ,2008
2. Biological Drug Products: Development and Strategies; Wei Wang , Manmohan Singh ; wiley ,2013
3. Development of Vaccines: From Discovery to Clinical Testing; Manmohan Singh , Indresh K. Srivastava ;Wiley, 2011
4. [www.who.int/biologicals/en](http://www.who.int/biologicals/en)
5. [www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/](http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/)
6. [www.ihn-org.com](http://www.ihn-org.com)
7. [www.isbtweb.org](http://www.isbtweb.org)
8. Guidelines on Similar Biologics: Regulatory Requirements for Marketing Authorization in India
9. [www.cdsc0.nic.in](http://www.cdsc0.nic.in)
10. [www.ema.europa.eu](http://www.ema.europa.eu) › scientific guidelines › Biologics
11. [www.fda.gov/biologicsbloodVaccines/GuidanceComplianceRegulatoryInformation](http://www.fda.gov/biologicsbloodVaccines/GuidanceComplianceRegulatoryInformation) (Biologics)

## INTERNATIONAL PHARMACEUTICAL REGULATIONS – II (MRA 203T)

### Scope

This course is designed to impart fundamental knowledge on Regulatory Requirements for registration of drugs, medical devices and post approval requirements in WHO and emerging market (rest of world countries) like CIS,GCC, LATAM, ASIAN and African region.

### Objectives

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

- Know the regulatory Requirements for drug and medical device registration in emerging market;
- Understand the registration requirements of emerging market by comparison; and
- Prepare dossiers for the registration of the products in emerging market.

### THEORY

60 HOURS

1. **Emerging Market:** Introduction, Countries covered, Study of the world map,study of various committees across the globe (ASEAN, APEC, EAC, GCC, PANDRH, SADC)  
**12Hrs**
2. **WHO:** WHO GMP,Regulatory Requirements for registration of drugs and post approval requirements in WHO through prequalification programme, Certificate of Pharmaceutical Product (CoPP) - General and Country Specific (South Africa, Egypt, Algeria and Morocco, Nigeria, Kenya and Botswana)  
**12Hrs**
3. **ASIAN Countries:** Introduction to ACTD, Regulatory Requirements for registration of drugs and post approval requirements in **China and South Korea & Association of Southeast Asian Nations (ASEAN) Region** i.e. Vietnam, Malaysia, Philippines, Singapore and Thailand.  
**12Hrs**
4. **CIS (Commonwealth Independent States):** Regulatory pre-requisites related to Marketing authorization requirements for drugs and post approval requirements in CIS countries i.e. Russia, Kazakhstan and Ukraine  
**12Hrs**
5. **GCC (Gulf Cooperation Council) for Arab states:** Regulatory pre-requisites related to Marketing authorization requirements for drugs and post approval requirements in Saudi Arabia and UAE  
**12Hrs**

## REFERENCES

1. [http://www.who.int/medicines/areas/quality\\_safety/regulation\\_legislation/ListMRAWebsites.pdf](http://www.who.int/medicines/areas/quality_safety/regulation_legislation/ListMRAWebsites.pdf)
2. Roadmap to an ASEAN economic community Edited by Denis Hew. ISEAS Publications, Singapore 2005, ISBN 981-230-347-2
3. ASEAN, Rodolfo C. Severino, ISEAS Publications, Singapore 2005, ISBN 978-981-230-750-7
4. Building a Future With Brics: The Next Decade for Offshoring, Mark Kobayashi-Hillary, Springer
5. Outsourcing to India: The Offshore Advantage, Mark Kobayashi-Hillary, Springer
6. Trade performance and Regional Integration of the CIS Countries, Lev Freinkman, The world Bank, Washington, DC, ISBN: 0-8212-5896-0
7. Global Pharmaceutical Policy: Ensuring Medicines for Tomorrow's World By Frederick M. Abbott, Graham Dukes, Maurice Nelson Graham Dukes 139
8. The Gulf Cooperation Council: A Rising Power and Lessons for ASEAN by Linda Low and Lorraine Carlos Salazar (Nov 22, 2010)
9. Doing Business in the Asean Countries, Balbir Bhasin, Business Expert Press ISBN: 13:978-1-60649-108-9
10. Realizing the ASEAN Economic Community: A Comprehensive Assessment, Michael G Plummer (Editor), Chia Siow Yue (Editor), Institute of South East Asian Studies, Singapore

## INDIA MEDICAL DEVICE REGULATIONS (MRA 204T)

### Scope:

This course is designed to impart the fundamental knowledge on the medical devices and *in vitro* diagnostics, basis of classification and product life cycle of medical devices, regulatory requirements for approval of medical devices in regulated countries like US, EU and ASEAN countries along with WHO regulations. It prepares the students to learn in detail on the harmonization initiatives, quality and ethical considerations, regulatory and documentation requirements for marketing medical devices in regulated countries.

### Objectives:

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

- basics of medical devices, process of development, ethical and quality considerations
- harmonization initiatives for approval and marketing medical devices
- regulatory approval process for medical devices in US, EU and Asia
- clinical aspects of medical devices

### THEORY

**60 Hours**

#### Unit-I

**12 Hours**

**Medical Devices:** Introduction, differentiating medical devices from IVDs and Combination Products, History of Medical Device Regulation, Product Lifecycle of Medical Devices, Classification of Medical Devices.

**IMDRF/GHTF:** Introduction, Organizational Structure, Purpose and Functions, Regulatory Guidelines, Working Groups, Summary Technical Document (STED), Global Medical Device Nomenclature (GMDN).

