ANDHRA UNIVERSITY

MASTER OF PHARMACY

(2020)

Regulations and Syllabus

Four semester pattern

With effect from 2020-21

M.PHARM (2020) REGULATIONS AND SYLLABUS

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1. Admission, instruction and attendance

The degree of Master of Pharmacy of the Andhra University will be conferred on a candidate who has satisfied the following conditions:

1.1. The candidate must have passed the B.Pharm. Degree examination of this University or B.Pharm. Degree examinations of any other University recognized by the Academic Council as equivalent thereto in First or Second class; and must have qualified in any entrance examination, if prescribed.

1.2. Every student, selected for admission to PG 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.

1.3. The candidate should have undergone a regular course of study as prescribed hereunder extending over a period of four semesters, ordinarily consecutive, and satisfied the academic requirements as prescribed hereinafter. The course of instruction and periods of study shall be as given in the scheme of instruction and in the syllabus.

1.4. The subjects of specializations for Master of Pharmacy Course shall be as follows:

1. Pharmaceutical Analysis
2. Pharmaceutical Chemistry
3. Pharmaceutics
4. Pharmaceutical Biotechnology
5. Pharmacology
6. Pharmacognosy
7. Pharmaceutical Regulatory Affairs
8. Pharmaceutical Quality Assurance
9. Industrial Pharmacy
10. Pharmacy Practice

1.5. Instruction and examination in each academic year is spread over two semesters with a minimum of 96 working days in each semester (192 in any given academic year). The odd semesters shall be conducted from the month of July to November and the even semesters shall be conducted from the month of December to April.

1.6. Each period of instruction is of 45 minutes duration. Eight periods of instruction are provided on each day and there are six working days in a week (Monday to Saturday).

1.7. Attendance Requirements: A regular course of study during an academic semester means a minimum of average attendance of 80% of all the courses of the semester computed by totaling the number of periods of lectures and practicals, as the case may be, held in every course. In special cases where sufficient causes were shown, the Vice-

Chancellor may on the recommendation of the Principal concerned condone the deficiency in the average attendance to an extent of 9% for reasons such as ill health, if the application for condonation is submitted at the time of actual illness and is supported by certificate of; authorized Medical officer approved by the Principal. However, in the case of students, who participate in activities like N.S.S., N.C.C., Inter-Collegiate tournaments conducted by Andhra University, Inter-University tournaments conducted by Inter-university Board and any such other activities involving the representation of the College/University with the prior approval of the principal, the candidate may be deemed to have attended the college during the period solely for the purpose of the examination.

1.7. A candidate who cannot satisfy the attendance requirements in clause 1.5 because of late admission under special circumstances reasonable and acceptable to the University on the basis of document, shall fulfill the following conditions; Average attendance: A candidate shall have attended at least a total of 90% of the periods-lectures/practicals as the case may be held from the date of admission and also shall attend at least 50% of the total working days during that academic semester (Late admission means, admissions made after 45 days from date of commencement of the academic semester for the course).

1.8. If any candidate fails to satisfy the regulation under 1.5 or 1.6 she/he shall not be allowed for the University Examinations at the end of the semester, and he/she shall not be allowed for promotion to the next higher class of study. He/she shall be required to repeat the regular course of study of that academic semester along with the next regular batch.

1.9. A regular record of attendance 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.

2. Examinations – Internal assessment and Semester-end

2.1. Assessment for the award of degree shall consists of (a) internal assessment for 30 marks in each of the theory and practical courses separately. (b) Semester-end examination as detailed in the scheme of examination for 70 marks in each of the theory and practical separately.

2.2. Regulations concerning internal assessment: Internal assessment consist of continuous mode (10 marks for theory and 15 marks for practical) and sessional examinations (20 marks for theory and 15 marks for practical)

2.2.1. Scheme for awarding continuous mode marks for theory and practical

Theory-Criteria	**Marks**
Attendance	5
Student-Teacher Interaction	5
Theory sessional examination	20
Total theory internal assessment	**30**
Practical-Criteria	
Attendance	5
Record + Viva-voce	10
Practical sessional examination	15
Total practical internal assessment	**30**

2.2.1.1. Guidelines for the allotment of marks for attendance

Percentage of Attendance	Theory/Practical
95 -100	5
90-94	4
85-89	3
80-84	2
Less than 80	0

2.2.1.2. Guidelines for allotment of marks for Student-Teacher interaction

The teacher shall create some interactive sessions for theory topics and every student shall interact on the given topic relating to its application in pharmacy. The teacher should assess the student capacity for understanding of the concept taught. It shall not be like seminars.

2.2.1.3. Guidelines for allotment of marks Record + Viva-voce

The teacher should conduct viva-voce at the end of each practical and evaluate the record on continuous mode and shall award these marks.

2.2.4. Guidelines for sessional examinations

Two sessional examinations shall be conducted for each theory/practical course. The average marks of the two shall be computed.

The teacher who teaches the subject shall ordinarily to be the internal examiner.

There shall be no provision for the improvement of the sessional marks.

There is no minimum mark prescribed for sessional examination for pass in the end semester examination.

If any student is absent for a single or both sessional examinations, the candidate will be awarded "ZERO" in the respective examination.

The theory average sessional mark shall be finally computed for 20 marks and average practical sessional mark shall be finally computed for 15 marks.

2.3. Regulations concerning M.Pharm I and II semester evaluation pattern:

2.3.1. There shall be one semester end examination in each theory course based on the question paper set by an external paper setter and there shall be single valuation. There shall be one semester end examination in each practical course as per the scheme of examination and valuation shall be done by examiner. The duration of the practical examination is of 6 hours as prescribed.

2.3.2. However the student may apply for revaluation of any subject in theory papers after declaring the results as per University examination guide lines.

2.3.3. Seminar

A seminar at the end of first and second semesters is separately conducted keeping in view of the enrichment of required communication, presentation and explanatory skills. A minimum of four seminars shall be given during the semester before the Program Committee and other students and documented separately for record in a Semester Seminar Register.

2.3.4. Comprehensive viva

At the end of II Semester comprehensive viva will be conducted for all the subjects

covering the theory subjects of I & II semesters by the external examiner and eligible internal examiners (at least two from the college) who taught these subjects. The candidate should obtain minimum of 50% marks for passing the examination.

2.3.4. Journal Club

In case of Journal Club, based on the research proposal, each student shall collect a minimum of 5 research papers (published in a reputed journal with impact factor of Thomson & Reuters of not less than 1.0) and should discuss in a Programme Committee (consisting of Head of the Department, Research Supervisor and other Senior faculty members) and documented separately for record in a Journal Club Register.

2.3.5. A student shall be eligible to carry forward all the courses of I, II semesters. However, he/she shall not be eligible to attend the courses of IV semester until the candidate clears III semester Midterm Project Review.

2.4. Regulations concerning M. Pharm. III and IV Semester evaluation pattern:

2.4.1. Evaluation of the seminar on the objectives and work plan of the proposed project is to be completed within one month from the commencement of the project date with three examiners from the same college consisting of research guide, another teacher in the concerned specialization and third teacher from different specialization. These teachers must fulfill the eligibility criteria laid down in Section 3.

2.4.2. Evaluation of the M.Pharm III Semester Mid-term project review and seminar on selected topic will be done by the research guide and external examiner. The seminar on the selected topic shall not be the one connected with the topic of the thesis work but should be related to concerned specialization.

2.4.3. A candidate shall submit four copies of his/her thesis either printed or typed, embodying the results of research work done by him under direction of an approved research director following the specific guidelines as stipulated under Section 5. All the candidates must submit their thesis within the prescribed date as per the academic calendar.

2.4.4. The thesis submitted by the candidate shall be examined by a Board of Examiners consisting of an External Examiner and the research director and shall have to be approved after holding a viva voce examination to test the knowledge of the candidate in the subject. The thesis will be evaluated independently by the external examiner and research director and in case the difference between examiners is more than 20%, the thesis shall be sent to a second external examiner whose award shall be the final. The viva-voce examination will be jointly conducted both by the external examiner and research director. A candidate can re-submit the thesis in a revised form after further work, if required to do so.

2.4.5. A candidate desires of improving his/her class shall take either or both of the first two semesters as a whole.

2.5. Guidelines for writing the thesis

The thesis should have the following pages in order:

1. Title page highlighting the title, name of the candidate, reg. no., guide name, college name and month and year of submission.
2. The inner title page containing the same details on white background.
3. Certificate from the Head of the institution
4. Certificate from the Research Director
5. Certificate from the ethical committees for approval of study, if any

6. Declaration by the student
7. Acknowledgements
8. Index highlighting chapter titles and sections titles
9. Index for tables, figures and plates, if any
10. Abbreviations and symbols
11. Materials used in the investigation with their procurement details like name of the company, batch number etc.
12. Equipment used in the study with the model number and other details
13. The thesis should contain the following chapters:
    a) Aim and objectives of the investigation
    b) Introduction and literature survey
    c) Description: Methods and Materials, etc.
    d) Experimental work
    e) Results and discussion
    f) Summary and conclusions
    g) References (The references may be included at the end of each chapter or at the end of the thesis according to the convenience)

2.5.1. The thesis should be typed in times new roman in 12 font size with 1.5 line spacing from the beginning of the thesis including titles to the chapters and sections. Bold font may be used wherever necessary. The students are expected to follow scientific grammar for writing *in vivo* etc. which should be in italics.

2.5.2. The citation of references should be done carefully by citing the complete reference i.e. name of all the authors. Usage of et al. is not allowed in the citation of reference. The students are expected to give the primary references rather than secondary or higher levels of references. The presentation of reference must be in Vancouver style.

2.5.3. No code names or numbers are allowed to be written in the thesis for the materials used in the project.

2.5.4. The examiners of thesis evaluation are expected to verify all this and appropriate corrections are to be made before conducting the viva-voce examination.

2.5.5 Project Work/IV Semester Assessment – Division of Marks:

Course 402 -Thesis Evaluation (Max. Marks – 150)

Criteria of Evaluation	**Marks**
Seminar/Presentation of work	20
Objective(s) of the work done	20
Methodology adopted	40
Results and Discussion	40
Conclusions and Outcomes	30
Total	**150**

The division of marks shall be clearly indicated for every candidate in the marks statement being sent to the University.

2.6. End Semester examinations

The End Semester examination for each theory, practical and other courses through

semesters I to IV shall be conducted by the University except for the subject with asterisk symbol (*) in the tables of the each specialization courses (Non University Examinations) for which examinations shall be conducted by the subject experts at college level and the marks/grades shall be submitted to the University. In case of theory examinations, the question paper of the corresponding subject shall be mailed (Official mail id) to the Controller of Examinations and Chairman, BOS with signature of the Head of the Institute in PDF format within twenty four hours after completion of the examination.

3. Eligibility criteria for appointment as examiner for M.Pharm examination

3.1. In order to eligible to be appointed as an internal examiner for the semester end examination in the respective specialization, a teacher shall have M. Pharm. or Ph.D. in the respective specialization with at least three years of M.Pharm teaching experience for the course concerned.

3.2. The eligibility of a teacher for guiding the M.Pharm III and IV semester project is as follows:

3.2.1. The teacher must have M.Pharm/Ph.D. in the respective specialization with an experience of minimum 3 years of Post Graduate teaching in the respective specialization.

3.2.2. The eligibility of such teachers qualified for guiding M.Pharm projects must be ratified by the Board of Studies before commencement of M.Pharm guidance.

3.2.3. The recognized M.Pharm guides are not eligible to guide more than **6** students in one academic year including joint guidance.

4. Regulations for pursuing M.Pharm III and IV Semester project

4.1. Students desirous of pursuing M.Pharm III and IV semester projects outside college are required to get the approval from the college before one month from the commencement of the project work. The research work can be carried out in a GMP compliant industry (as approved by WHO, USFDA etc.) and Central research laboratories like IICT, CDRI, NIH etc. or DSIR and Drug Control Administration recognized laboratories. A certificate to that effect must be incorporated in the M.Pharm thesis indicating the duration of stay. If the duration of stay is less than nine months the remaining period of stay in the college should be certified by the research supervisor and the Principal.

4.2. All the students should present a seminar on the objectives of their work, work plan, etc. within one month from the commencement of the project. The students should attend a mid-term review seminar in the presence of a committee consisting of one external examiner, research director. The suggestions made by the committee are to be taken into consideration for further work and should be presented in the thesis.

5. Declaration of results and classification:

5.1. A candidate shall be declared to have passed the examination held at the end of each semester if obtains i) not less than 40% in the each theory and 50% in each practical, seminar, comprehensive viva, thesis and thesis viva-voce at the end of each semester end examination and ii) an aggregate of 50% of all examinations of that semester including sessoinals. There are no minimum marks prescribed for sessional examination.

5.2. A candidate who has successfully completed the examination in a course by securing not less than 50% of marks shall not be permitted to retake the examination in that course.

5.3. A candidate who fails to secure 50% of marks on the aggregate but secures 50% or

more in some courses and between 40-49% in the other courses, he/she shall be required to retake the semester and supplementary examination in one or more of the courses in which he/she secures less than 50% of marks as per his/her choice to satisfy the requirement of 50% aggregate.

5.4. Declaration of class

The classes 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

6. Grading system:

6.1. Appropriate letter grades are awarded in each theory and practical subject to only such candidates who have passed in the university examinations. Internal assessment marks and university examination marks put together will be taken into account for the letter grading system in each subject separately.

6.2. A candidate registered for the university examination but fails to appear or fails to score the minimum required 40% marks in the university examination will get a grade 'F', indicating failure or grade of incompletion.

6.3. A subject successfully completed cannot be repeated. Final evaluation of each subject (theory and practical separately) will be carried out on a 10- point grading system corresponding to the marks obtained in that subject. Each subject letter grade is converted into a specific grade value associated with the letter grade as given below (Table).

6.4. Grading of performances

Based on the performance, 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 below.

10-Point grading system

Percentage of marks	Grade	Grade points
90.00 - 100	O	10.0
80.00 - 89.99	A	9.0
70.00 – 79.99	B	8.0
60.00 – 69.99	C	7.0
50.00 – 59.99	D	6.0
40.00 – 49.99	E	5.0
< 40.00	F (Fail)	0.0
The grade W represents failure due to insufficient attendance in the semester or year	W	0.0
Incomplete (subsequently to be changed into pass or E or O or F grade in the same semester)	I	0.0

6.5 The Semester grade point average (SGPA):

The performance of a student in a semester is indicated by a number called 'Semester Grade Point Average' (SGPA). The SGPA is the weighted average of the

grade points obtained in all the courses by the student during the semester. For example, if a student takes five courses (Theory/Practical) in a semester with credits C1, C2, C3 and C4 and the student's grade points in these courses are G1, G2, G3 and G4, respectively, and then students' SGPA is equal to:

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

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

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

The credits allotted to each course are given in the respective specialization **Tables 1-10**.

6.6. 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:

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

Where C_1,C_2,C_3, C4…is the total number of credits for semester I, II, III and IV and S1, S2, S3 and S4 are the SGPA of semester I, II, III and IV.

7. Guidelines for paper setting and model papers.

7.1. Guidelines for theory paper setting for semester end examinations

7.1.1. The semester end question paper in each theory course is to be set for a total of 70 marks by an external paper setter as per the general model given below.

7.1.2. Question paper consists of 5 questions each carrying 5 marks out of which 4 questions are to be answered by the candidate and 7 questions each carrying 10 marks out of which 5 questions are to be answered by the candidate for a total of 70 marks. Each main question may contain subsections like a, b, c etc.

7.1.3. The questions given should be spread over the entire syllabus in an even manner covering all the units as per the pattern of the question paper given below.

7.1.4. Model question paper for theory course:

Course No.

Specialization Name:

Title of the course:

Time: 3 Hours **Max. Marks: 70**

Part A (Question Numbers 1-5)

Answer any **four** questions out of five questions 4X5=20

One question has to be set from each unit.

Part B

Answer any **five** questions out of **seven** questions (Question Numbers 6-12) 5X10=50

Five questions are to be set from five units and the remaining two should cover at least four out of five units. The main questions may contain sub question like 6(a), 6(b) etc.

7.2. Guidelines for practical paper setting for semester end examination

7.2.1. The question paper in each semester end practical examination is to be set jointly by two examiners and evaluated, one external and one internal as per the general model provided below.

7.2.2. Model question paper for practical course:

Course No.

Title of the course

Time: 6 hrs.

1. Synopsis	10 marks
2. Major experiment	30 marks
3. Minor experiment	20 marks
4. Viva voce	10 marks
Total:	**70 marks**

7.3. Guidelines for theory/practical sessional examination paper setting:

Question paper pattern for theory Sessional examinations

Max. Marks: 30

Time: 2 Hours

Part A

Answer any **two** questions out of three questions 2X5=10

Part B

Answer any **two** questions out of three questions 2X10=20

Each of the sessional examination question paper should cover at least half the units of the syllabus.

Question paper pattern for practical sessional examinations

Max. Marks: 30

Time: 4 hours

1. Synopsis	5 Marks
2. Experiment	20 Marks
3. Viva	5 Marks
Total:	**30 Marks**

Table 1: Pharmaceutical Analysis (MPA)

Code	Course	Credits	Hours/ week	Internal Assessment			Semester End Exam	Total
				Continuous mode	Sessional Exam	Total		
I Semester								
MPA 101T	Modern Pharmaceutical Analytical Techniques	4	4	10	20	30	70	100
MPA 102T	Advanced Pharmaceutical Analysis	4	4	10	20	30	70	100
MPA 103T	Pharmaceutical Validation (Common paper for MPA and MQA)	4	4	10	20	30	70	100
MPA 104T	Food Analysis	4	4	10	20	30	70	100
MPA 105P	Pharmaceutical Analysis Practical - I	2	6	15	15	30	70	100
MPA 106P	Pharmaceutical Analysis Practical - II	2	6	15	15	30	70	100
MPA 107	Seminar*	2	4	50	---	---	---	50
	Total	**22**	**32**	**---**	**---**	**---**	**---**	**650**
II Semester								
MPA 201T	Advanced Instrumental Analysis	4	4	10	20	30	70	100
MPA 202T	Modern Bio-Analytical Techniques	4	4	10	20	30	70	100
MPA 203T	Quality Control and Quality Assurance (Common paper for MPA and MQA)	4	4	10	20	30	70	100
MPA 204T	Herbal and Cosmetic Analysis	4	4	10	20	30	70	100
MPA 205P	Pharmaceutical Analysis Practical - III	2	6	15	15	30	70	100
MPA 206	Comprehensive Viva	2	---	---	---	---	---	50
MPA 207	Seminar*	2	2	50	---	---	---	50
	Total	**22**	**26**	**---**	**---**	**---**	**---**	**600**

Table 1: Pharmaceutical Analysis (MPA) continued

III Semester								
MRM 301T	Research Methodology and Biostatistics*	2	4	10	20	30	70	100
MPA 302	Journal Club*	2	2	50	---	---	---	50
MPA 303	Discussion /Presentation (Dissertation Title & Project Proposal)*	2	---	50	---	---	---	50
MPA 304	Seminar on selected topic	4	4	---	---	---	100	100
MPA 305	Research Work Progress (Mid Term Report)	10	20	---			200	100
	Total:	**20**	**30**	**---**	**---**	**---**	---	**400**
IV Semester								
MPA 401	Journal Club*	2	2	50	**---**	**---**	---	50
MPA 402	Thesis evaluation	12	20	---	**---**	**---**	150	150
MPA 403	Thesis viva	4	---	---	**---**	**---**	50	50
	Total:	**20**	**22**	**---**	**---**	**---**	---	**250**

* Non-University Examination

Table 2: Pharmaceutical Chemistry (MPC)

Code	Course	Credits	Hours/ week	Internal Assessment			Semester End Exam	Total
				Continuous mode	Sessional Exam	Total		
I Semester								
MPC 101T	Modern Pharmaceutical Analytical Techniques	4	4	10	20	30	70	100
MPC 102T	Advanced Organic Chemistry - I	4	4	10	20	30	70	100
MPC 103T	Advanced Medicinal Chemistry	4	4	10	20	30	70	100
MPC 104T	Chemistry of Natural Products	4	4	10	20	30	70	100
MPC 105P	Pharmaceutical Chemistry Practical - I	2	6	15	15	30	70	100
MPC 106P	Pharmaceutical Chemistry Practical - II	2	6	15	15	30	70	100
MPC 107	Seminar*	2	4	50	---	---	---	50
	Total	**22**	**32**	**---**	**---**	**---**	**---**	**650**
II Semester								
MPC 201T	Advanced Spectral Analysis	4	4	10	20	30	70	100
MPC 202T	Advanced Organic Chemistry - II	4	4	10	20	30	70	100
MPC 203T	Computer Aided Drug Design (CADD)	4	4	10	20	30	70	100
MPC 204T	Pharmaceutical Process Chemistry	4	4	10	20	30	70	100
MPC 205P	Pharmaceutical Chemistry Practical - III	2	6	15	15	30	70	100
MPC 206	Comprehensive Viva	2	---	---	---	---	---	50
MPC 207	Seminar*	2	2	50	---	---	---	50
	Total	**22**	**26**	**---**	**---**	**---**	**---**	**600**

Table 2: Pharmaceutical Chemistry (MPC) continued

III Semester								
MRM 301T	Research Methodology and Biostatistics*	2	4	10	20	30	70	100
MPC 302	Journal Club*	2	2	50	---	---	---	50
MPC 303	Discussion /Presentation (Dissertation Title & Project Proposal)*	2	---	50	---	---	---	50
MPC 304	Seminar on selected topic	4	4	---	---	---	100	100
MPC 305	Research Work Progress (Mid Term Report)	10	20	---			200	100
	Total:	**20**	**30**	**---**	**---**	**---**	---	**400**
IV Semester								
MPC 401	Journal Club*	2	2	50	**---**	**---**	---	50
MPC 402	Thesis evaluation	12	20	---	**---**	**---**	150	150
MPC 403	Thesis viva	4	---	---	**---**	**---**	50	50
	Total:	**20**	**22**	**---**	**---**	**---**	---	**250**

* Non-University Examination

Table 3: Pharmaceutics (MPH)

Code	Course	Credits	Hours/ week	Internal Assessment			Semester End Exam	Total
				Continuous mode	Sessional Exam	Total		
I Semester								
MPH 101T	Modern Pharmaceutical Analytical Techniques	4	4	10	20	30	70	100
MPH 102T	Advanced Biopharmaceutics & Pharmacokinetics (Common paper for MPH and MIP)	4	4	10	20	30	70	100
MPH 103T	Modern Pharmaceutics	4	4	10	20	30	70	100
MPH 104T	Regulatory Affairs	4	4	10	20	30	70	100
MPH 105P	Pharmaceutics Practical – I	2	6	15	15	30	70	100
MPH 106P	Pharmaceutics Practical – II	2	6	15	15	30	70	100
MPH 107	Seminar*	2	4	50	---	---	---	50
	Total	**22**	**32**	**---**	**---**	**---**	**---**	**650**
II Semester								
MPH 201T	Molecular Pharmaceutics (Nano Technology and Targeted DDS)	4	4	10	20	30	70	100
MPH 202T	Drug Delivery Systems (DDS)	4	4	10	20	30	70	100
MPH 203T	Computer Aided Drug Development (CADD)	4	4	10	20	30	70	100
MPH 204T	Pharmaceutical and Cosmetic Product Development	4	4	10	20	30	70	100
MPH 205P	Pharmaceutics Practical - III	2	6	15	15	30	70	100
MPH 206	Comprehensive Viva	2	---	---	---	---	---	50
MPH 207	Seminar*	2	2	50	---	---	---	50
	Total	**22**	**26**	**---**	**---**	**---**	**---**	**600**

Table 3: Pharmaceutics (MPH) continued

III Semester								
MRM 301T	Research Methodology and Biostatistics*	2	4	10	20	30	70	100
MPH 302	Journal Club*	2	2	50	---	---	---	50
MPH 303	Discussion /Presentation (Dissertation Title & Project Proposal)*	2	---	50	---	---	---	50
MPH 304	Seminar on selected topic	4	4	---	---	---	100	100
MPH 305	Research Work Progress (Mid Term Report)	10	20	---			200	100
	Total:	**20**	**30**	**---**	**---**	**---**	---	**400**
IV Semester								
MPH 401	Journal Club*	2	2	50	**---**	**---**	---	50
MPH 402	Thesis evaluation	12	20	---	**---**	**---**	150	150
MPH 403	Thesis viva	4	---	---	**---**	**---**	50	50
	Total:	**20**	**22**	**---**	**---**	**---**	---	**250**

* Non-University Examination

Table 4: Pharmaceutical Biotechnology (MPB)

Code	Course	Credits	Hours/ week	Internal Assessment			Semester End Exam	Total
				Continuous mode	Sessional Exam	Total		
I Semester								
MPB 101T	Modern Pharmaceutical Analytical Techniques	4	4	10	20	30	70	100
MPB 102T	Microbial Genetics and Cellular Biology	4	4	10	20	30	70	100
MPB 103T	Bioprocess Engineering and Technology	4	4	10	20	30	70	100
MPB 104T	Advanced Pharmaceutical Biotechnology	4	4	10	20	30	70	100
MPB 105P	Pharmaceutical Biotechnology Practical - I	2	6	15	15	30	70	100
MPB 106P	Pharmaceutical Biotechnology Practical - II	2	6	15	15	30	70	100
MPB 107	Seminar*	2	4	50	---	---	---	50
	Total	**22**	**32**	---	---	---	---	**650**
II Semester								
MPB 201T	Proteins and Protein Formulation	4	4	10	20	30	70	100
MPB 202T	Immunotechnology	4	4	10	20	30	70	100
MPB 203T	Bioinformatics and Computational Biotechnology	4	4	10	20	30	70	100
MPB 204T	Biological Evaluation of Drug Therapy	4	4	10	20	30	70	100
MPB 205P	Pharmaceutical Biotechnology Practical III	2	6	15	15	30	70	100
MPB 206	Comprehensive Viva	2	---	---	---	---	---	50
MPB 207	Seminar*	2	2	50	---	---	---	50
	Total	**22**	**26**	---	---	---	---	**600**

Table 4: Pharmaceutical Biotechnology (MPB) continued

III Semester								
MRM 301T	Research Methodology and Biostatistics*	2	4	10	20	30	70	100
MPB 302	Journal Club*	2	2	50	---	---	---	50
MPB 303	Discussion /Presentation (Dissertation Title & Project Proposal)*	2	---	50	---	---	---	50
MPB 304	Seminar on selected topic	4	4	---	---	---	100	100
MPB 305	Research Work Progress (Mid Term Report)	10	20	---			200	100
	Total:	**20**	**30**	**---**	**---**	**---**	---	**400**
IV Semester								
MPB 401	Journal Club*	2	2	50	**---**	**---**	---	50
MPB 402	Thesis evaluation	12	20	---	**---**	**---**	150	150
MPB 403	Thesis viva	4	---	---	**---**	**---**	50	50
	Total:	**20**	**22**	**---**	**---**	**---**	---	**250**

* Non-University Examination

Table 5: Pharmacology (MPL)

Code	Course	Credits	Hours/ week	Internal Assessment			Semester End Exam	Total
				Continuous mode	Sessional Exam	Total		
I Semester								
MPL 101T	Modern Pharmaceutical Analytical Techniques	4	4	10	20	30	70	100
MPL 102T	Advanced Pharmacology – I	4	4	10	20	30	70	100
MPL 103T	Pharmacokinetics and Drug Metabolism	4	4	10	20	30	70	100
MPL 104T	Cellular and Molecular Pharmacology	4	4	10	20	30	70	100
MPL 105P	Pharmacology Practical - I	2	6	15	15	30	70	100
MPL 106P	Pharmacology Practical – II	2	6	15	15	30	70	100
MPL 107	Seminar*	2	4	50	---	---	---	50
	Total	**22**	**32**	**---**	**---**	**---**	**---**	**650**
II Semester								
MPL 201T	Advanced Pharmacology - II	4	4	10	20	30	70	100
MPL 202T	Pharmacological and Toxicological Screening Methods	4	4	10	20	30	70	100
MPL 203T	Principles of Drug Discovery	4	4	10	20	30	70	100
MPL 204T	Clinical Research and Pharmacovigilance	4	4	10	20	30	70	100
MPL 205P	Pharmacology Practical – III	2	6	15	15	30	70	100
MPL 206	Comprehensive Viva	2	---	---	---	---	---	50
MPL 207	Seminar*	2	2	50	---	---	---	50
	Total	**22**	**26**	**---**	**---**	**---**	**---**	**600**

Table 5: Pharmacology (MPL) continued

III Semester								
MRM 301T	Research Methodology and Biostatistics*	2	4	10	20	30	70	100
MPL 302	Journal Club*	2	2	50	---	---	---	50
MPL 303	Discussion /Presentation (Dissertation Title & Project Proposal)*	2	---	50	---	---	---	50
MPL 304	Seminar on selected topic	4	4	---	---	---	100	100
MPL 305	Research Work Progress (Mid Term Report)	10	20	---			200	100
	Total:	**20**	**30**	**---**	**---**	**---**	---	**400**
IV Semester								
MPL 401	Journal Club*	2	2	50	**---**	**---**	---	50
MPL 402	Thesis evaluation	12	20	---	**---**	**---**	150	150
MPL 403	Thesis viva	4	---	---	**---**	**---**	50	50
	Total:	**20**	**22**	**---**	**---**	**---**	---	**250**

* Non-University Examination

Table 6: Pharmacognosy (MPG)

Code	Course	Credits	Hours/ week	Internal Assessment			Semester End Exam	Total
				Continuous mode	Sessional Exam	Total		
I Semester								
MPG 101T	Modern Pharmaceutical Analytical Techniques	4	4	10	20	30	70	100
MPG 102T	Advanced Pharmacognosy - I	4	4	10	20	30	70	100
MPG 103T	Phytochemistry	4	4	10	20	30	70	100
MPG 104T	Industrial Pharmacognostical Technology	4	4	10	20	30	70	100
MPG 105P	Pharmacognosy Practical – I	2	6	15	15	30	70	100
MPG 106P	Pharmacognosy Practical - II	2	6	15	15	30	70	100
MPG 107	Seminar*	2	4	50	---	---	---	50
	Total	**22**	**32**	**---**	**---**	**---**	**---**	**650**
II Semester								
MPG 201T	Medicinal Biotechnology	4	4	10	20	30	70	100
MPG 202T	Advanced Pharmacognosy - II	4	4	10	20	30	70	100
MPG 203T	Indian Systems of Medicine	4	4	10	20	30	70	100
MPG 204T	Herbal Cosmetics	4	4	10	20	30	70	100
MPG 205P	Pharmacognosy Practical - III	2	6	15	15	30	70	100
MPG 206	Comprehensive Viva	2	---	---	---	---	---	50
MPG 207	Seminar*	2	2	50	---	---	---	50
	Total	**22**	**26**	**---**	**---**	**---**	**---**	**600**