#### Unit-II

**12 Hours**

**Ethics:** Clinical Investigation of Medical Devices, Clinical Investigation Plan for Medical Devices, Good Clinical Practice for Clinical Investigation of medical devices (ISO 14155:2011)

**Quality:** Quality System Regulations of Medical Devices: ISO 13485, Quality Risk Management of Medical Devices: ISO 14971, Validation and Verification of Medical device, Adverse Event Reporting of Medical device

#### Unit-III

**12 Hours**

**USA:** Introduction, Classification, Regulatory approval process for Medical Devices (510k) Premarket Notification, Pre-Market Approval (PMA), Investigational Device Exemption (IDE) and *In vitro* Diagnostics, Quality System Requirements 21 CFR Part 820, Labeling requirements

21 CFR Part 801, Post marketing surveillance of MD and Unique Device Identification (UDI).  
Basics of *In vitro* diagnostics, classification and approval process.

**Unit-IV**

**12 Hours**

**European Union:** Introduction, Classification, Regulatory approval process for Medical Devices (Medical Device Directive, Active Implantable Medical Device Directive) and *In vitro* Diagnostics (*In Vitro* Diagnostics Directive), CE certification process.  
Basics of *In vitro* diagnostics, classification and approval process.

**Unit-V**

**12 Hours**

**Medical Device Regulations in World Health Organization (WHO):** Registration Procedures, Quality System requirements and Regulatory requirements  
**Asia:** Clinical Trial Regulations specific for Medical Devices, Registration Procedures, Quality System requirements and Regulatory requirements for Japan, India and China

**REFERENCES:**

1. FDA regulatory affairs: a guide for prescription drugs, medical devices, and biologics by Douglas J. Pisano, David Mantus.
2. Medical Device Development: A Regulatory Overview by Jonathan S. Kahan
3. Medical Product Regulatory Affairs: Pharmaceuticals, Diagnostics, Medical Devices by John J. Tobin and Gary Walsh
4. Compliance Handbook for Pharmaceuticals, Medical Devices and Biologics by Carmen Medina
5. Country Specific Guidelines from official websites.



### **PRACTICAL (MRA205P)**

1. Case studies on
  - Change Management/ Change control. Deviations
  - Corrective & Preventive Actions (CAPA)
2. Documentation of raw materials analysis as per official monographs
3. Preparation of audit checklist for various agencies
4. Preparation of submission to FDA using eCTD software
5. Preparation of submission to EMA using eCTD software
6. Preparation of submission to MHRA using eCTD software
7. Preparation of Biologics License Applications (BLA)
8. Preparation of documents required for Vaccine Product Approval
9. Comparison of clinical trial application requirements of US, EU and India of Biologics
10. Preparation of Checklist for Registration of Blood and Blood Products
11. Registration requirement comparison study in 5 emerging markets (WHO) and preparing check list for market authorization
12. Registration requirement comparison study in emerging markets (BRICS) and preparing check list for market authorization
13. Registration requirement comparison study in emerging markets (China and South Korea) and preparing check list for market authorization
14. Registration requirement comparison study in emerging markets (ASEAN) and preparing check list for market authorization
15. Registration requirement comparison study in emerging markets (GCC) and preparing check list for market authorization
16. Checklists for 510k and PMA for US market
17. Checklist for CE marking for various classes of devices for EU
18. STED Application for Class III Devices
19. Audit Checklist for Medical Device Facility
20. Clinical Investigation Plan for Medical Devices

**M. PHARM. PHARMACEUTICAL  
BIOTECHNOLOGY (MPB)**

## MODERN PHARMACEUTICAL ANALYSIS (MPA101T)

### 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,

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

### THEORY

60 HOURS

1. **UV-Visible spectroscopy:** Introduction, Theory, Laws, Instrumentation **12 Hrs**  
associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV-Visible spectroscopy.  
**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  
**Spectrofluorimetry:** Theory of Fluorescence, Factors affecting fluorescence, Quenchers, Instrumentation and Applications of fluorescence spectrophotometer.  
**Flame emission spectroscopy and Atomic absorption spectroscopy:** Principle, Instrumentation, Interferences and Applications.
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. **12 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 **12 Hrs**
- 4 Chromatography:** Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution and applications of the following: **12 Hrs**  
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
- 5 Electrophoresis:** Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following: **12 Hrs**  
a) Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresis  
d) Zone electrophoresis e) Moving boundary electrophoresis f) Iso electric focusing
- 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.

## 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

## MICROBIAL AND CELLULAR BIOLOGY (MPB101T)

### Scope

This subject is designed to provide the advanced knowledge to the biotechnology students in invaluable areas of advanced microbiology which plays a crucial role in determining its future use and applications in medicine, drug discovery and in pharmaceutical industry.

### Objective

At the completion of this course it is expected that the students will get an understanding about the following aspects;

- Importance of Microorganisms in Industry
- Central dogma of molecular biology
- Structure and function of cell and cell communication
- Cell culture technology and its applications in pharmaceutical industries.
- Microbial pathogenesis

### THEORY

60Hrs

#### UNIT I

12Hrs

#### Microbiology

Introduction – Prokaryotes and Eukaryotes. Bacteria, fungi, actinomyocytes and virus - structure, chemistry and morphology, cultural, physiological and reproductive features. Methods of isolation, cultivation and maintenance of pure cultures. Industrially important microorganisms - examples and applications

#### UNIT II

12 Hrs

#### Molecular Biology

05 Hrs

Structure of nucleus and chromosome, Nucleic acids and composition, structure and types of DNA and RNA. Central dogma of molecular biology: Replication, Transcription and transcription.

#### Gene regulation

02 Hrs

Gene copy number, transcriptional control and translational control.

#### RNA processing

05 Hrs

Modification and Maturation, RNA splicing, RNA editing, RNA amplification. Mutagenesis and repair mechanisms, types of mutants, application of mutagenesis in strain

improvement, gene mapping of plasmids- types purification and application. Phage genetics, genetic organization, phage mutation and lysogeny.

**UNIT III** **12 Hrs**

**Cell structure and function** **05 Hrs**

Cell organelles, cytoskeleton & cell movements, basic aspects of cell regulation, bioenergetics and fuelling reactions of aerobics and anaerobics, secondary metabolism & its applications. Cell communication, cell cycle and apoptosis, mechanism of cell division. Cell junctions/adhesion and extra cellular matrix, germ cells and fertilization, histology – the life and death of cells in tissues.

**Cell Cycle and Cytoskeleton** **03 Hrs**

Cell Division and its Regulation, G-Protein Coupled Receptors, Kinases, Nuclear receptors, Cytoskeleton & cell movements, Intermediate Filaments.

**Apoptosis and Oncogenes** **02 Hrs**

Programmed Cell Death, Tumor cells, carcinogens & repair.

**Differentiation and Developmental Biology** **02 Hrs**

Fertilization, Events of Fertilization, *In vitro* Fertilization, Embryonic Germ Cells, Stem Cells and its Application.

**UNIT IV** **12 Hrs**

**Principles of microbial nutrition** **05 Hrs**

Physical and chemical environment for microbial growth, Stability and degeneration of microbial cultures.

**Growth of animal cells in culture** **07 Hrs**

General procedure for cell culture, Nutrient composition, Primary, established and transformed cell cultures, applications of cell cultures in pharmaceutical industry and research. Growth of viruses in cell culture propagation and enumeration. *In vitro* screening techniques- cytotoxicity, anti-tumor, anti-viral assays.

**UNIT V** **12 Hrs**

**Microbial pathology**

Identifying the features of pathogenic bacteria, fungi and viruses. Mechanism of microbial pathogenicity, etiology and pathology of common microbial diseases and currently recommended therapies for common bacterial, fungal & viral infections. Mechanism of action of antimicrobial agents and possible sites of chemotherapy.

## REFERENCES

1. W.B. Hugo and A.D. Russel: Pharmaceutical Microbiology, Blackwell Scientific publications, Oxford London.
2. Prescott and Dunn, Industrial Microbiology, 4<sup>th</sup> edition, CBS Publishers & Distributors, Delhi.
3. Pelczar, Chan Kreig, Microbiology, Tata McGraw Hill edn.
4. David Freifelder, Molecular Biology, 2<sup>nd</sup> edition, Narosa Publishing House.
5. R. Ian Freshney, Culture of animal cells – A manual of Basic techniques, 6<sup>th</sup> edition, Wileys publication house.
6. David Baltimore, Molecular cell biology, W H Freeman & Co publishers.
7. Cell biology vol-I,II,III by Julio E.Cells
8. Bergeys manual of systematic bacteriology, Williams and Wilkins- A Waverly company.

## **BIOPROCESS ENGINEERING AND TECHNOLOGY (MPB102T)**

### **Scope**

This paper has been designed to provide the knowledge to the biotechnology students in invaluable areas of bioprocess technology to develop skills to modify, design and operate different types of fermenters, to understand and implement various fermentation procedures, to train students in scale up fermentation operations.

### **Objective**

At the completion of this subject it is expected that students will be able to,

- Understand basics and design of fermentation technology
- Scale up and scale down processing of fermentation technology
- Bioprocessing of the industrially important microbial metabolites for the growth of microorganisms in industries and R & D organizations.
- Regulation governing the manufacturing of biological products
- Understand and conduct fermentation process kinetics.

**THEORY** **60 Hrs**

**UNIT I** **12 Hrs**

#### **Introduction to fermentation technology**

Basic principles of fermentation **02 Hrs**

#### **Study of the design and operation of bioreactor** **04 Hrs**

Ancillary parts and function, impeller design and agitation, power requirements on measurements and control of dissolved oxygen, carbon dioxide, temperature, pH and foam.

#### **Types of bioreactor** **04 Hrs**

CSTR, tower, airlift, bubble column, packed glass bead, hollow fiber, configuration and application

#### **Computer control of fermentation process** **02 Hrs**

System configuration and application

**UNIT II** **12 Hrs**

#### **Mass transfer and Rheology**

#### **Mass transfer** **07 Hrs**

Theory, diffusional resistance to oxygen requirements of microorganisms, measurements of mass transfer co- efficient and factor affecting them, effects of aeration and agitation on



mass transfer, supply of air, air compressing, cleaning and sterilization of air and plenumventilation, air sampling and testing standards for air purity.

**Rheology** **05 Hrs**

Rheological properties of fermentation system and their importance in bioprocessing.

**UNIT III** **12 Hrs**

**Scale up of fermentation process** **04 Hrs**

Principles, theoretical considerations, techniques used, media for fermentation, HTST sterilization, advantage and disadvantage, liquid sterilization.

**Cultivation and immobilized culture system** **04 Hrs**

Cultivation system - batch culture, continuous culture, synchronous cultures, fed batch culture. Graphical plot representing the above systems.

**Introduction to immobilization** **04 Hrs**

Techniques, immobilization of whole cell, immobilized culture system to prepare fine chemicals. Immobilization of enzymes and their applications in the industry. Reactors for immobilized systems and perspective of enzyme engineering.

**UNIT IV** **12 Hrs**

**Scale down of fermentation process** **08 Hrs**

Theory, equipment design and operation, methods of filtration, solvent extraction, chromatographic separation, crystallization turbidity analysis and cell yield determination, metabolic response assay, enzymatic assay, bioautographic techniques and disruption of cells for product recovery.