Table 6: Pharmacognosy (MPG) continued

III Semester								
MRM 301T	Research Methodology and Biostatistics*	2	4	10	20	30	70	100
MPG 302	Journal Club*	2	2	50	---	---	---	50
MPG 303	Discussion /Presentation (Dissertation Title & Project Proposal)*	2	---	50	---	---	---	50
MPG 304	Seminar on selected topic	4	4	---	---	---	100	100
MPG 305	Research Work Progress (Mid Term Report)	10	20	---			200	100
	Total:	**20**	**30**	**---**	**---**	**---**	---	**400**
IV Semester								
MPG 401	Journal Club*	2	2	50	**---**	**---**	---	50
MPG 402	Thesis evaluation	12	20	---	**---**	**---**	150	150
MPG 403	Thesis viva	4	---	---	**---**	**---**	50	50
	Total:	**20**	**22**	**---**	**---**	**---**	---	**250**

* Non-University Examination

Table 7: Pharmaceutical Regulatory Affairs (MRA)

Code	Course	Credits	Hours/ week	Internal Assessment			Semester End Exam	Total
				Continuous mode	Sessional Exam	Total		
I Semester								
MRA 101T	Good Regulatory Practices	4	4	10	20	30	70	100
MRA 102T	Documentation and Regulatory Writing	4	4	10	20	30	70	100
MRA 103T	Clinical Research Regulations	4	4	10	20	30	70	100
MRA 104T	Regulations and Legislation for Drugs & Cosmetics, Medical Devices, Biologicals, Herbals & Food and Neutraceuticals in India & Intellectual Property Rights	4	4	10	20	30	70	100
MRA 105P	Regulatory Affairs Practical - I	2	6	15	15	30	70	100
MRA 106P	Regulatory Affairs Practical - II	2	6	15	15	30	70	100
MRA 107	Seminar*	2	4	50	---	---	---	50
	Total	**22**	**32**	**---**	**---**	**---**	**---**	**650**

Table 7: Pharmaceutical Regulatory Affairs (MRA) continued

II Semester								
MRA 201T	Regulatory Aspects of Drugs & Cosmetics	4	4	10	20	30	70	100
MRA 202T	Regulatory Aspects of Herbal & Biologicals	4	4	10	20	30	70	100
MRA 203T	Regulatory Aspects of Medical Devices	4	4	10	20	30	70	100
MRA 204T	Regulatory Aspects of Food & Neutraceuticals	4	4	10	20	30	70	100
MRA 205P	Regulatory Affairs Practical - III	2	6	15	15	30	70	100
MRA 206	Comprehensive Viva	2	---	---	---	---	---	50
MRA 207	Seminar*	2	2	50	---	---	---	50
	Total	**22**	**26**	---	---	---	---	**600**
III Semester								
MRM 301T	Research Methodology and Biostatistics*	2	4	10	20	30	70	100
MRA 302	Journal Club*	2	2	50	---	---	---	50
MRA 303	Discussion /Presentation (Dissertation Title & Project Proposal)*	2	---	50	---	---	---	50
MRA 304	Seminar on selected topic	4	4	---	---	---	100	100
MRA 305	Research Work Progress (Mid Term Report)	10	20	---			200	100
	Total:	**20**	**30**	**---**	**---**	**---**	---	**400**
IV Semester								
MRA 401	Journal Club*	2	2	50	**---**	**---**	---	50
MRA 402	Thesis evaluation	12	20	---	**---**	**---**	150	150
MRA 403	Thesis viva	4	---	---	**---**	**---**	50	50
	Total:	**20**	**22**	**---**	**---**	**---**	---	**250**

* Non-University Examination

Table 8: Pharmaceutical Quality Assurance (MQA)

Code	Course	Credits	Hours/ week	Internal Assessment			Semester End Exam	Total
				Continuous mode	Sessional Exam	Total		
I Semester								
MQA 101T	Modern Pharmaceutical Analytical Techniques	4	4	10	20	30	70	100
MQA 102T	Quality Management System	4	4	10	20	30	70	100
MQA 103T	Pharmaceutical Validation (Common paper for MPA and MQA)	4	4	10	20	30	70	100
MQA 104T	Product Development and Technology Transfer	4	4	10	20	30	70	100
MQA 105P	Pharmaceutical Quality Assurance Practical - I	2	6	15	15	30	70	100
MQA 106P	Pharmaceutical Quality Assurance Practical - II	2	6	15	15	30	70	100
MQA 107	Seminar*	2	4	50	---	---	---	50
	Total	**22**	**32**	**---**	**---**	**---**	**---**	**650**
II Semester								
MQA 201T	Hazards and Safety Management	4	4	10	20	30	70	100
MQA 202T	Audits and Regulatory Compliance	4	4	10	20	30	70	100
MQA 203T	Quality Control and Quality Assurance (Common paper for MPA and MQA)	4	4	10	20	30	70	100
MQA 204T	Pharmaceutical Manufacturing Technology	4	4	10	20	30	70	100
MQA 205P	Pharmaceutical Quality Assurance Practical - III	2	6	15	15	30	70	100
MQA 206	Comprehensive Viva	2	---	---	---	---	---	50
MQA 207	Seminar*	2	2	50	---	---	---	50
	Total	**22**	**26**	**---**	**---**	**---**	**---**	**600**

Table 8: Pharmaceutical Quality Assurance (MQA) continued

III Semester								
MRM 301T	Research Methodology and Biostatistics*	2	4	10	20	30	70	100
MQA 302	Journal Club*	2	2	50	---	---	---	50
MQA 303	Discussion /Presentation (Dissertation Title & Project Proposal)*	2	---	50	---	---	---	50
MQA 304	Seminar on selected topic	4	4	---	---	---	100	100
MQA 305	Research Work Progress (Mid Term Report)	10	20	---			200	100
	Total:	**20**	**30**	**---**	**---**	**---**	---	**400**
IV Semester								
MQA 401	Journal Club*	2	2	50	**---**	**---**	---	50
MQA 402	Thesis evaluation	12	20	---	**---**	**---**	150	150
MQA 403	Thesis viva	4	---	---	**---**	**---**	50	50
	Total:	**20**	**22**	**---**	**---**	**---**	---	**250**

* Non-University Examination

Table 9: Industrial Pharmacy (MIP)

Code	Course	Credits	Hours/ week	Internal Assessment			Semester End Exam	Total
				Continuous mode	Sessional Exam	Total		
I Semester								
MIP 101T	Modern Pharmaceutical Analytical Techniques	4	4	10	20	30	70	100
MIP 102T	Advanced Biopharmaceutics & Pharmacokinetics (Common paper for MPH and MIP)	4	4	10	20	30	70	100
MIP 103T	Novel Drug Delivery Systems	4	4	10	20	30	70	100
MIP 104T	Intellectual Property Rights	4	4	10	20	30	70	100
MIP 105P	Industrial Pharmacy Practical - I	2	6	15	15	30	70	100
MIP 106P	Industrial Pharmacy Practical - II	2	6	15	15	30	70	100
MIP 107	Seminar*	2	4	50	---	---	---	50
	Total	**22**	**32**	**---**	**---**	**---**	**---**	**650**
II Semester								
MIP 201T	Scale Up and Technology Transfer	4	4	10	20	30	70	100
MIP 202T	Pharmaceutical Production Technology	4	4	10	20	30	70	100
MIP 203T	Entrepreneurship Management	4	4	10	20	30	70	100
MIP 204T	Pharmaceutical Formulation Development	4	4	10	20	30	70	100
MIP 205P	Industrial Pharmacy Practical - III	2	6	15	15	30	70	100
MIP 206	Comprehensive Viva	2	---	---	---	---	---	50
MIP 207	Seminar*	2	2	50	---	---	---	50
	Total	**22**	**26**	**---**	**---**	**---**	**---**	**600**

Table 9: Industrial Pharmacy (MIP) continued

III Semester								
MRM 301T	Research Methodology and Biostatistics*	2	4	10	20	30	70	100
MIP 302	Journal Club*	2	2	50	---	---	---	50
MIP 303	Discussion /Presentation (Dissertation Title & Project Proposal)*	2	---	50	---	---	---	50
MIP 304	Seminar on selected topic	4	4	---	---	---	100	100
MIP 305	Research Work Progress (Mid Term Report)	10	20	---			200	100
	Total:	**20**	**30**	**---**	**---**	**---**	---	**400**
IV Semester								
MIP 401	Journal Club*	2	2	50	**---**	**---**	---	50
MIP 402	Thesis evaluation	12	20	---	**---**	**---**	150	150
MIP 403	Thesis viva	4	---	---	**---**	**---**	50	50
	Total:	**20**	**22**	**---**	**---**	**---**	---	**250**

* Non-University Examination

Table 10: Pharmacy Practice (MPP)

Code	Course	Credits	Hours/ week	Internal Assessment			Semester End Exam	Total
				Continuous mode	Sessional Exam	Total		
I Semester								
MPP 101T	Clinical Pharmacy Practice	4	4	10	20	30	70	100
MPP 102T	Pharmacotherapeutics I	4	4	10	20	30	70	100
MPP 103T	Hospital & Community Pharmacy	4	4	10	20	30	70	100
MPP 104T	Clinical Research	4	4	10	20	30	70	100
MPP 105P	Pharmacy Practice Practical - I	2	6	15	15	30	70	100
MPP 106P	Pharmacy Practice Practical - II	2	6	15	15	30	70	100
MPP 107	Seminar*	2	4	50	---	---	---	50
	Total	**22**	**32**	**---**	**---**	**---**	**---**	**650**
II Semester								
MPP 201T	Principles of Quality Use of Medicines	4	4	10	20	30	70	100
MPP 202T	Pharmacotherapeutics - II	4	4	10	20	30	70	100
MPP 203T	Clinical Pharmacokinetics and Therapeutic Drug Monitoring	4	4	10	20	30	70	100
MPP 204T	Pharmacoepidemiology & Pharmacoeconomics	4	4	10	20	30	70	100
MPP 205P	Pharmacy Practice Practical - III	2	6	15	15	30	70	100
MPP 206	Comprehensive Viva	2	---	---	---	---	---	50
MPP 207	Seminar*	2	2	50	---	---	---	50
	Total	**22**	**26**	**---**	**---**	**---**	**---**	**600**

Table 10: Pharmacy Practice (MPP) continued

III Semester								
MRM 301T	Research Methodology and Biostatistics*	2	4	10	20	30	70	100
MPP 302	Journal Club*	2	2	50	---	---	---	50
MPP 303	Discussion /Presentation (Dissertation Title & Project Proposal)*	2	---	50	---	---	---	50
MPP 304	Seminar on selected topic	4	4	---	---	---	100	100
MPP 305	Research Work Progress (Mid Term Report)	10	20	---			200	100
	Total:	**20**	**30**	**---**	**---**	**---**	---	**400**
IV Semester								
MPP 401	Journal Club*	2	2	50	**---**	**---**	---	50
MPP 402	Thesis evaluation	12	20	---	**---**	**---**	150	150
MPP 403	Thesis viva	4	---	---	**---**	**---**	50	50
	Total:	**20**	**22**	**---**	**---**	**---**	---	**250**

* Non-University Examination

PHARMACEUTICAL ANALYSIS (MPA)

First Semester

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES (MPA 101T)

(Note: Common paper for MPA, MPC, MPH, MPB, MPL, MPG, MQA, & MIP, specializations)

Unit 1:

a. UV-visible spectroscopy: Introduction, theory, laws and instrumentation associated with UV-visible spectroscopy, choice of solvents and solvent effect and applications of UV-visible spectroscopy.

b. IR spectroscopy: Theory, modes of molecular vibrations, sample handling, instrumentation of dispersive and Fourier-Transform IR Spectrometer, factors affecting vibrational frequencies and applications of IR spectroscopy, data interpretation.

c. Spectroflourimetry: Theory of fluorescence, factors affecting fluorescence (characteristics of drugs that can be analyzed by flourimetry), quenchers, instrumentation and Applications of fluorescence spectrophotometer.

d. Flame emission spectroscopy and Atomic absorption spectroscopy: Principle, instrumentation, interferences and applications. **12 Hours**

Unit 2:

NMR spectroscopy: Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and 13C NMR. Applications of NMR spectroscopy. **10 Hours**

Unit 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. 1**0 Hours**

Unit 4:

Chromatography: Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution, isolation of drug from excipients, data interpretation and applications of the following:

a) Thin Layer chromatography **b)** High Performance Thin Layer Chromatography **c)** Ion exchange chromatography **d)** Column chromatography **e)** Gas chromatography **f)** High Performance Liquid chromatography **g)** Ultra High Performance Liquid chromatography **h)** Affinity chromatography **i)** Gel Chromatography. **14 Hours**

Unit 5:

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

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

c. Thermal Techniques: Principle, instrumentation, advantage and disadvantages, Pharmaceutical applications of DSC, DTA & TGA.

d. Microscopic techniques: Principles and applications of Scanning Electron Microscopy and Transmission Electron Microscopy analysis. **14 Hours**

REFERENCES

1. Spectrometric Identification of Organic compounds - Robert M Silverstein. 6th ed. John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman. 5th ed. Eastern Press, Bangalore, 1998.
3. Instrumental Methods of Analysis – Willards. 7th ed. CBS Publishers, New Delhi.
4. Practical Pharmaceutical Chemistry – Beckett and Stenlake. Vol 2. 4th ed. CBS Publishers, New Delhi
5. Organic Spectroscopy - William Kemp. 3rd ed. ELBS, 1991.
6. Quantitative Analysis of Drugs in Pharmaceutical Formulation – P.D. Sethi. 3rd ed. CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis - Modern Methods – Part B – J.W. Munson. Vol 11. Marcel-Dekker Series.
8. Spectroscopy of Organic Compounds - P.S. Kalsi. 2nd ed. Wiley Estern Ltd., Delhi.
9. Textbook of Pharmaceutical Analysis – K.A. Connors. 3rd ed. John Wiley & Sons.

ADVANCED PHARMACEUTICAL ANALYSIS (MPA 102T)

Unit 1:

Impurities and stability studies: Definition, classification of impurities in drug substance or active pharmaceutical ingredients and quantification of impurities as per ICH guidelines – Q3A & Q3D. 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.

12 Hours

Unit 2:

Impurity profiling and degradent characterization (ICH Q2A & Q2B): Stability studies accelerated stability testing & shelf life calculation, WHO and ICH stability testing guidelines, stability zones.

Elemental impurities: Basics of impurity profiling and degradent characterization with special emphasis. Method development and concepts of validation. Element classification, control of elemental impurities, Potential Sources of elemental impurities, Identification of potential elemental impurities, analytical procedures, instrumentation & C, H, N and S analysis. (Ref: USP 38 NF 33, Vol. I, 2015, Chapter 232 & 233). **14 Hours**

Unit 3:

Stability testing protocols (ICH Q1A): Selection of batches, container orientation, test parameters, sampling frequency, specification, storage conditions, recording of results, concept of stability, commitment etc. Important mechanistic and stability related information provided by results of study of factors like temperature, pH, buffering species ionic strength and dielectric constant etc. on the reaction rates with practical considerations. Photostability testing guidelines, ICH stability guidelines for biological products (ICHQ5C).

Stability testing of phytopharmaceuticals: Regulatory requirements, protocols, HPTLC/HPLC finger printing, interactions and complexity. **12 Hours**

Unit 4:

Biological tests: Preservative challenging test, disinfectant efficacy test and its validation. Neutralizer efficacy test, membrane filter integrity test, bacterial endotoxin test & microbial limit test. Container–closure integrity test for sterile products. **12 Hours**

Unit 5:

Immunoassays (IA): Basic principles, Production of antibodies, Separation of bound and unbound drug, Radioimmunoassay, Optical IA, Enzyme IA (ELISA), Fluoro IA, Luminescence IA, Quantification and applications of IA. **10 Hours**

REFERENCES

1. Vogel's Textbook of Quantitative Chemical Analysis - Jeffery J Bassett, J. Mendham, R. C. Denney. 5th ed. ELBS, 1991.
2. Practical Pharmaceutical Chemistry - Beckett and Stenlake. Vol 2, 4th ed. CBS Publishers, New Delhi.
3. Textbook of Pharmaceutical Analysis – K.A. Connors. 3rd ed. John Wiley & Sons, 1982
4. Pharmaceutical Analysis - Higuchi, 2nd ed. Wiley – Inter Science Publication, 1961.
5. Quantitative Analysis of Drugs in Pharmaceutical Formulation – P.D. Sethi, 3rd ed. CBS Publishers, New Delhi.
6. Pharmaceutical Analysis- Modern Methods – J.W. Munson – Part B. Volume 11, Marcel Dekker.
7. The Quantitative Analysis of Drugs – D.C. Carratt. 3rd ed. CBS Publishers, New Delhi, 1964.
8. Indian Pharmacopoeia 2007, 2010, 2014 & 2018.
9. Methods of Sampling and Microbiological Examination of Water, First Revision, BIS
10. Analytical Profiles of Drug Substances – Klaus Florey. Vol 1 – 20, Elsevier, 2005
11. Analytical Profiles of Drug Substances and Excipients – Harry G Brittain. Volume 30, Elsevier, 2005.
12. The Analysis of Drugs in Biological Fluids - Joseph Chamberlain. 2nd ed. CRC Press,
13. ICH Guidelines for Impurity Profiles and Stability Studies

PHARMACEUTICAL VALIDATION (MPA 103T)

(Note: Common paper for MPA and MQA specializations)

Unit 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 Hours**

Unit 2:

Qualification of analytical instruments/Equipment: Training & qualification of analyst. qualification of UV-visible spectrophotometer, FTIR, DSC, GC, HPLC, HPTLC, and dissolution test apparatus. **10 Hours**

Unit 3:

Validation of utility systems: Pharmaceutical water system, HVAC system, compressed air and nitrogen. Facility qualification, AHU validation, clean room validation.

Cleaning validation: Cleaning method development, sampling techniques, 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 significance-21 CFR part 11 and GAMP 5, LIMS, audit trail and data integrity. **12 Hours**

Unit 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 (Q2A) and USP. Preparation & qualification of working standards and reference standards. **12 Hours**

Unit 5:

General principles of intellectual property: Concepts of intellectual property (IP), intellectual property protection (IPP), intellectual property rights (IPR); economic importance, mechanism for protection of intellectual property – patents, copyright, trademark; factors affecting choice of IP protection; penalties for violation; role of IP in pharmaceutical industry; global ramification and financial implications. Filing a patent application; patent application forms and guidelines. Types of patent applications-provisional and non-provisional, PCT and convention patent applications; International patenting requirement procedures and costs; rights and responsibilities of a patentee; practical aspects regarding maintaining of a patent file; patent infringement meaning and scope. Significance of transfer of technology (TOT), IP and ethics-positive and negative aspects of IPP; societal responsibility, avoiding unethical practices. **14 Hours**

REFERENCES

1. Pharmaceutical Process Validation - B. T. Loftus & R. A. Nash. Drugs and Pharm Sci. Series, Vol. 129, 3rd ed. Marcel Dekker.
2. The Theory & Practice of Industrial Pharmacy - Leon Lachman, Herbert A Lieberman & Joseph L Kanig. 3rd ed. Varghese Publishing House, Bombay.
3. Validation of Aseptic Pharmaceutical Processes - Carleton & Agalloco. 2nd ed. Marcel Dekker.
4. Pharmaceutical Process Scale-Up - Michael Levin. Drugs and Pharm. Sci. Series. Vol. 157. 2nd ed. Marcel Dekker.
5. Validation Standard Operating Procedures: A Step by Step Guide for Achieving Compliance in the Pharmaceutical, Medical Device, and Biotech Industries - Syed Imtiaz Haider.
6. Validation of Pharmaceutical Processes: Sterile Products - Frederick J Carlton and James Agalloco. 2nd ed. Marcel Dekker.
7. Pharmaceutical Equipment Validation: The Ultimate Qualification Handbook - Phillip A Cloud. Interpharm Press.
8. Analytical Method Validation and Instrument Performance Verification - Churg Chan, Heiman Lam, Y.C. Lee & Yue. Zhang. Wiley Inter Science.

9. Validation Master Plan - Terveeks or Deeks. Davis Harwood International Publishing.

FOOD ANALYSIS (MPA 104T)

Unit 1:

Carbohydrates: Classification and properties of food carbohydrates, general methods of analysis of food carbohydrates, changes in food carbohydrates during processing, digestion, absorption and metabolism of carbohydrates. Dietary fiber, crude fiber and application of food carbohydrates.

Proteins: Chemistry and classification of amino acids and proteins, physico-chemical properties of protein and their structure, general methods of analysis of proteins and amino acids. **12 Hours**

Unit 2:

Lipids: Classification, general methods of analysis, determination of adulteration in fats and oils, various methods used for measurement of spoilage of fats and fatty foods.

Vitamins: Classification of vitamins, principle & microbial assays of vitamin-B_1, B_2 & B_{12}. **12 Hours**

Unit 3:

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

Pigments and synthetic dyes: Natural pigments, their occurrence and characteristic properties, permitted synthetic dyes, non-permitted synthetic dyes used by industries, method of detection of natural, permitted and non-permitted dyes. **12 Hours**

Unit 4: General analytical methods for milk, milk constituents and milk products like ice cream, milk powder, butter, margarine, cheese including adulterants and contaminants of milk. Analysis of fermentation products like wine, spirits, beer and vinegar. **12 Hours**

Unit 5:

Pesticide analysis: Effects of pest and insects on various food, use of pesticides in agriculture, pesticide cycle, organophosphorus and organochlorine pesticides analysis, determination of pesticide residues in grain, fruits, vegetables, milk and milk products. Legislation regulations of food products with special emphasis on BIS, Agmark, FDA and US-FDA. FSSAI guidelines-special emphasis on mycotoxins, microbiology, antibiotic residues in foods. HACCP (Biological, Physical & Chemical hazards), Regulatory aspects of CODEX Alimentarius. **12 Hours**

REFERENCES

1. The Chemical Analysis of Foods – David Pearson. 7th ed. 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. 6th ed. Volume 1 & 2. 1997.
4. Analysis of Food Constituents – Multon. John Wiley & Sons.
5. Official methods of analysis of AOAC International - Dr. William Horwitz. 18th ed. 2005.

PHARMACEUTICAL ANALYSIS PRACTICAL - I (MPA 105P)

1. Analysis of Pharmacopoeial compounds and their formulations by UV-Vis spectrophotometer
2. Simultaneous estimation of multi component containing formulations by UV spectrophotometry

3. Experiments based on HPLC
4. Experiments based on gas chromatography
5. Estimation of riboflavin/quinine sulphate by fluorimetry
6. Estimation of sodium/potassium by flame photometry
7. Assay of official compounds by different titrations
8. Assay of official compounds by instrumental techniques.
9. Quantitative determination of hydroxyl group.
10. Quantitative determination of amino group
11. Colorimetric determination of drugs by using different reagents
12. Impurity profiling of drugs

PHARMACEUTICAL ANALYSIS PRACTICAL - II (MPA 106P)

1. Calibration of glassware
2. Calibration of pH meter
3. Calibration of UV-Visible spectrophotometer
4. Calibration of FTIR spectrophotometer
5. Calibration of GC instrument
6. Calibration of HPLC instrument
7. Cleaning validation of any one equipment
8. Determination of total reducing sugar
9. Determination of proteins
10. Determination of saponification value, iodine value, peroxide value, acid value in food products
11. Determination of fat content and rancidity in food products
12. Analysis of natural and synthetic colors in food
13. Determination of preservatives in food
14. Determination of pesticide residue in food products
15. Analysis of vitamin content in food products
16. Determination of density and specific gravity of foods
17. Determination of food additives.
18. Analysis of vanillin content in foods
19. Analysis of oxalate content in guava fruit
20. ELISA & CLIA – demonstration
21. IMVIC test - Indole test, methyl red test, Voges-Proskauer test, citrate utilization test

Second Semester

ADVANCED INSTRUMENTAL ANALYSIS (MPA 201T)

Unit 1:

HPLC: Principle, analytical method development, pharmaceutical applications, peak shapes, capacity factor, selectivity, plate number, plate height, resolution, band broadening, pumps, injector, detectors, columns, column problems, gradient HPLC, HPLC solvents, trouble shooting, sample preparation, method development, new developments in HPLC-role and principles of ultra, nano liquid chromatography, and preparative HPLC in pharmaceutical analysis. Advancement in enantiomeric separations, Immobilized polysaccharide CSP's and HILIC approaches. **12 Hours**

Unit 2:

Biochromatography: Size exclusion chromatography, ion exchange chromatography, ion pair chromatography, affinity chromatography general principles - stationary phases and mobile phases.

Gas chromatography: Derivatization, head space sampling, analytical method development and quantification. **12 Hours**

Unit 3:

Super critical fluid chromatography: Principle, instrumentation, pharmaceutical applications.

Capillary electrophoresis: General considerations and method development in CE, Crown ethers as buffer additives in capillary electrophoresis. CE-MS hyphenation & its applications.

12 Hours

Unit 4:

Mass spectrometry: LC-MS hyphenation and DART MS analysis. Mass analyzers (Quadrupole, Time of flight, FT-ICR, Ion Trap and Orbitrap) instruments. MS/MS systems (Tandem: QqQ, TOF-TOF; Q-IT, Q-TOF, LTQ-FT, LTQ-Orbitrap. **12 Hours**

Unit 5:

NMR spectroscopy:

Brief outline of principles of NMR &FT-NMR. Spin-spin and spin-lattice relaxation phenomenon. 13C NMR, 1-Dand 2-D NMR, NOESY and COSY techniques, interpretation and qualitative and quantitative applications of NMR spectroscopy. LC-NMR hyphenations. ICP-MS, ICP-OES, PES, TOC Analysis, KF titration, melting point determination using advanced instrumentation. **12 Hours**

REFERENCES

1. Spectrometric Identification of Organic Compounds - Robert M Silverstein. 6th ed. John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler & Timothy A Nieman. 5th ed. Eastern Press, Bangalore, 1998.
3. Instrumental Methods of Analysis – Willards. 7th ed. CBS Publishers, New Delhi.
4. Organic Spectroscopy - William Kemp. 3rd ed. ELBS, 1991.
5. Quantitative Analysis of Pharmaceutical Formulations by HPTLC – P.D. Sethi. CBS Publishers, New Delhi.
6. Quantitative Analysis of Drugs in Pharmaceutical Formulation – P.D. Sethi. 3rd ed. CBS Publishers, New Delhi.
7. Pharmaceutical Analysis- Modern Methods – Part B – J.W. Munson. Vol 11, Marcel Dekker Series.
8. Organic Spectroscopy - Donald L Paviya. 5th ed.

MODERN BIO-ANALYTICAL TECHNIQUES (MPA 202T)

Unit 1:

Extraction of drugs and metabolites from biological matrices: General need, principle and procedure involved in the bioanalytical methods such as protein precipitation, liquid - liquid extraction and solid phase extraction and other novel sample preparation approach.

Bioanalytical method validation: USFDA and EMEA guidelines. **12 Hours**

Unit 2:

Biopharmaceutical consideration: Introduction, in vitro: dissolution and drug release

testing, alternative methods of dissolution testing. Solubility: experimental methods. permeability: in-vitro, in-situ and in-vivo methods. **12 Hours**

Unit 3:

Pharmacokinetics and toxicokinetics: Basic consideration, drug interaction (PK-PD interactions), the effect of protein-binding interactions, the effect of tissue-binding interactions, toxicokinetics-toxicokinetic evaluation in preclinical studies, importance and applications of toxicokinetic studies. LC-MS in bioactivity screening and proteomics.

12 Hours

Unit 4:

Metabolite identification: In vitro/in vivo approaches, protocols and sample preparation. Microsomal approaches (rat liver microsomes (RLM) and human liver microsomes (HLM) in Met-ID - Regulatory perspectives. In vitro assay of drug metabolites & drug metabolizing enzymes. **12 Hours**

Unit 5:

Drug product performance: In vivo: bioavailability and bioequivalence. Drug product performance, purpose of bioavailability studies, relative and absolute availability. Methods for assessing bioavailability, bioequivalence studies, design and evaluation of bioequivalence studies, study designs, crossover study designs, generic biologics (biosimilar drug products), clinical significance of bioequivalence studies. **12 Hours**

REFERENCES

1. Analysis of Drugs in Biological Fluids - Joseph Chamberlain. 2nd ed. CRC Press.
2. Principles of Instrumental Analysis - Doglas A Skoog. 5th ed. Eastern Press, Bangalore.
3. Pharmaceutical Analysis - Higuchi, Brochmman & Hassen. 2nd ed. Wiley Interscience
4. Pharmaceutical Analysis - Modern methods – Part B – J.W. Munson. Vol 11, Marcel Dekker.
5. Practical HPLC Method Development – Snyder & Kirkland. 2nd ed. John Wiley & Sons.
6. Chromatographic Analysis of Pharmaceuticals – John A Adamovics. 2nd ed. Marcel Dekker.
7. Chromatographic Methods in Clinical Chemistry & Toxicology – Roger L Bertholf & Ruth E Winecker. John Wiley & Sons, New Jersey, USA, 2007.
8. Good Laboratory Practice Regulations - Sandy Weinberg. Vol. 69. 2nd ed. Marcel Dekker.
9. Good laboratory Practice Regulations – Allen F. Hirsch. Vol. 38. Marcel Dekker, 1989.
10. ICH, USFDA & CDSCO Guidelines.

QUALITY CONTROL AND QUALITY ASSURANCE (MPA 203T)

(Common paper for MPA and MQA specializations)

Unit 1:

Introduction: Concept and evolution of quality control and quality assurance. Good laboratory practice, GMP, overview of ICH guidelines - QSEM, with special emphasis on Q-series guidelines.

Good laboratory practices: Scope of GLP, definitions, quality assurance unit, protocol for conduct of non-clinical testing.

CPCSEA guidelines: Control on animal house, report preparation and documentation.

12 Hours

Unit 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, clean room validation, control of contamination, sterility assurance, AHU system & qualification, and Good Warehousing Practice. **12 Hours**

Unit 3:

Developing specification (ICH Q6 and Q3), sampling methods for raw and packing materials. Purchase specifications, vendor qualification and maintenance of stores for various materials.

Testing of primary packing materials as per IP & USP: Glass containers, plastics, rubber.