**Isolation, screening** **04 Hrs**

Primary and secondary, maintenance of stock culture, strain improvement for increased yield.

**UNIT V** **12 Hrs**

**Bioprocessing of the industrially important microbial metabolites** **08 Hrs**

- a. Organic solvents – Alcohol and Glycerol
- b. Organic acids - Citric acids, Lactic acids,
- c. Antibiotics - Penicillin, Streptomycin, Griseofulvin,
- d. Vitamins - B12, Riboflavin and Vitamin C
- e. Amino acids - Glutamic acids, Lysine, Cyclic AMP and GMP

Biosynthetic pathways for some secondary metabolites, microbial transformation of steroids and alkaloids

**02 Hrs**

**REFERENCES**

1. Peter Stanbury, Allan Whitaker, Stephen Hall, Principles of Fermentation technology, 3<sup>rd</sup> edition, Elsevier stores.
2. L.E. Casida, Industrial Microbiology, 3<sup>rd</sup> edition, John Wiley & sons Inc.
3. F.M. Asubel, Current protocols in molecular biology, volume I and II, John Wiley Publishers.
4. Biotol Board, Bioreactor design and product yield, Butterworth and Helhemann publishers.
5. A. H. Patel, Industrial microbiology, 2<sup>nd</sup> edition, Macmillan India Limited; Second edition

## **ADVANCED PHARMACEUTICAL BIOTECHNOLOGY (MPB103T)**

### **Scope**

This paper has been designed to provide the knowledge to the students to develop skills of advanced techniques of isolation and purification of enzymes, to enrich students with current status of development of vaccines and economic importance of biotechnology products.

### **Objective**

At the completion of this subject it is expected that students will be able to –

- Understand about the latest technology development in biotechnology technique, tools and their uses in drug and vaccine development.
- Identify appropriate sources of enzymes.
- Understand and perform genetic engineering techniques in gene manipulation, r-DNA technology and gene amplification.
- Understand the overview of pharmacogenomics.
- Learn the regulatory approval process and key regulatory agencies for new drugs, biologics, devices, and drug-device combinations.

### **THEORY**

**60 Hrs**

#### **UNIT I**

**12 Hrs**

##### **Enzyme Technology**

Classification, general properties of enzymes, dynamics of enzymatic activity, sources of enzymes, extraction and purification, Applications pharmaceutical, therapeutic and clinical. Production of amyloglucosidase, glucose isomerase, amylase and trypsin.

#### **UNIT II**

**12 Hrs**

##### **Genetic Engineering**

**06 Hrs**

Techniques of gene manipulation, cloning strategies, procedures, cloning vectors expression vectors, recombinant selection and screening, expression in E.coli and yeast.

Site directed mutagenesis, polymerase chain reaction, and analysis of DNA sequences .

**02 Hrs**

Gene library and cDNA

**01 Hrs**

Applications of the above technique in the production of,

**03 Hrs**

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

### **UNIT III**

**12 Hrs**

#### **Therapeutic peptides**

**05 Hrs**

Study on controlled and site specified delivery of therapeutic peptides and proteins through various routes of administration.

#### **Transgenic animals**

**02 Hrs**

Production of useful proteins in transgenic animals and gene therapy.

#### **Human Genome**

**05 Hrs**

The human genome project-a brief study, Human chromosome – Structure and classification, chromosomal abnormalities – Syndromes

### **UNIT IV**

**12Hrs**

#### **Signal transduction**

**08 Hrs**

Introduction, cell signaling pathways, Ion channels, Sensors and effectors, ON and OFF mechanisms, Spatial and temporal aspects of signaling, cellular process, development, cell cycle and proliferation, neuronal signaling, cell stress, inflammatory responses and cell death, signaling defects and diseases.

#### **Oncogenes**

**04 Hrs**

Introduction, definition, various oncogenes and their proteins.

## **UNIT V**

**12 Hrs**

### **Microbial Biotransformation**

**04 Hrs**

Biotransformation for the synthesis of chiral drugs and steroids.

### **Microbial Biodegradation**

**04 Hrs**

Biodegradation of xenobiotics, chemical and industrial wastes,

Production of single-cell protein,

Applications of microbes in environmental monitoring.

### **Biosensors**

**04 Hrs**

Definition, characteristics of ideal biosensors, types of biosensors, biological recognition elements, transducers, application of biosensors.

## **REFERENCES**

1. Biotechnology-The biological principles: MD Trevan, S Boffey, KH Goulding and P.F. Stanbury.
2. Immobilization of cells and enzymes: HosevearKennadycabral& Bicker staff
3. Principles of Gene Manipulating: RW Old and S.B.Primrose.
4. Molecular Cell Biology: Harvey Lodish, David Baltimore, Arnold Berk, S LawenceZipursky, Paul Matsudaira, James Darnell.
5. Modern Biotechnology: S.B Primrose
6. Gene transfer and expression protocols-methods in Molecular Biology, vol. VII, Edit E.T. Murray
7. Current protocols in Molecular Biology, Vo1.I & II:F.M. Asubel, John wiley Publishers
8. Current protocols in cellular biology, Vo1.1 & II John wiley publishers.
9. Principles of human genetics; by Curt Stern, published by W.H. Freeman, 1960.