Analysis of raw materials, packaging materials: In-process quality control and finished products quality control for following formulations in pharma industry according to Indian, US and British pharmacopoeias: tablets, capsules, ointments, suppositories, creams, parenterals, ophthalmic and surgical products. Quality control test for containers, closures and secondary packing materials. **12 Hours**

Unit 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 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). **12 Hours**

Unit 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 Hours**

REFERENCES

1. Quality Assurance Guide by organization of Pharmaceutical Procedures of India. 3rd Revised ed. Vol 1 & 2, Mumbai, 1996.
2. Good Laboratory Practice Regulations - Sandy Weinberg. Vol. 69. 2nd ed. Marcel Dekker.
3. Quality Assurance of Pharmaceuticals - A compendium of Guidelines and Related Materials. Vol 1 & 2. 2nd ed. WHO Publications, 1999.
4. How to Practice GMP's – P.P. Sharma. Vandana Publications, Agra, 1991.
5. The International Pharmacopoeia – Vol. I, II, III, IV & V - General Methods of Analysis and Quality Specification for Pharmaceutical Substances, Excipients and Dosage forms, 3rd ed. WHO, Geneva, 2005.
6. Good Laboratory Practice Regulations – Allen F Hirsch. Vol 38. Marcel Dekker.
7. ICH guidelines
8. ISO 9000 and Total Quality Management

9. The Drugs and Cosmetics Act 1940 – Deshpande & Nilesh Gandhi. 4th ed. Susmit Publishers.
10. QA Manual – D.H. Shah 1st ed. Business Horizons, 2000.
11. Good Manufacturing Practices for Pharmaceuticals; A Plan for Total Quality Control – Sidney H. Willig. Vol. 52. 3rd ed. Marcel Dekker.
12. GMP/ISO Quality Audit Manual for Healthcare Manufacturers and Their Suppliers - Steinborn L (Volume 1 - With Checklists and Software Package). 6th ed. Taylor & Francis.
13. Quality Systems and Controls for Pharmaceuticals – D.K. Sarker. John Wiley & Sons, 2008.

HERBAL AND COSMETIC ANALYSIS (MPA 204T)

Unit 1:

Herbal remedies: Toxicity and regulations: Herbals vs. conventional drugs, Efficacy of herbal medicine products, validation of herbal therapies, pharmacodynamics and pharmacokinetic issues. Herbal drug standardization: WHO and AYUSH guidelines.

Regulatory requirements for setting herbal drug industry: Global marketing management, Indian and international patent law as applicable herbal drugs and natural products and its protocol. **12 Hours**

Unit 2:

Adulteration and deterioration: Introduction, types of adulteration/substitution of herbal drugs, causes and measure of adulteration, sampling procedures, determination of foreign matter, DNA finger printing techniques in identification of drugs of natural origin, heavy metals, pesticide residues, phototoxin and microbial contamination in herbal formulations.

12 Hours

Unit 3:

Testing of natural products and drugs: Effect of herbal medicine on clinical laboratory testing, adulterant screening using modern analytical instruments, stability testing of natural products, protocol. Monographs of herbal drugs: Study of monographs of herbal drugs and comparative study in IP, USP, Ayurvedic Pharmacopoeia, American Herbal Pharmacopoeia, British Herbal Pharmacopoeia, WHO guidelines in quality assessment of herbal drugs.

12 Hours

Unit 4:

Herbal drug-drug interaction: WHO and AYUSH guidelines for safety monitoring of natural medicine, spontaneous reporting schemes for bio drug adverse reactions, bio drug-drug and bio drug-food interactions with suitable examples. Challenges in monitoring the safety of herbal medicines. **12 Hours**

Unit 5:

Evaluation of cosmetic products: Determination of moisture, ash, volatile matter, heavy metals, fineness of powder, density, viscosity of cosmetic raw materials and finished products. Study of quality of raw materials and general methods of analysis of raw material used in cosmetic manufacture as per BIS.

Schedule S: Standards for cosmetics. Indian Standard specification laid down for sampling and testing of various cosmetics in finished forms such as baby care products, skin care products, dental products, personal hygiene preparations, lips sticks. Hair products and skin creams by the Bureau Indian Standards. **12 Hours**

REFERENCES

1. Pharmacognosy - G. E. Trease & W.C. Evans. Saunders Edinburgh, New York.
2. Pharmacognosy - Kokate, Purohit & Gokhale.
3. Quality Control Methods for Medicinal Plant, WHO, Geneva.
4. Pharmacognosy & Pharmacobiotechnology - Ashutosh Kar.
5. Essential of Pharmacognosy - S.H.Ansari.
6. Cosmetics – Formulation, Manufacturing and Quality Control - P.P. Sharma. 4th ed. Vandana Publications Pvt. Ltd., Delhi.
7. Indian Standard Specification for Raw Materials, BIS, New Delhi.
8. Indian Standard Specification for 28 Finished Cosmetics BIS, New Delhi.
9. Harry's Cosmeticology. 8th ed.
10. Suppliers Catalogue on Specialized Cosmetic Excipients.
11. Poucher's Perfumes, Cosmetics & Soaps – Hilda Butler. 10th ed. Kluwer Academic Publishers.
12. Handbook of Cosmetic Science and Technology. 3rd ed.

PHARMACEUTICAL ANALYSIS PRACTICAL - III (MPA 205P)

1. Comparison of absorption spectra by UV and Wood ward - Fiesure rule
2. Interpretation of organic compounds by FTIR
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 FTIR, NMR, CNMR and mass spectra
7. In process and finished product quality control tests for tablets, capsules, parenterals and creams
8. Quality control tests for primary and secondary packing materials
9. Assay of raw materials as per official monographs
10. Bio molecules separation utilizing various sample preparation techniques and quantitative analysis of components by gel electrophoresis.
11. Bio molecules separation utilizing various sample preparation techniques and quantitative analysis of components by HPLC techniques
12. Isolation of analgesics from biological fluids (blood, serum and urine)
13. Protocol preparation and performance of analytical/bio analytical method validation
14. Protocol preparation for the conduct of BA/BE studies according to guidelines
15. Testing of related and foreign substances in drugs and raw materials
16. Preparation of Master Formula Record
17. Preparation of Batch Manufacturing Record
18. Quantitative analysis of rancidity in lipsticks and hair oil
19. Determination of aryl amine content and developer in hair dye
20. Determination of foam height and SLS content of shampoo
21. Determination of total fatty matter in creams (soap, skin and hair creams)
22. Determination of acid value and saponification value
23. Determination of calcium thioglycolate in depilatories

PHARMACEUTICAL CHEMISTRY (MPC 101T)

First Semester

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES (MPC 101T)

(Note: Common paper for MPA, MPC, MPH, MPB, MPL, MPG, MQA, & MIP, specializations)

Unit 1:

a. UV-visible spectroscopy: Introduction, theory, laws and instrumentation associated with UV-visible spectroscopy, choice of solvents and solvent effect and applications of UV-visible spectroscopy.

b. IR spectroscopy: Theory, modes of molecular vibrations, sample handling, instrumentation of dispersive and Fourier-Transform IR Spectrometer, factors affecting vibrational frequencies and applications of IR spectroscopy, data interpretation.

c. Spectroflourimetry: Theory of fluorescence, factors affecting fluorescence (characteristics of drugs that can be analyzed by flourimetry), quenchers, instrumentation and Applications of fluorescence spectrophotometer.

d. Flame emission spectroscopy and Atomic absorption spectroscopy: Principle, instrumentation, interferences and applications. **12 Hours**

Unit 2:

NMR spectroscopy: Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and 13C NMR. Applications of NMR spectroscopy. **10 Hours**

Unit 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. 1**0 Hours**

Unit 4:

Chromatography: Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution, isolation of drug from excipients, data interpretation and applications of the following:

a) Thin Layer chromatography **b)** High Performance Thin Layer Chromatography **c)** Ion exchange chromatography **d)** Column chromatography **e)** Gas chromatography **f)** High Performance Liquid chromatography **g)** Ultra High Performance Liquid chromatography **h)** Affinity chromatography **i)** Gel Chromatography. **14 Hours**

Unit 5:

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

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

c. Thermal Techniques: Principle, instrumentation, advantage and disadvantages, Pharmaceutical applications of DSC, DTA & TGA.

d. Microscopic techniques: Principles and applications of Scanning Electron Microscopy

and Transmission Electron Microscopy analysis. **14 Hours**

REFERENCES

1. Spectrometric Identification of Organic compounds - Robert M Silverstein. 6th ed. John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler & Timothy A Nieman. 5th ed. Eastern Press, Bangalore, 1998.
3. Instrumental Methods of Analysis – Willards. 7th ed. CBS Publishers, New Delhi.
4. Practical Pharmaceutical Chemistry – Beckett and Stenlake. Vol 2. 4th ed. CBS Publishers, New Delhi
5. Organic Spectroscopy - William Kemp. 3rd ed. ELBS, 1991.
6. Quantitative Analysis of Drugs in Pharmaceutical Formulation – P.D. Sethi. 3rd ed. CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis - Modern Methods – Part B – J.W. Munson. Vol 11. Marcel-Dekker Series.
8. Spectroscopy of Organic Compounds - P.S. Kalsi. 2nd ed. Wiley Estern Ltd., Delhi.
9. Textbook of Pharmaceutical Analysis – K.A. Connors. 3rd ed. John Wiley & Sons.

ADVANCED ORGANIC CHEMISTRY – I (MPC 102T)

Unit 1:

Basic aspects of organic chemistry:

1. Organic intermediates: Carbocations, carbanions, free radicals, carbenes and nitrenes. Their method of formation, stability and synthetic applications.
2. Types of reaction mechanisms and methods of determining them.
3. Detailed knowledge regarding the reactions, mechanisms and their relative reactivity and orientations. Addition reactions: a) Nucleophilic uni- and bimolecular reactions (SN1 and SN2) b) Elimination reactions (E1 & E2; Hoffman & Saytzeff's rule) c) Rearrangement reaction. **12 Hours**

Unit 2:

Study of mechanism and synthetic applications of following named reactions: Ugi reaction, Brook rearrangement, Ullmann coupling reactions, Dieckmann Reaction, Doebner-Miller Reaction, Sandmeyer Reaction, Mitsunobu reaction, Mannich reaction, Vilsmeyer-Haack Reaction, Sharpless asymmetric epoxidation, Baeyer-Villiger oxidation, Shapiro & Suzuki reaction, Ozonolysis and Michael addition reaction. **12 Hours**

Unit 3:

Synthetic reagents & applications: Aluminium isopropoxide, N-bromo succinamide, diazomethane, dicyclo hexyl carbodimide, Wilkinson reagent, Witting reagent. Osmium tetroxide, titanium chloride, diazopropane, diethyl azido carboxylate, triphenyl phosphine, benzotriazol-1-yloxy) tris(dimethylamino) phosphonium hexafluoro-phosphate (BOP), potassium-t-butoxide, lead tetra acetate, sodium methoxide

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 **12 Hours**

Unit 4:

Heterocyclic chemistry:

Organic name reactions with their respective mechanism and application involved in synthesis of drugs containing five, six membered and fused heterocyclics such as Debus-Radziszewski imidazole synthesis, Knorr pyrazole synthesis Pinner pyrimidine synthesis, Combes quinoline synthesis, Bernthsen acridine synthesis, Smiles rearrangement and Traube purine synthesis.

Synthesis of few representative drugs containing these heterocyclic nucleus such as ketoconazole, metronidazole, miconazole, celecoxib, antipyrin, metamizole sodium, terconazole, alprazolam, triamterene, sulfamerazine, trimethoprim, hydroxy chloroquine, quinine, chloroquine, quinacrine, amsacrine, prochlorpherazine, promazine, chlorpromazine, theophylline , mercaptopurine and thioguanine. **12 Hours**

Unit 5:

Synthon approach and retrosynthesis applications

1. Basic principles, terminologies and advantages of retro synthesis; guidelines for dissection of molecules.
2. Functional group interconvert ion and addition (FGI and FGA), C-X disconnections; C-C disconnections – alcohols and carbonyl compounds; 1,2-, 1,3-,1,4-, 1,5-, 1,6-difunctionalized compounds.
3. Strategies for synthesis of three, four, five and six-membered ring with examples.

12 Hours

REFERENCES

1. Advanced Organic Chemistry, Reaction, Mechanisms and Structure – J. March. John Wiley & Sons, New York.
2. Mechanism and Structure in Organic Chemistry – E.S. Gould, Hold Rinchart & Winston.
3. Organic Chemistry - Clayden, Greeves, Warren & Woihers. Oxford University Press 2001.
4. Organic Chemistry - I.L. Finar. Vol 1 and 2. ELBS, Pearson Education.
5. A guide to Mechanisms in Organic Chemistry - Peter Skyes. Orient Longman, New Delhi.
6. Reactive Intermediates in Organic Chemistry - Tandom & Gowel. Oxford & IBH Publishers.
7. Combinational Chemistry - Synthesis and Applications – Stephen R Wilson & Anthony W Czarnik. Wiley-Blackwell.
8. Organic Chemistry – Carey. 5th ed. Viva Books Pvt. Ltd.
9. Organic Synthesis - The Disconnection Approach - S. Warren. Wily India
10. Principles of Organic Synthesis – R.O.C. Norman & J.M. Coxan. Nelson Thorns.
11. Organic Synthesis - Special Techniques – V.K. Ahluwalia and R. Agarwal. Narosa Publishers.
12. Organic Reaction Mechanisms – V.K. Ahluwalia & R.K. Parashar 4th ed. Narosa Publishers.

ADVANCED MEDICINAL CHEMISTRY (MPC 103T)

Unit 1:

Drug discovery: Stages of drug discovery, lead discovery; identification, validation and diversity of drug targets. Biological drug targets: Receptors, types, binding and activation, theories of drug receptor interaction, drug receptor interactions, agonists vs. antagonists,

artificial enzymes. 12 **Hours**

Unit 2:

Pro-drug design and analog design:

1. Pro-drug design: Basic concept, Carrier linked pro-drugs/Bio-precursors, pro-drugs of functional group, pro-drugs to improve patient acceptability, drug solubility, drug absorption and distribution, site specific drug delivery and sustained drug action. Rationale of pro-drug design and practical consideration of pro- drug design.
2. Combating drug resistance: Causes for drug resistance, strategies to combat drug resistance in antibiotics and anticancer therapy, genetic principles of drug resistance.
3. Analog design: Introduction, classical & non classical, bio-isosteric 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. **12 Hours**

Unit 3:

1. **Medicinal chemistry aspects** of the following classes of drugs, systematic study, SAR, mechanism of action and synthesis of new generation molecules of following classes of drugs:

   a) Anti-hypertensive drugs, psycho-active drugs, anti-convulsant drugs, H1 & H2 receptor antagonist, COX-1 & COX-2 inhibitors, adrenergic & cholinergic agents, anti-neoplastic and antiviral agents. b) Stereochemistry and drug action: Realization that stereo selectivity is a pre-requisite for evolution. Role of chirality in selective and specific therapeutic agents. Case studies, enantio selectivity in drug adsorption, metabolism, distribution and elimination. **12 Hours**

Unit 4:

Rational design of enzyme inhibitors: Enzymes as targets - 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 Hours**

Unit 5:

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

REFERENCES

1. Medicinal Chemistry – Burger. Vol. 1 –6.
2. Wilson and Gisvold's Text Book of Organic Medicinal and Pharmaceutical Chemistry, 12th ed. Lippincott, New Delhi.
3. Comprehensive Medicinal Chemistry - Corwin & Hansch. Permagon Publishers.
4. Computational and Structural Approaches to Drug Design - Robert M Stroud
5. Introduction to Quantitative Drug Design - Y.C. Martin.
6. Principles of Medicinal Chemistry - William Foye. 7th ed. Lippincott, New Delhi.
7. Drug Design Volumes – Arienes. Academic Press, Elsevier Publishers, Noida, UP.
8. Principles of Drug Design - Smith.
9. The Organic Chemistry of the Drug Design and Drug Action - Richard B Silverman. 2nd ed. Elsevier Publishers, New Delhi.
10. An Introduction to Medicinal Chemistry - Graham L Patrick. 3rd ed. Oxford University Press, USA.