## **SEMESTER – I**

### **PRACTICALS (MPB104P)**

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. Isolation and Purification of microorganism from the soil
8. Microbial contamination of Water and biochemical parameters.
9. Determination of Minimum Inhibitory concentration by gradient plate technique and serial dilution method.
10. UV- survival curve and Dark repair
11. Sterility test for pharmaceutical preparations
12. Sub culturing of cells and cytotoxicity assays.
13. Construction of growth curve and determination of specific growth rate and doubling time
14. Fermentation process of alcohol and wine production
15. Fermentation of vitamins and antibiotics
16. Whole cell immobilization engineering
17. Thermal death kinetics of bacteria
18. Replica plating
19. Bio-autography.
20. Isolation and estimation of DNA
21. Isolation and estimation of RNA
22. Isolation of plasmids
23. Agarose gel electrophoresis.
24. Transformation techniques
25. SDS – polyacrylamide gel electrophoresis for proteins
26. Polymerase chain reaction technique.

## **PROTEINS AND PROTEIN FORMULATIONS (MPB201T)**

### **Scope**

This course is designed to impart knowledge and skills necessary for knowing fundamental aspects of proteins and their formulations is a part of drug research and development process. Basic theoretical discussions of the principles of more integrated and coherent use of information for protein formulation and design are provided to help the students to clarify the various biological concepts of protein.

### **Objective**

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

- Various methods of purification of proteins
- Peptides in drug development
- Protein identification and characterization
- Protein based formulations
- Sequencing proteins

### **THEORY**

**60 Hrs**

#### **UNIT I**

**12 Hrs**

##### **Protein engineering**

Concepts for protein engineering. Isolation and purification of proteins, Stability and activity based approaches of protein engineering, Chemical and Physical Considerations in Protein and Peptide Stability, Different methods for protein engineering, gene shuffling, and direct evolution

#### **UNIT II**

**12 Hrs**

##### **Peptidomimetics**

Introduction, classification; Conformationally restricted peptides, design, pseudopeptides, peptidomimetics and transition state analogs; Biologically active template; Amino acid replacements; Peptidomimetics and rational drug design; CADD techniques in peptidomimetics; Development of non peptide peptidomimetics.

### **UNIT III**

**12 Hrs**

#### **Proteomics**

**08 Hrs**

Protein identification and characterization: Methods/strategies, protein identification, de novo protein characterization, Isotope labelling, N- and C-terminal tags.

#### **2-Dimensional gel electrophoresis**

**04 Hrs**

Methods (including IPGs), resolution, reproducibility and image analysis, future developments

### **UNIT IV**

**12 Hrs**

#### **Protein formulation**

Different strategies used in the formulation of DNA and proteins, Analytical and biophysical parameters of proteins and DNA in pre-formulation, Liposomes, Neon-spears, Neon-particulate system, Pegilation, Biological Activity, Biophysical Characterization Techniques, Forced degradation studies of protein.

### **UNIT V**

**12 Hrs**

#### **Methods of protein sequencing**

Various methods of protein sequencing, characterisation, Edman degradation, Tryptic and/or Chymotryptic Peptide Mapping.

### **REFERENCE**

1. H. Lodhishet. Al. Molecular Cell Biology, W. H. Freeman and Company
2. Protein Purification – Hand Book – 1998 Amersham pharmacia biotech
3. EngelbertBuxbaum, Fundamentals of Protein Structure and Function (2007), Springer Science
4. Sheldon J. Park, Jennifer R. Cochran, Protein Engineering and Design (2009), CRC press.
5. Robert K. Skopes. Protein purification, principle and practice (1993), springer link.
6. David Whitford, Proteins-Structure and Function (2005), John Wiley & Sons Ltd.



7. James Swarbrick, Protein Formulation and Delivery (2008) Informa Healthcare USA, Inc.
8. Rodney Pearlman, Y. John Wang Formulation, Characterization, and Stability of Protein Drugs (2002), Kluwer Academic Publishers.

## IMMUNOTECHNOLOGY (MPB202T)

### Scope

This course is designed to impart knowledge on production and engineering of antibodies, the application of antigens, the design of (recombinant) vaccines, strategies for immune intervention, etc. The Immunotechnology - based techniques will be used in the medicine for therapeutics and diagnostics, industries in the production, quality control and quality assurance, and in R&D.

### Objective

After this course, the students will be able to:-

- Understand the techniques like immunodiagnostic tests,
- Characterization of lymphocytes, purification of antigens and antibody, etc.
- Access health problems with immunological background;
- Develop approaches for the immune intervention of diseases

### THEORY

60 Hrs

#### UNIT I

12 Hrs

#### Fundamental aspects of immunology

06 Hrs

Introduction, cells and organs of the immune system, cellular basis of Immune response, primary and secondary lymphoid organs, antigen antibody and their structure.

Types of immune responses, anatomy of immune response.

Overview of innate and adaptive Immunity.

#### Humoral Immunity

03 Hrs

B – Lymphocytes and their activation. Structure and function of immunoglobulins, idiotypes and anti idiotypic antibodies.

#### Cell mediated Immunity

03 Hrs

Thymus derived lymphocytes (T cells) – their ontogeny and types, MHC complex, antigen presenting cells (APC), mechanisms of T cell activation, macrophages, dendritic cells, langerhans cells, mechanism of phagocytosis

## **UNIT II**

**12 Hrs**

### **Immune Regulation and Tolerance**

**08 Hrs**

Complement activation and types and their biological functions, cytokines and their role in immune response.

### **Hypersensitivity**

**02 Hrs**

Hypersensitivity Types I-IV, Hypersensitivity reactions and treatment

### **Autoimmune diseases**

**02 Hrs**

## **UNIT III**

**12 Hrs**

### **Vaccine technology**

**06 Hrs** Vaccine and their types, conventional vaccines, novel methods for vaccine production, antiidiotype vaccine, DNA vaccine, genetically engineered vaccine, iscoms, synthetic peptides, and immunodiagnostics.

### **Stem cell technology**

**06 Hrs**

Stem cell technology and applications to immunology

## **UNIT IV**

**12 Hrs**

### **Hybridoma Technology**

Hybridoma techniques – fusion methods for myeloma cells and B-Lymphocytes, selection and screening techniques. Production and purification of monoclonal antibodies and their applications in Pharmaceutical industry.

## **UNIT V**

**12 Hrs**

### **Immunological Disorder**

**06 Hrs**

Autoimmune disorders and types, pathogenic mechanisms, treatment, experimental models of auto immune diseases, primary and secondary immunodeficiency disorders.

### **Immunodiagnosis**

**06 Hrs**

Antigen antibody interaction – Precipitation reaction, Agglutination reactions, Principles and applications of ELISA, Radio Immuno Assay, Western blot analysis, immune-

electrophoresis, immunofluorescence, chemiluminescence assay.

### **References**

1. J. Kubey, Immunology – an Introduction, 2004.
2. S.C. Rastogi, Immunodiagnosics, New Age International, 1996.
3. Ashim Chakravarty, Immunology and Immunotechnology, Oxford University Press, 2006.
4. E. Benjamini, Molecular Immunology, 2002.

## **BIOINFORMATICS AND COMPUTATIONAL BIOTECHNOLOGY (MPB203T)**

### **Scope**

This paper has been designed to provide the advanced knowledge to the biotechnology students in invaluable areas of advanced bioinformatics which plays a crucial role in determining its future use and applications in medicine, drug discovery and in pharmaceutical industry.

### **Objectives**

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

- Usage of computers in developing a new drugs
- Biological concepts for bioinformatics
- Proteins and their diversity
- Various gene finding methods
- Searching the biological databases
- Target searching
- Various methods of drug designing

### **THEORY**

**60 Hrs**

### **UNIT I**

**12Hrs**

#### **Introduction to Bioinformatics**

**04 Hrs**

Definition and History of Bioinformatics, Internet and Bioinformatics, Introduction to Data Mining, Applications of Data Mining to Bioinformatics,

## **Biological Database**

**08 Hrs**

Protein and nucleic acid databases. Structural data bases. Collecting and storing the sequence and Applications of Bioinformatics.

## **UNIT II**

**12 Hrs**

### **Sequence analysis**

Sequence alignment, pair wise alignment techniques, multiple sequence analysis, multiple sequence alignment; Flexible sequence similarity searching with the FAST3 program package, the use of CLUSTAL W and CLUSTAL X for the multiple sequence alignment. Tools used for sequence analysis.

## **UNIT III**

**12 Hrs**

### **Protein informatics**

**05 Hrs**

Introduction; Force field methods; Energ, buried and exposed residues, side chains and neighbours; Fixed regions, hydrogen bonds, mapping properties onto surfaces; Fitting monomers, rms fit of conformers, assigning secondary structures; Sequence alignment-methods, evaluation, scoring; Protein completion, backbone construction and side chain addition; Small peptide methodology, software accessibility, building peptides; Protein displays; Substructure manipulations, annealing.

### **Protein structure prediction**

**05 Hrs**

Protein folding and model generation; Secondary structure prediction, analyzing secondary structures; Protein loop searching, loop generating methods, loop analysis; Homology modeling, concepts of homology modeling, potential applications, description, methodology, homologous sequence identification; Align structures, align model sequence; Construction of variable and conserved regions, threading techniques, Topology fingerprint approach for prediction, evaluation of alternate models; Structure prediction on a mystery sequence, structure aided sequence techniques of structure prediction, structural profiles, alignment algorithms, mutation tables, prediction, validation, sequence based methods of structure prediction, prediction using inverse folding, fold prediction; Significance analysis,scoring techniques, sequence- sequence scoring.

### **Docking**

**02 Hrs**

Docking problems, methods for protein- ligand docking, validation studies and applications; Screening small molecule databases, docking of combinatorial libraries, input data, analyzing docking results.

#### **UNIT IV**

**12Hrs**

##### **Diversity of Genomes**

**04Hrs**

Prokaryotic and Eukaryotic Gene Families. Genome Analysis: Introduction, Gene prediction methods, Gene mapping and applications- Genetic and Physical Mapping, Integrated map, Sequence assembly and gene expression.

##### **Completed Genomes**

**02 Hrs**

Bacterium, Nematode, Plant and Human

##### **Evolution of Genomes**

**04 Hrs**

Lateral or Horizontal Transfer among Genomes, Transcriptome and Proteome-General Account

##### **Phylogenetic analysis**

**02 Hrs**

Evolutionary Change in Nucleotide Sequences, Rates and Patterns of Nucleotide Substitution, Models for Nucleotide Substitution, Construction of Phylogenetic Tree, Genome Annotation technique.

#### **UNIT V**

**12Hrs**

##### **Target searching and Drug Designing**

Target and lead, timeline for drug development, target discovery, target modulators, *insilico* gene expression, microarray, and lead discovery, libraries of ligands, active site analysis, and prediction of drug quality.

##### **REFERENCE**

1. David W. Mount, Bioinformatics Sequence and Genome Analysis, Second Edition – 2005, CBS Publishers and Distributors
2. S. C. Rastogiet. al. Bioinformatics- Concepts Skill and Applications, First Edition –2003, CBS Publishers and Distributors
3. T. E. Creighton, Protein Structure and Molecular Properties, Second Edition-1993 W. H.Freeman and Company
4. Andreas D. Baxevanis, B. F. Francis Ouellette, Bioinformatics; A Practical Guide to the Analysis of Genes and Proteins, 2nd Edition. 2001 John Wiley & Sons, Inc.
5. Arthur M. Lesk, Introduction to Bioinformatics (2002), Oxford University Press.