11. Biopharmaceutics and Pharmacokinetics – D.M. Brahmankar. 2nd ed. Vallabh Prakashan.
12. Peptidomimetics in Organic and Medicinal Chemistry - Antonio Guarna & Andrea Trabocchi. 1st ed. Wiley Publishers.

CHEMISTRY OF NATURAL PRODUCTS (MPC 104T)

Unit 1:

Study of Natural products as leads for new pharmaceuticals for the following classes 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) Neuro-muscular blocking drugs: curare alkaloids e) Anti-malarial drugs and analogues f) Chemistry of macrolide antibiotics: erythromycin, azithromycin, roxithromycin, and clarithromycin, tetracycline and β - lactam antibiotics (cephalosporins and carbapenem). **12 Hours**

Unit 2:

1. Alkaloids: General introduction, classification, isolation, purification, molecular modification and biological activity of alkaloids, general methods of structural determination of alkaloids, structural elucidation and stereochemistry of ephedrine, morphine, ergot, emetine and reserpine, Cinchona alkaloids, artemisin and its derivatives**.**

2. Flavonoids: Introduction, isolation and purification of flavonoids, general methods of structural determination of flavonoids; Structural elucidation of quercetin.

3. Steroids: General introduction, chemistry of sterols, sapogenin and cardiac glycosides. Stereochemistry and nomenclature of steroids, chemistry of contraceptive agents male & female sex hormones (testosterone, estradiol, progesterone), adrenocorticoids (cortisone), contraceptive agents and steroids (vitamin D). **12 Hours**

Unit 3:

1. Terpenoids: Classification, isolation, isoprene rule and general methods of structural elucidation of terpenoids; Structural elucidation of drugs belonging to mono (citral, menthol, camphor), di (retinol, phytol, taxol) and tri terpenoids squalene, ginsenoside) carotinoids (β carotene).

2. Vitamins: Chemistry and physiological significance of vitamin A, B_1, B_2, B_{12}, C, E, folic acid and niacin. 1**2 Hours**

Unit 4:

1. Recombinant DNA technology and drug discovery: rDNA technology, hybridoma technology, new pharmaceuticals derived from biotechnology; oligo-nucleotide therapy. Gene therapy: Introduction, clinical application and recent advances in gene therapy, principles of RNA & DNA estimation.

2. 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.*

12 Hours

Unit 5: Structural characterization of natural compounds: Structural characterization of natural compounds using IR, 1H NMR, ^{13C}NMR and MS spectroscopy of specific drugs, e.g., penicillin, morphine, camphor, vitamin D, quercetin and digitalis glycosides. **12 Hours**

REFERENCES

1. Modern Methods of Plant Analysis - Peech & M.V. Tracey. Springer–Verlag, Berlin.
2. Phytochemistry – Miller - Jan Nostrant Rein Hld, Vol. 1 and 2.
3. Recent Advances in Phytochemistry - Scikel Runeckles. Vol. 1 to 4. Springer Science.

4. Chemistry of Natural Products, Vol 1 onwards IWPAC.
5. Natural Product Chemistry - Nakanishi Gggolo. University Science Books, California.
6. Natural Product Chemistry "A laboratory Guide" – Rapheal Khan.
7. The Alkaloid Chemistry and Physiology - RHF Manske. Academic Press.
8. Introduction to Molecular Phytochemistry – C.H.J. Wells. Chapmannstall.
9. Organic Chemistry of Natural Products - Gurdeep & Chatwall, Vol 1 and 2. Himalaya Publishing House.
10. Organic Chemistry of Natural Products - O.P. Agarwal, Vol 1 and 2. Krishan Prakashan.
11. Organic Chemistry - I.L. Finar. Vol 1 and 2. Pearson Education.
12. Elements of Biotechnology - P.K. Gupta. Rastogi Publishers.
13. Pharmaceutical Biotechnology - S.P.Vyas and V.K. Dixit. CBS Publishers, New Delhi.
14. Biotechnology - Purohit and Mathur. 13th ed. Agro-Bios.
15. Phytochemical Methods of Harborne. Springer, Netherlands.
16. Medicinal Chemistry – Burger. Vol. 1-6.

PHARMACEUTICAL CHEMISTRY PRACTICAL – I (MPC 105P)

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

PHARMACEUTICAL CHEMISTRY PRACTICAL - II (MPC 106P)

To perform the following reactions of synthetic importance:

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

Second Semester

ADVANCED SPECTRAL ANALYSIS (MPC 201T)

Unit 1:

UV and IR spectroscopy: Wood Ward – Fieser rule for 1,3-butadienes, cyclic dienes and α,β-carbonyl compounds and interpretation compounds of enones. ATR-IR, IR Interpretation of organic compounds. **12 Hours**

Unit 2:

NMR spectroscopy: 1-D and 2-D NMR, NOESY and COSY, HECTOR, INADEQUATE techniques, interpretation of organic compounds. **12 Hours**

Unit 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 Hours**

Unit 4:

Chromatography: Principle, instrumentation and applications of the following:

a) GC-MS b) GC-AAS c) LC-MS d) LC-FTIR e) LC-NMR f) CEMS g) High performance thin layer chromatography h) Supercritical fluid chromatography i) Ion chromatography j) I-EC (Ion-exclusion chromatography) k) Flash chromatography. **12 Hours**

Unit 5:

1. Thermal methods of analysis: Introduction, principle, instrumentation and application of DSC, DTA and TGA.

2. Raman Spectroscopy, introduction, principle, instrumentation and applications.

3. Immuno and radio immuno assay, biological standardization, bioassay, ELISA, radioimmunoassay of digitalis and insulin. **12 Hours**

REFERENCES

1. Spectrometric Identification of Organic Compounds - Robert M Silverstein. 6th ed. John Wiley.
2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler & Timothy A Nieman. 5th ed. Eastern Press, Bangalore, 1998.
3. Instrumental Methods of Analysis – Willards. 7th ed. CBS Publishers, New Delhi.
4. Organic Spectroscopy - William Kemp. 3rd ed. ELBS, 1991.
5. Quantitative Analysis of Pharmaceutical Formulations by HPTLC – P.D. Sethi. CBS Publishers, New Delhi.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation – P.D. Sethi. 3rd ed. CBS Publishers, New Delhi.
7. Pharmaceutical Analysis- Modern Methods - Part B – J.W. Munson. Vol 11. Marcel Dekker.

ADVANCED ORGANIC CHEMISTRY – II (MPC 202T)

Unit 1:

Green chemistry: Introduction, principles of green chemistry. 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 heterocycle synthesis. Ultrasound assisted reactions: Types of sonochemical reactions, homogenous, heterogeneous liquid-liquid and liquid-solid reactions, synthetic applications. Continuous flow reactors: Working principle, advantages and synthetic applications. **12 Hours**

Unit 2:

Chemistry of peptides: Coupling reactions in peptide synthesis. 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. Segment and sequential strategies for solution phase peptide synthesis with any two case studies. Side reactions in peptide synthesis: Deletion peptides, side reactions initiated by proton abstraction, protonation, over activation and side reactions of individual amino acids. **12 Hours**

Unit 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 sigmatrophic rearrangement reactions with examples. **12 Hours**

Unit 4:

Catalysis: Types of catalysis, heterogeneous and homogenous catalysis, advantages and disadvantages. Heterogeneous catalysis – preparation, characterization, kinetics, supported catalysts, catalyst deactivation and regeneration, some examples of heterogeneous catalysis used in synthesis of drugs. Homogenous catalysis, hydrogenation, hydro formylation, hydrocyanation, Wilkinson catalysts, chiral ligands and chiral induction, Ziegler-Natta catalysts, some examples of homogenous catalysis used in synthesis of drugs. Transition-metal and organo-catalysis in organic synthesis: Metal-catalyzed reactions. Biocatalysis: Use of enzymes in organic synthesis, immobilized enzymes/cells in organic reaction. Phase transfer catalysis - theory and applications, ionic liquids. **12 Hours**

Unit 5:

Stereochemistry & asymmetric synthesis: Basic concepts in stereochemistry – optical activity, specific rotation, racemates and resolution of racemates, the Cahn, Ingold, Prelog (CIP) sequence rule, meso compounds, pseudo asymmetric centres, axes of symmetry, Fischers D and L notation, cis-trans isomerism, E and Z notation. Methods of asymmetric synthesis using chiral pool, chiral auxiliaries and catalytic asymmetric synthesis, enantiopure separation and Stereo selective synthesis with examples. **12 Hours**

REFERENCES

1. Advanced Organic Chemistry, Reaction, Mechanisms and Structure – J. March. John Wiley & Sons, New York.
2. Mechanism and Structure in Organic Chemistry – E.S. Gould, Hold Rinchart & Winston.
3. Organic Chemistry - Clayden, Greeves, Warren & Woihers. Oxford University Press 2001.
4. Organic Chemistry - I.L. Finar. Vol 1 and 2. ELBS, Pearson Education.
5. Organic Chemistry – Carey. 5th ed. Viva Books Pvt. Ltd.
6. Organic Synthesis - The Disconnection Approach - S. Warren. Wily India
7. Principles of Organic Synthesis – R.O.C. Norman & J.M. Coxan. Nelson Thorns.
8. Organic Synthesis - Special Techniques – V.K. Ahluwalia & R. Agarwal. Narosa Publishers.
9. Organic Reaction Mechanisms – V.K. Ahluwalia and R.K. Parashar 4th ed. Narosa Publishers.

COMPUTER AIDED DRUG DESIGN (CADD) (MPC 203T)

Unit 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 Hours**

Unit 2:

Quantitative Structure Activity Relationships/Applications: Hansch analysis, Free Wilson analysis, 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 Hours**

Unit 3:

Molecular modeling and docking: Molecular and Quantum mechanics in drug design. 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 Hours**

Unit 4:

Molecular properties and drug design: Prediction and analysis of ADMET properties of new molecules and its importance in drug design. 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. Homology modeling and generation of 3D-structure of protein. **12 Hours**

Unit 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. Application of bioinformatics in drug design. **12 Hours**

REFERENCES

1. Computational and Structural Approaches to Drug Discovery - Robert M Stroud and Janet F Moore. RCS Publishers.
2. Introduction to Quantitative Drug Design - Y.C. Martin. CRC Press, Taylor & Francis.
3. Drug Design – Ariens. Vol 1 to 10. Academic Press, 1975, Elsevier Publishers.
4. Principles of Drug Design - Smith & Williams. CRC Press, Taylor & Francis.
5. The Organic Chemistry of the Drug Design and Drug Action - Richard B Silverman. Elsevier Publishers.
6. Medicinal Chemistry - Burger, Vol. 1 –6.
7. An Introduction to Medicinal Chemistry - Graham L Patrick. 3rd ed. Oxford University Press, USA.
8. Wilson and Gisvold's Text Book of Organic Medicinal and Pharmaceutical Chemistry. 12th ed. Lippincott, New Delhi.
9. Comprehensive Medicinal Chemistry – Corwin & Hansch. Pergamon Publishers.

10. Computational and Structural Approaches to Drug Discovery - Robert M Stroud & Janet F Moore. RCS Publishers.

PHARMACEUTICAL PROCESS CHEMISTRY (MPC 204T)

Unit 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 Hours**

Unit 2:

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 Hours**

Unit 3:

Unit processes - I: Nitration: Nitrating agents, aromatic nitration, kinetics and mechanism of aromatic nitration, process equipment for technical nitration, mixed acid for nitration. Halogenation: Kinetics of halogenations, types of halogenations, catalytic halogenations. Case study on industrial halogenation process. Oxidation: Introduction, types of oxidative reactions, liquid phase oxidation with oxidizing agents. Non-metallic oxidizing agents such as H_2O_2, sodium hypochlorite, oxygen gas, ozonolysis. **12 Hours**

Unit 4:

Unit processes - II:

Reduction: Catalytic hydrogenation, heterogeneous and homogeneous catalyst; hydrogen transfer reactions, metal hydrides. Case study on industrial reduction process. Fermentation: Aerobic and anaerobic fermentation. Production of antibiotics (penicillin and streptomycin), vitamins (B_2 and B_{12}), statins (lovastatin, simvastatin). Reaction progress kinetic analysis: streamlining reaction steps, route selection, characteristics of expedient routes, characteristics of cost-effective routes, reagent selection, families of reagents useful for scale-up. **12 Hours**

Unit 5:

Industrial safety: MSDS (Material Safety Data Sheet), hazard labels of chemicals and personal protection equipment (PPE). Fire hazards, types of fire & fire extinguishers. Occupational Health & Safety Assessment Series 1800 (OHSAS-1800) and ISO-14001 (Environmental Management System). Effluents and its management. **12 Hours**

REFERENCES

1. Process Chemistry in the Pharmaceutical Industry: Challenges in an Ever-Changing Climate - An Overview - K. Gadamasetti. CRC Press.
2. Pharmaceutical Manufacturing Encyclopedia. 3rd ed. Volume 2.
3. Medicinal Chemistry – Burger. Vol. 1–6.
4. Unit Operations of Chemical Engineering - W.L. McCabe, J.C. Smith & Peter Harriott. 7th ed.
5. Polymorphism in Pharmaceutical Solids – H.G. Britain. Vol 95. Dekker Series, 1999.
6. Introduction to Chemical Processes: Principles, Analysis, Synthesis - Regina M Murphy.
7. Pharmaceutical Process Chemistry for Synthesis: Rethinking the Routes to Scale-Up - Peter J Harrington.

8. Unit Processes in Organic Synthesis (MGH) - P.H. Groggins.
9. Chemical Technology - F.A. Henglein. Permagon Publishers.
10. Dryden's Outlines of Chemical Technology - M. Gopal. WEP East-West Press.
11. Principle of Industrial Chemistry – Clausen & Mattson. Wiley Publishing Co.
12. Industrial Chemicals - Lowenheim & M.K. Moran.
13. A text book of Chemical Technology - S.D. Shukla & G.N. Pandey. Vol. 2. Vikas Publishing.
14. Industrial Organic Chemistry - J.K. Stille: (Prentice Hall publishers)
15. Chemical Process – Shreve. Mc Graw-Hill.
16. Industrial Chemistry - B.K. Sharma. Goel Publishing House.
17. ICH Guidelines website www.ich.org
18. United States Food and Drug Administration official website www.fda.gov

PHARMACEUTICAL CHEMISTRY PRACTICAL – III (MPC 205P)

1. Synthesis of organic compounds by adapting different approaches involving a) oxidation b) reduction/hydrogenation c) Nitration (3 experiments)
2. Comparative study of synthesis of APIs/intermediates by different synthetic routes (2 experiments)
3. Assignments on regulatory requirements in API (2 experiments)
4. To carry out the preparation of following organic compounds
5. Preparation of 4-chlorobenzhydrylpiperazine. (an intermediate for cetirizine HCl).
6. Preparation of 4-iodotolene from p-toluidine.
7. $NaBH_4$ reduction of vanillin to vanillyl alcohol
8. Preparation of umbelliferone by Pechhman reaction
9. Preparation of triphenyl imidazole
10. To perform the microwave irradiated reactions of synthetic importance (Any two)
11. Determination of log P, MR, hydrogen bond donors and acceptors of selected drugs using software
12. Calculation of ADMET properties of drug molecules and its analysis using software Pharmacophore modeling
13. 2D-QSAR based experiments
14. 3D-QSAR based experiments
15. Docking study based experiment
16. Virtual screening based experiment
17. Comparison of absorption spectra by UV and Wood ward – Fieser rule
18. Interpretation of organic compounds by FTIR
19. Interpretation of organic compounds by NMR
20. Interpretation of organic compounds by MS
21. Determination of purity by DSC in pharmaceuticals
22. Identification of organic compounds using FTIR, NMR, C13 NMR and Mass spectra

PHARMACEUTICS (MPH)

First Semester

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES (MPH 101T)

(Note: Common paper for MPA, MPC, MPH, MPB, MPL, MPG, MQA, & MIP, specializations)

Unit 1:

a. UV-visible spectroscopy: Introduction, theory, laws and instrumentation associated with UV-visible spectroscopy, choice of solvents and solvent effect and applications of UV-visible spectroscopy.

b. IR spectroscopy: Theory, modes of molecular vibrations, sample handling, instrumentation of dispersive and Fourier-Transform IR Spectrometer, factors affecting vibrational frequencies and applications of IR spectroscopy, data interpretation.

c. Spectroflourimetry: Theory of fluorescence, factors affecting fluorescence (characteristics of drugs that can be analyzed by flourimetry), quenchers, instrumentation and Applications of fluorescence spectrophotometer.

d. Flame emission spectroscopy and Atomic absorption spectroscopy: Principle, instrumentation, interferences and applications. **12 Hours**

Unit 2:

NMR spectroscopy: Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and 13C NMR. Applications of NMR spectroscopy. **10 Hours**

Unit 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. 1**0 Hours**

Unit 4:

Chromatography: Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution, isolation of drug from excipients, data interpretation and applications of the following:

a) Thin Layer chromatography **b)** High Performance Thin Layer Chromatography **c)** Ion exchange chromatography **d)** Column chromatography **e)** Gas chromatography **f)** High Performance Liquid chromatography **g)** Ultra High Performance Liquid chromatography **h)** Affinity chromatography **i)** Gel Chromatography. **14 Hours**

Unit 5:

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

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

c. Thermal Techniques: Principle, instrumentation, advantage and disadvantages, Pharmaceutical applications of DSC, DTA & TGA.

d. Microscopic techniques: Principles and applications of Scanning Electron Microscopy

and Transmission Electron Microscopy analysis. **14 Hours**

REFERENCES

1. Spectrometric Identification of Organic compounds - Robert M Silverstein. 6th ed. John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler & Timothy A. Nieman. 5th ed. Eastern Press, Bangalore, 1998.
3. Instrumental Methods of Analysis – Willards. 7th ed. CBS Publishers, New Delhi.
4. Practical Pharmaceutical Chemistry – Beckett and Stenlake. Vol 2. 4th ed. CBS Publishers, New Delhi
5. Organic Spectroscopy - William Kemp. 3rd ed. ELBS, 1991.
6. Quantitative Analysis of Drugs in Pharmaceutical Formulation – P.D. Sethi. 3rd ed. CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis - Modern Methods – Part B – J.W. Munson. Vol 11. Marcel-Dekker Series.
8. Spectroscopy of Organic Compounds - P.S. Kalsi. 2nd ed. Wiley Estern Ltd., Delhi.
9. Textbook of Pharmaceutical Analysis - K.A. Connors. 3rd ed. John Wiley & Sons.

ADVANCED BIOPHARMACEUTICS & PHARMACOKINETICS (MPH 102T)

(Common paper for MPH and MIP specializations)

Unit 1:

Drug absorption from the gastrointestinal tract and other routes of administration: Mechanisms and factors affecting drug absorption from different routes, influence of pH–partition theory on drug absorption. Factors affecting dissolution rate and its process, Noyes-Whitney equation. dissolution testing methods for solids - tablets, capsules and for suspensions. Correlation of in vivo and in vitro dissolution data. **12 Hours**

Unit 2:

Biopharmaceutical considerations in drug product design and in vitro drug product performance. Introduction - biopharmaceutical factors affecting bioavailability, rate limiting steps in drug absorption, physicochemical nature of drug, formulation factors affecting drug product performance. In vitro dissolution and drug release testing, dissolution test apparatus and methods as per IP and USP for different types of drug delivery systems, design of dissolution testing for conventional and controlled release products. Data handling and correction factor, bio relevant media, similarity and dissimilarity factors f_1 & f_2, alternative methods of dissolution testing, problems of variable control in dissolution testing performance of drug products. Drug product stability during dissolution testing, in vitro evaluation of drug release from different dosage forms. **12 Hours**

Unit 3:

Pharmacokinetics: Basic considerations, pharmacokinetic models, compartment modeling: one compartment model - IV bolus, IV infusion, extra-vascular. Multi compartment models in brief, calculation of parameters in two compartment models. Non-linear pharmacokinetics: causes of non-linearity, Michaelis – Menten equation, estimation of k_m and V_{max}. Concept of clearance and its applications. Problems related to the above. **12 Hours**

Unit 4:

Drug Product Performance: Bioavailability and bioequivalence, drug product performance, purpose of bioavailability studies, relative and absolute availability. Methods, protocol design for assessing bioavailability, bioequivalence studies, design and evaluation of bioequivalence studies, study designs, cross over study designs, evaluation of the data, bioequivalence example, study submission and drug review process. In vitro - in vivo correlations in protocol

design, levels of correlation, biopharmaceutical classification system, methods. Permeability: Generic biologics (biosimilar drug products), clinical significance of bioequivalence studies. **12 Hours**

Unit 5:

Application of pharmacokinetics: Modified-release drug products, targeted drug delivery systems and biotechnological products. Significance of pharmacokinetic and pharmacodynamic drug interactions in the design of the modified release products. **12 Hours**

REFERENCES

1. Pharmacokinetics - Milo Gibaldi. 2nd ed.
2. Applied Biopharmaceutics and Pharmacokinetics - Leon Shargel. 5th ed.
3. Biopharmaceutics and Clinical Pharmacokinetics - Robert E Notari. 4th ed.
4. Modern Pharmaceutics - Gilbert S. Banker, Christopher T Rhodes. 4th ed.
5. Clinical Pharmacokinetics & Pharmacodynamics - Malcolm Rowland & Tozer. 4th ed. Lippincott Publications.
6. Drug Disposition and Pharmacokinetics - Stephen H Curry. 3rd ed.
7. Current Concepts in the Pharmaceutical Sciences : Biopharmaceutics - James Swarbrick
8. Current Concepts in the Pharmaceutical Sciences:Dosage Form Design and Bioavailability - James Swarbrick.

MODERN PHARMACEUTICS (MPH 103T)

Unit 1:

Preformulation Concepts – Drug excipient interactions-different methods, kinetics of stability, stability testing. Theories of dispersion and pharmaceutical dispersion (emulsions and suspensions, SMEDDS) preparation and stability. Large and small volume parenterals – physiological and formulation consideration, manufacturing and evaluation.

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. **12 Hours**

Unit 2:

Validation: Introduction to pharmaceutical validation, scope & merits of validation. Validation and calibration of master plan, ICH & WHO guidelines for calibration and validation of equipment, validation of specific dosage form, types of validation. Government regulations, manufacturing process model, user requirement specifications (URS), design qualification (DQ), installation qualification (IQ), operational qualification (OQ) & performance qualification (PQ) of facilities. **12 Hours**

Unit 3:

cGMP & industrial management: Objectives and policies of current good manufacturing practices (cGMP), layout of buildings, services, equipment 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 (TQM). **12 Hours**

Unit 4:

Compression and compaction: Physics of tablet compression, compression, consolidation, effect of friction, distribution of forces, compaction profiles. Heckel plots, Strain gauges, evaluation of forces, energy consumption, factors influencing consolidation parameters.

12 Hours

Unit 5:

Drug release characteristics and modeling: Diffusion parameters, evaluation of matrix and reservoir systems and swelling matrix tablets, burst effect, modeling of drug release using different equations (Higuchi model, Peppas model, Hixson Crowell, zero order & first order). Linearity, concept of significance, standard deviation, Chi square test, students T-test, ANOVA test. **12 Hours**

REFERENCES

1. Encyclopedia of Pharmaceutical Technology - James Swarbrick. 3rd ed. Informa Healthcare Publishers.
2. Pharmaceutical Dosage Forms : Tablets - Herbert A Lieberman & Leon Lachman, Volume 1 - 3. Marcel Dekker, Inc.
3. The Theory and Practice of Industrial Pharmacy - Roop K Khar, S.P. Vyas, Farhan J Ahmad, Gaurav K Jain. 4th ed. CBS Publishers, New Delhi.
4. Martin's Physical Pharmacy and Pharmaceutical Sciences - Patrick J Sinko. 6th ed. BI Publications Pvt. Ltd.
5. Pharmaceutical Dosage Forms : Disperse Systems - Herbert A Lieberman, Martin M Rieger & Gilbert S Banker. Vol 1 – 3. Informa Healthcare.
6. Pharmaceutical Dosage Forms : Parenteral Medication – Sandeep Nema & John Ludwig, Vol 1 – 3. 3rd ed. Informa Healthcare.
7. Aulton's Pharmaceutics – The Design and Manufacture of Medicines - M.E. Aulton & M.G. Kevin Taylor. 5th ed. Elsevier.
8. Remington – The Science and Practice of Pharmacy – Loyd V Allen. 22nd ed.

REGULATORY AFFAIRS (MPH 104T)

Unit 1:

Documentation in pharmaceutical industry: Master formula record, DMF drug master file (DMF), distribution records. Generic drugs product development, introduction, Hatch-Waxman Act and amendments, Code of Federal Regulations (CFR), drug product performance in vitro, ANDA regulatory approval process, NDA approval process. **12 Hours**

Unit 2:

Bioequivalence and drug product assessment: Scale up post approval changes, post marketing surveillance, outsourcing BA and BE to CRO. Regulatory requirement for product approval, active pharmaceutical ingredient (API), biologics, novel therapies by obtaining NDA, ANDA generic drugs. Pharmaceutical product development (Q8), quality risk management (Q9) and pharmaceutical quality systems (Q10). Quality by design (Q_bD), principles in pharmaceutical development, regulatory and industry views on Q_bD, elements of Q_bD, ANDA applications and examples. **12 Hours**

Unit 3:

Critical manufacturing controls (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 Hours**

Unit 4:

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

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 Hours**

Unit 5:

General principles of intellectual property rights (IPR): IP protection, economic importance, mechanism of protection. Patents, criteria, types of patent application-steps, trademarks and copy rights. **12 Hours**

REFERENCES

1. The Theory and Practice of Industrial Pharmacy - Leon Lachman, H.A. Lieberman & Joseph L Kanig. 3rd ed. Varghese Publishing, 1991.
2. Lachman/Lieberman's The Theory and Practice of Industrial Pharmacy - Roop K Khar, S.P. Vyas, Farhan J Ahmad & Gaurav K Jain. 4th ed. CBS Publishers, New Delhi.
3. Quality Assurance of Pharmaceuticals – WHO. Vol. 1 & 2. Pharma Book Syndicate.
4. Pharmaceutical Product development - N.K. Jain. CBS Publishers, New Delhi.
5. Law relating to Drugs & Cosmetics - Vijay Malik. Eastern Book Company.

PHARMACEUTICS PRACTICAL - I (MPH 105P)

1. Analysis of Pharmacopoeial compounds and their formulations by UV - Visible spectrophotometer.
2. Colorimetric analysis of aspirin.
3. Kinetic studies of aspirin degradation.
4. Molecular weight determination of polymers by viscosity method.
5. Preparation of granules, drying by conventional dryer and fluidized bed dryer and comparing the granules by their flow property.
6. HPLC analysis of any one drug.
7. GMP audit requirements as per CDSCO.
8. Preparation of check-lists for registration of IND as per ICH CTD format.
9. Preparation of check-lists for registration of NDA as per ICH CTD format.
10. Preparation of check-lists for registration of ANDA as per ICH CTD format.
11. To carry out pre formulation studies of tablets.
12. To study the effect of Compression force on tablets disintegration time.

PHARMACEUTICS PRACTICAL - II (MPH 106P)

1. Improvement of dissolution of drugs by solid dispersions, cyclo dextrin complexation etc.
2. Effect of ointment base on drug diffusion using agar plate method and diffusion membrane.
3. To study the effect of particle size on dissolution of a tablet.
4. To study the effect of binders on dissolution of a tablet.
5. To plot Heckel plot, Higuchi and Peppas plot and determine similarity factors.
6. Improvement of dissolution characteristics of slightly soluble drug by solid dispersion technique.
7. Protein binding studies of a highly protein bound drug and poorly protein bound drug.

8. Absorption kinetics of paracetamol in goat intestine (ex vivo study)
9. Pharmacokinetic and IVIVC data analysis by WinNonlin® Software (Demo).
10. In vitro cell studies for permeability and metabolism (Demo).
11. Effect of surfactant on drug dissolution using BCS II drugs.

Second Semester

MOLECULAR PHARMACEUTICS (NANO TECHNOLOGY & TARGETED DDS) (MPH 201T)

Unit 1:

Targeted drug delivery systems: Concepts, events and biological process involved in drug targeting. Tumor targeting and brain specific delivery. **12 Hours**

Unit 2:

Targeting Methods: Introduction, preparation, evaluation and application of nano particles & liposomes. **12 Hours**

Unit 3:

Micro capsules/micro spheres: Types, preparation, evaluation and applications of monoclonal antibodies, niosomes, aquasomes, phytosomes, electrosomes. **12 Hours**

Unit 4:

Pulmonary drug delivery systems: Aerosols, metered dose inhalers, dry powder inhalers, propellants, containers, types, preparation and evaluation. Intra nasal route delivery systems; types, preparation and evaluation. **12 Hours**

Unit 5:

Nucleic acid based therapeutic delivery system: Gene therapy, introduction (ex vivo & in vivo gene therapy). Potential target diseases for gene therapy (inherited disorder and cancer). Gene expression systems (viral and non viral gene transfer). Liposomal gene delivery systems. Bio distribution and pharmacokinetics. Knowledge of therapeutic antisense molecules and aptamers as drugs of future. **12 Hours**

REFERENCES

1. Novel Drug Delivery Systems – Y.W. Chien. 2nd ed. (Revised and expanded). Marcel Dekker.
2. Controlled Drug Delivery: Concepts and Advances - S.P. Vyas & R.K. Khar. 1st ed. Vallabh Prakashan, New Delhi.
3. Controlled and Novel Drug Delivery - N.K. Jain. 1st ed. CBS Publishers, New Delhi, 1997.

DRUG DELIVERY SYSTEMS (MPH 202T)

Unit 1:

Sustained release (SR) and controlled release (CR) formulations: Introduction & basic concepts, advantages/disadvantages, factors influencing, physicochemical & biological approaches for SR/CR formulation, mechanism of drug delivery from SR/CR formulation. Polymers: introduction, definition, classification, properties and application. Dosage Forms for personalized medicine: Introduction, definition, pharmacogenetics, categories of patients for personalized medicines. Customized drug delivery systems, bioelectronic medicines, 3D printing of pharmaceuticals, tele pharmacy. **12 Hours**

Unit 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. **12 Hours**

Unit 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 mucoadhesion, advantages and disadvantages, mechanism of drug permeation, methods of formulation and evaluation. **12 Hours**

Unit 4:

Ocular drug delivery systems: Barriers of drug permeation, methods to overcome barriers. Transdermal drug delivery systems: Structure of skin and barriers, penetration enhancers, formulation and evaluation. **12 Hours**

Unit 5:

Protein and Peptide Delivery: Barriers for protein delivery. Formulation and evaluation of delivery systems of proteins and other macromolecules.

Vaccine delivery systems: Vaccines, uptake of antigens, single shot vaccines, mucosal and transdermal delivery of vaccines.