6. Shui Qing Ye. Bioinformatics: A Practical Approach (2008), Chapman & Hall/CRC.
7. David Posada, Bioinformatics for DNA Sequence Analysis (2008), Humana press.
8. Lesk, A.M. 2002 Introduction to Bioinformatics. Oxford University Press.
9. Letovsky, S.I. 1999 Bioinformatics. Kluwer Academic Publishers.
10. Baldi, P. and Brunak, S. 1998 Bioinformatics. The MIT Press.

## **BIOLOGICAL EVALUATION OF DRUG THERAPY (MPB204T)**

### **Scope**

This paper has been designed to provide the knowledge to the biotechnology students to understand the importance of biological and evaluation of drug therapy of biological medicines.

### **Objective**

At the completion of this subject it is expected that students will be able to –

- Understand about the general concept of standardization of biological.
- Understand the importance of transgenic animals and knockout animals.
- Understand the biological medicines in development of various diseases.
- Learn the biological evaluation of drugs *in vitro* and *in vivo*

### **THEORY**

**60 Hrs**

#### **UNIT I**

**12 Hrs**

##### **Biological Standardization**

**04 Hrs**

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

##### **Preclinical drug evaluation**

**06 Hrs**

Preclinical drug evaluation of its biological activity, potency and toxicity-Toxicity test in animals including acute, sub-acute and chronic toxicity, ED50 and LD50 determination, special toxicity test like teratogenicity and mutagenicity.

##### **Guidelines for toxicity studies**

**02 Hrs**

Various guidelines for toxicity studies. Animal experiments assessing safety of packaging materials.

#### **UNIT II**

**12 Hrs**

##### **Pyrogens**

**04 Hrs**



Pyrogens: Sources, Chemistry and properties of bacterial pyrogens and endotoxins, Official pyrogen tests.

**Microbiological assay**

**04 Hrs**

Assay of antibiotics and vitamins.

**Biological evaluation of drugs**

**04 Hrs**

Screening and evaluation (including principles of screening, development of models for diseases: *In vivo* models / *In vitro* models / cell line study).

**UNIT III**

**12 Hrs**

**Biologic Medicines in Development for various diseases —**

**06 Hrs**

**By Therapeutic Category**

- Genetic Disorders
- Eye Conditions
- Digestive Disorders
- Diabetes/Related Conditions
- Cardiovascular Disease
- Cancer/Related Conditions
- Blood Disorders
- Autoimmune Disorders
- Infectious Diseases
- Neurologic Disorders
- Skin Diseases
- Transplantation

**Biologic Medicines in Development for various diseases —**

**06 Hrs**

**by Product Category**

- Antisense
- Vaccines
- Recombinant Hormones/Proteins
- Monoclonal Antibodies (mAb)
- Interferons
- Growth Factors
- Gene Therapy

- RNA Interference

#### **UNIT IV**

**12 Hrs**

##### **Regulatory aspects : drugs, biologics and medical devices**

**04 Hrs**

An introduction to the regulations and documents necessary for approval of a medical product.

##### **Regulatory consideration**

**04 Hrs**

Regulatory consideration for pre-clinical testing and clinical testing of drugs, biologics and medical devices.

New Drug Applications for Global Pharmaceutical Product Approvals

**04 Hrs**

#### **UNIT V**

**12 Hrs**

##### **Bioavailability**

**06 Hrs**

Objectives and consideration in bio-availability studies, Concept of equivalents, Measurements of bio-availability.

Determination of the rate of absorption, Bioequivalence and its importance, Regulatory aspects of bio-availability and bioequivalence studies for conventional dosage forms and controlled drug delivery systems.

##### **Pharmacokinetics**

**06 Hrs**

Pharmacokinetics:- Basic consideration, Pharmacokinetic models, Application of Pharmacokinetics in new drug development and designing of dosage forms and Novel drug delivery systems.

##### **References:**

1. Perkins F.T., Hennesen W. Standardization and Control of Biologicals Produced by Recombinant DNA Technology, International Association of Biological Standardization
2. J.H. Burn., Biological Standardization, Oxford University Press
3. Drug Discovery and Evaluation in Pharmacology assay: Vogel

4. Chow, Shein, Ching, Design and analysis of animal studies in pharmaceutical development,
5. Nodine and Siegler, Animal and Clinical pharmacologic Techniques in Drug Evaluation-
6. Screening methods in pharmacology (vol I & II)-R.A. Turner

## **SEMESTER – II**

### **PRACTICALS (MPB205P)**

1. Protein identification
2. Protein characterization
3. Protein biochemistry
4. Recombinant DNA Technology
5. Protein expression
6. Protein formulations
7. Database searching
8. Sequence analysis methods
9. Protein structure prediction
10. Gene annotation methods
11. Phylogenetic analysis
12. Protein, DNA binding studies
13. Preparation of DNA for PCR applications – Isolation, Purity and Quantification
14. Introduction to PCR – working of PCR, Programming.
15. Introduction to RT-PCR – working, programming.
16. Primer design using softwares.
17. Gene DNA amplification by random / specific primers.
18. Southern Hybridization
19. Western Blotting
20. Gene transformation

**PHARMACY PRACTICE**  
**(MPP)**

## CLINICAL PHARMACY PRACTICE (MPP101T)

### 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

**1**

**2 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:** Haematological 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

**1**

**2 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 (latest edition)
2. Practice Standards and Definitions - The Society of Hospital Pharmacists of Australia (latest edition)
3. Basic skills in interpreting laboratory data - Scott LT, American Society of Health System Pharmacists Inc (latest edition)
4. Relevant review articles from recent medical and pharmaceutical literature.

## PHARMACOTHERAPEUTICS-I (MPP102T)

### 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 individualising 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, 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- 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

## HOSPITAL & COMMUNITY PHARMACY (MPP103T)

### 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  
**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. **Education and training:** 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, relationship of community pharmacists 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

**12 Hrs**

4. **Prescription** – Legal requirements & interpretation, prescription related problems

**Responding to symptoms of minor ailments:** Head ache, pyrexia, menstrual pains, food and drug allergy,

**OTC medication:** Rational use of over the counter medications

Medication adherence and Patient referrals to the doctors

ADR monitoring in community pharmacies

**12 Hrs**

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

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

Research in community pharmacy

**12 Hrs**

## REFERENCES

1. Hospital Pharmacy - Hassan WE. Lec and Febiger publication.
2. Textbook of hospital pharmacy - Allwood MC and Blackwell.
3. Avery's Drug Treatment, 4th Edn, 1997, Adis International Limited.
4. Remington Pharmaceutical Sciences.
5. Relevant review articles from recent medical and pharmaceutical literature

## CLINICAL RESEARCH (MPP104T)

### 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

#### 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, Andrew 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; 2001.
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 2000. Indian Council of Medical Research, New Delhi.
7. Textbook of Clinical Trials edited by David Machin, Simon Day and Sylvan Green, March 2005, John Wiley and Sons.
8. Principles of Clinical Research edited by Giovanna di Ignazio, Di Giovanna and Haynes.
9. Clinical Data Management edited by R K Rondels, S A Varley, C F Webbs. Second Edition, Jan 2000, Wiley Publications.
10. Goodman & Gilman: JG Hardman, LE Limbard, 10th Edn. McGraw Hill Publications, 2001.
11. Relevant review articles from recent medical and pharmaceutical literature.

## PHARMACY PRACTICE PRACTICAL – I (MPP105P)

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 (MPP201T)

### 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 (Latest edition)
2. Andrews EB, Moore N. Mann's Pharmacovigilance (Latest Edition)
3. Dipiro JT, Talbert RL, Yee GC. Pharmacotherapy: A Pathophysiologic Approach (Latest Edition)
4. Straus SE, Richardson WS, Glasziou P, Haynes RB. Evidence-Based Medicine: How to practice and teach it (Latest Edition)
5. Cohen MR. Medication Errors (Latest Edition)
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 (MPP202T)

### 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 individualising 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

1

2 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

**1**

**2 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 (MPP203T)

### 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 Linear 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 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

**12 Hrs**

## REFERENCES

1. Leon Shargel, Susanna Wu-Pong, Andrew Yu. Applied Biopharmaceutics & Pharmacokinetics. 6<sup>th</sup> edition. New York: Mc Graw Hill;2012.
2. Peter L. Bonate. Pharmacokinetic - Pharmacodynamic Modeling and Simulation. 2nd edition. USA: Springer;2011.

3. Michael E. Burton, Leslie M. Shaw, Jerome J. Schentag, William E. Evans. Applied Pharmacokinetics & Pharmacodynamics: Principles of Therapeutic Drug Monitoring. 4th edition. US: Ippincott Williams & Wilkins; 2005.
4. Steven How-Yan Wong, Irving Sunshine. Handbook of Analytical Therapeutic Drug Monitoring and Toxicology. 1st edition. USA: CRC Press; 1996.
5. Soraya Dhillon, Andrzej Kostrzewski. Clinical pharmacokinetics. 1st edition. London: Pharmaceutical Press; 2006.
6. Joseph T. Dipiro, William J. Spruill, William E. Wade, Robert A. Blouin and Jane M. Pruemmer. Concepts in Clinical Pharmacokinetics. 4th edition. US: American Society of Health-System Pharmacists; 2005.
7. Malcolm Rowland, Thomas N. Tozer. Clinical Pharmacokinetics and pharmacodynamics: concepts and applications. 4th edition. US: Ippincott Williams & Wilkins; 2010.
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10. Milo Gibaldi. Biopharmaceutics and Clinical Pharmacokinetics. 4th edition. India: Pharma Book Syndicate; 2005.
11. Dhillon and Kostrzewski. Clinical pharmacokinetics. 1st edition. London: Pharmaceutical Press; 2006.
12. John E. Murphy. Clinical Pharmacokinetics. 5th edition. US: American Society of Health- System Pharmacist; 2004.
13. Relevant review articles from recent medical and pharmaceutical literature

## PHARMACOEPIDEMIOLOGY & PHARMACOECONOMICS (MPP204T)

### Scope

This course enable 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

#### 60 Hrs

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 Oddss 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, 2<sup>nd</sup> ed. Philadelphia: Woulters Kluwer Lippincott Williams & Wilkins, 2013.
2. Thomas E Getzen. Health economics. Fundamentals and Flow of Funds. 1997, 2003. John Wiley & Sons, second edition.
3. Andrew Briggs, Karl Claxton, Mark Sculpher. Decision Modelling for Health Economic Evaluation, Published by the Oxford University Press 2006.
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 (Third Edition) – 2005.
5. George E Mackinnon III. Understanding health outcomes and pharmacoeconomics, 2013.
6. Graker, Dennis. Pharmacoeconomics and outcomes, 2<sup>nd</sup> edition.
7. Walley, Pharmacoeconomics, 1<sup>st</sup> edition.
8. Pharmacoeconomic – ed. by Nowakowska – University of Medical Sciences, Poznan 2009.

9. Relevant review articles from recent medical and pharmaceutical literature

## PHARMACY PRACTICE PRACTICAL - II (MPP205T)

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)