Medical devices: Materials and their requirements for manufacture of specialized medical devices-disposable hypodermic needles and syringes, prefilled syringes, drug eluting stents, orthopedic implants and intra ocular lenses. **12 Hours**

REFERENCES

1. Novel Drug Delivery Systems – Y.W. Chien. 2nd ed. (Revised and expanded). Marcel Dekker.
2. Controlled Drug Delivery Systems - J. R. Robinson & V.H.L. Lee. Marcel Dekker, Inc.
3. Encyclopedia of Controlled Delivery - Edith Mathiowitz. John Wiley and Sons, Inc.
4. Controlled Drug Delivery: Concepts and Advances - S.P. Vyas & R.K. Khar. 1st ed. Vallabh Prakashan, New Delhi.
5. Controlled and Novel Drug Delivery - N.K. Jain. 1st ed. CBS Publishers, New Delhi, 1997.

COMPUTER AIDED DRUG DEVELOPMENT (MPH 203T)

Unit 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 non parametric and parametric modeling. Statistical parameters, estimation, confidence regions, nonlinearity at the optimum, sensitivity analysis, optimal design, population modeling. **12 Hours**

Unit 2:

Computational modeling of drug disposition: Introduction, modeling techniques: Drug absorption, solubility, intestinal permeation, drug distribution, drug excretion, active transport; P-gp, BCRP, nucleoside transporters, hPEPT1, ASBT, OCT, OATP, BBB-choline transporter. **12 Hours**

Unit 3:

Computer-aided formulation development: Solid dosage forms, disperse systems such as suspensions, emulsions and micro emulsion drug carrier system with examples. Legal protection of innovative uses of computers in R&D, the ethics of computing in pharmaceutical research. Computers in clinical development: Clinical data collection and management, computers in market analysis. **12 Hours**

Unit 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.

12 Hours

Unit 5:

Artificial intelligence (AI): Concepts and applications, robotics. Computational fluid dynamics: General overview and applications. Pharmaceutical automation, pharmaceutical applications, advantages and disadvantages. Current challenges and future directions.

12 Hours

REFERENCES

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

PHARMACEUTICAL AND COSMETIC PRODUCT DEVELOPMENT (MPH 204T)

Unit 1:

Preformulation studies: Molecular optimization of APIs (drug substances), crystal morphology and variations, powder flow, structure modification, drug-excipient compatibility studies by TLC, DTA, DSC and TGA spectral studies, formulation additives: Study of different formulation additives, factors influencing their incorporation, role of formulation development and processing, new developments in excipient science. **12 Hours**

Unit 2:

Solubility: Importance, experimental determination, phase solubility analysis, pH-solubility profile, techniques to improve solubility of drugs and utilization of analytical methods – cosolvency, salt formation, complexation, solid dispersion, micellar solubilization and hydrotropy, methods of characterization. **12 Hours**

Unit 3:

Product stability: Mechanisms of degradation and protection, 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. **12 Hours**

Unit 4:

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. **12 Hours**

Unit 5:

Cosmetics: Formulation, manufacturing and quality control methods of following cosmetic products. Hair care products - Shampoos, hair dyes, shaving products and depilatories. Dental hygiene products: Tooth paste, mouth washes. Skin care products: Hand cream, cleansing

cream, foundation creams. **12 Hours**

REFERENCES

1. Harry's Cosmeticology. 8th ed.
2. Poucher's Perfumes, Cosmetics & Soaps – Hilda Butler. 10th ed. Kluwer Academic Publishers.
3. Cosmetics - Formulation, Manufacture and Quality Control – P.P. Sharma. 4th ed.
4. Hand Book of Cosmetic Science and Technology - A.O. Barel, M. Paye & H.I. Maibach. 3rd ed.
5. Cosmetic and Toiletries Recent Suppliers' Catalogue.
6. CTFA Directory.

PHARMACEUTICS PRACTICAL – III (MPH 205P)

1. To perform in vitro dissolution profile of Controlled release or Sustained release marketed formulation.
2. Formulation and evaluation of sustained release matrix tablets.
3. Formulation and evaluation of osmotically controlled DDS.
4. Preparation and evaluation of Floating DDS- Hydro dynamically balanced DDS.
5. Formulation and evaluation of Muco-adhesive tablets.
6. Formulation and evaluation of transdermal patches.
7. To study the effect of temperature change, non solvent addition, incompatible polymer addition in micro capsule preparation.
8. Formulation and evaluation of microspheres.
9. Formulation and evaluation of liposomes or niosomes.
10. Demonstration statistical designing in formulation development through QBD approach.
11. Development and evaluation of Creams.
12. Development and evaluation of Shampoo and Tooth paste.
13. Effect of surfactant on the solubility of drugs.
14. Effect of pH on the solubility of drugs.
15. Stability testing of drugs in dosage forms at 25^0C/60% RH and 40^0C/75% RH and determine the shelf life.
16. Compatibility evaluation of drugs and excipients (DSC & FTIR).

PHARMACEUTICAL BIOTECHNOLOGY (MPB)

First Semester

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES (MPA 101T)

(Note: Common paper for MPA, MPC, MPH, MPB, MPL, MPG, MQA, & MIP, specializations)

Unit 1:

a. UV-visible spectroscopy: Introduction, theory, laws and instrumentation associated with UV-visible spectroscopy, choice of solvents and solvent effect and applications of UV-visible spectroscopy.

b. IR spectroscopy: Theory, modes of molecular vibrations, sample handling, instrumentation of dispersive and Fourier-Transform IR Spectrometer, factors affecting vibrational frequencies and applications of IR spectroscopy, data interpretation.

c. Spectroflourimetry: Theory of fluorescence, factors affecting fluorescence (characteristics of drugs that can be analysed by flourimetry), quenchers, instrumentation and Applications of fluorescence spectrophotometer.

d. Flame emission spectroscopy and Atomic absorption spectroscopy: Principle, instrumentation, interferences and applications. **12 Hours**

Unit 2:

NMR spectroscopy: Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and 13C NMR. Applications of NMR spectroscopy. **10 Hours**

Unit 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. 1**0 Hours**

Unit 4:

Chromatography: Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution, isolation of drug from excipients, data interpretation and applications of the following:

a) Thin Layer chromatography **b)** High Performance Thin Layer Chromatography **c)** Ion exchange chromatography **d)** Column chromatography **e)** Gas chromatography **f)** High Performance Liquid chromatography **g)** Ultra High Performance Liquid chromatography **h)** Affinity chromatography **i)** Gel Chromatography. **14 Hours**

Unit 5:

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

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

c. Thermal Techniques: Principle, instrumentation, advantage and disadvantages, Pharmaceutical applications of DSC, DTA & TGA.

d. Microscopic techniques: Principles and applications of Scanning Electron Microscopy

and Transmission Electron Microscopy analysis. **14 Hours**

REFERENCES

1. Spectrometric Identification of Organic compounds - Robert M Silverstein. 6th ed. John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler & Timothy A Nieman. 5th ed. Eastern Press, Bangalore, 1998.
3. Instrumental Methods of Analysis – Willards. 7th ed. CBS Publishers, New Delhi.
4. Practical Pharmaceutical Chemistry – Beckett and Stenlake. Vol 2. 4th ed. CBS Publishers, New Delhi
5. Organic Spectroscopy - William Kemp. 3rd ed. ELBS, 1991.
6. Quantitative Analysis of Drugs in Pharmaceutical Formulation – P.D. Sethi. 3rd ed. CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis - Modern Methods – Part B – J.W. Munson. Vol 11. Marcel-Dekker Series.
8. Spectroscopy of Organic Compounds - P.S. Kalsi. 2nd ed. Wiley Estern Ltd., Delhi.
9. Textbook of Pharmaceutical Analysis - K.A. Connors. 3rd ed. John Wiley & Sons.

MICROBIAL GENETICS AND CELLULAR BIOLOGY (MPB 102T)

Unit 1:

Microbiology: Introduction – Prokaryotes and eukaryotes. Bacteria, fungi, actionomycetes 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. **12 Hours**

Unit 2:

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

Gene regulation, Gene copy number, transcriptional control and translational control.

RNA processing, modification and maturation, RNA splicing, RNA editing, RNA amplification. Mutagenesis and repair mechanisms, types of mutants, application of mutagenesis in stain improvement, gene mapping of plasmids- types purification and application. Phage genetics, genetic organization, phage mutation and lysogeny. **12 Hours**

Unit 3:

Cell structure and function: 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: Cell division and its regulation, G-Protein cCoupled receptors, kinases, nuclear receptors, cytoskeleton & cell movements, intermediate filaments.

Apoptosis and oncogenes

Programmed cell death, tumor cells, carcinogens & repair.

Differentiation and developmental biology: Fertilization, events of fertilization, in vitro fertilization, embryonic germ cells, stem cells and their application. **12 Hours**

Unit 4:

Principles of microbial nutrition: Physical and chemical environment for microbial growth, Stability and degeneration of microbial cultures. Growth of animal cells in culture. 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. **12 Hours**

Unit 5:

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.

12 Hours

REFERENCES

1. Pharmaceutical Microbiology - W.B. Hugo & A.D. Russel. Blackwell Scientific Publications, Oxford London.
2. Industrial Microbiology - Prescott & Dunn. CBS Publishers, New Delhi.
3. Microbiology – Pelczar & Chan Kreig. Tata McGraw Hill.
4. Molecular Biology - David Freifelder. 2nd ed. Narosa Publishing House.
5. Culture of Animal Cells – A Manual of Basic Techniques - R. Ian Freshney. 6th ed. John Wiley & Sons.
6. Molecular Cell Biology - David Baltimore. W.H. Freeman & Co Publishers.
7. Cell biology - Julio E Cells. Vol 1-3.
8. Bergeys Manual of Systematic Bacteriology, Williams and Wilkins - A Waverly Company.

BIOPROCESS ENGINEERING AND TECHNOLOGY (MPB 103T)

Unit 1:

Introduction to fermentation technology: Basic principles of fermentation. Study of the design and operation of bioreactor. 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: CSTR, tower, airlift, bubble column, packed glass bead, hollow fiber, configuration and application. Computer control of fermentation process. System configuration and application **12 Hours**

Unit 2:

Mass transfer: 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 plenum ventilation, air sampling and testing standards for air purity.

Rheology: Rheological properties of fermentation system and their importance in bioprocessing. **12 Hours**

Unit 3:

Scale up of fermentation process: Principles, theoretical considerations, techniques used, media for fermentation, HTST sterilization, advantage and disadvantage, liquid sterilization.

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

Introduction to immobilization: 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.

12 Hours

Unit 4:

Scale down of fermentation process: 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 and screening: Primary and secondary, maintenance of stock culture, strain improvement for increased yield. **12 Hours**

Unit 5:

Bioprocessing of the industrially important microbial metabolites

a) Organic solvents – alcohol and glycerol
b) Organic acids - citric acids, lactic acids,
c) Amino acids - glutamic acids, lysine, cyclic AMP and GMP
d) Antibiotics - penicillin, streptomycin, griseofulvin,
e) Vitamins - B_{12}, riboflavin and vitamin C

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

Regulations governing the manufacturing of biological products. **12 Hours**

REFERENCES

1. Principles of Fermentation technology - Peter Stanbury, Allan Whitaker & Stephen Hall. Elsevier.
2. Industrial Microbiology - L.E. Casida. John Wiley & Sons.
3. Current protocols in Molecular Biology - F.M. Asubel. Vol 1 & 2. John Wiley Publishers.
4. Bioreactor Design and Product Yield - Biotol Board. Butterworth and Helhemann Publishers.
5. Industrial Microbiology - H. Patel. Macmillan India Limited.

ADVANCED PHARMACEUTICAL BIOTECHNOLOGY (MPB 104T)

Unit 1:

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

12 Hours

Unit 2:

Genetic engineering: 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. Gene library and cDNA

Applications of the above technique in the production of regulatory proteins - interferon, interleukins, blood products - erythropoietin, vaccines - hepatitis-B, hormones – insulin.

12 Hours

Unit 3:

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

Transgenic animals: Production of useful proteins in transgenic animals and gene therapy.

Human genome: The human genome project - a brief study. Human chromosome – structure and classification, chromosomal abnormalities – syndromes. **12 Hours**

Unit 4:

Signal transduction: Introduction, cell signalling pathways, ion channels, sensors and effectors, ON and OFF mechanisms, spatial and temporal aspects of signalling, cellular process, development, cell cycle and proliferation, neuronal signalling, cell stress, inflammatory responses and cell death, signalling defects and diseases.

Oncogenes: Introduction, definition, various oncogenes and their proteins. **12 Hours**

Unit 5:

Microbial biotransformation:

Biotransformation for the synthesis of chiral drugs and steroids.

Microbial biodegradation: Biodegradation of xenobiotics, chemical and industrial wastes, Production of single-cell protein. Applications of microbes in environmental monitoring.

Biosensors: Definition, characteristics of ideal biosensors, types of biosensors, biological recognition elements, transducers, application of biosensors. **12 Hours**

REFERENCES

1. Biotechnology - The biological principles – M.D. Trevan, S. Boffey, K.H. Goulding & P.F. Stanbury.
2. Immobilization of Cells and Enzymes – Hosevear Kennadycabral & Bicker Staff
3. Principles of Gene Manipulating - R.W. Old & S.B. Primrose.
4. Molecular Cell Biology - Harvey Lodish, David Baltimore, Arnold Berk, S. Lawence Zipursky, Paul Matsudaira & James Darnell.
5. Modern Biotechnology - S.B. Primrose.
6. Gene Transfer and Expression Protocols - Methods in Molecular Biology - E.T. Murray. Vol 7.
7. Current Protocols in Molecular Biology - F.M. Asubel. Vo1 1 & 2. John Wiley Publishers.
8. Current Protocols in Cellular Biology, Vo1 1 & 2. John Wiley Publishers.
9. Principles of Human Genetics - Curt Stern. Published by W.H. Freeman.

PHARMACEUTICAL BIOTECHNOLOGY PRACTICAL - I (MPB 105P)

1. Experiments based on HPLC
2. Isolation and purification of microorganism from the soil
3. Microbial contamination of water and biochemical parameters.
4. Determination of minimum inhibitory concentration by gradient plate technique and serial dilution method.
5. UV- survival curve and Dark repair
6. Sterility test for pharmaceutical preparations
7. Sub culturing of cells and cytotoxicity assays.
8. Construction of growth curve and determination of specific growth rate and doubling time
9. Fermentation process of alcohol and wine production

10. Fermentation of vitamins and antibiotics

PHARMACEUTICAL BIOTECHNOLOGY PRACTICAL - II (MPB 106P)

1. Whole cell immobilization engineering
2. Thermal death kinetics of bacteria
3. Replica plating
4. Bio-autography.
5. Isolation and estimation of DNA
6. Isolation and estimation of RNA
7. Isolation of plasmids
8. Agarose gel electrophoresis.
9. Transformation techniques
10. SDS – polyacrylamide gel electrophoresis for proteins
11. Polymerase chain reaction technique.

Second Semester

PROTEINS AND PROTEIN FORMULATIONS (MPB 201T)

Unit 1:

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. **12 Hours**

Unit 2:

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. **12 Hours**

Unit 3:

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

2-Dimensional gel electrophoresis. Methods including immobilized pH gradients (IPGs), resolution, reproducibility and image analysis, future developments **12 Hours**

Unit 4:

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, PEGylation, biological activity, biophysical characterization techniques, forced degradation studies of protein. **12 Hours**

Unit 5:

Methods of protein sequencing:

Various methods of protein sequencing, characterisation, Edman degradation, tryptic and/or chymotryptic peptide mapping. **12 Hours**

REFERENCES

1. Molecular Cell Biology - H. Lodhishet Al. W. H. Freeman and Company
2. Protein Purification – Hand Book – Amersham. Pharmacia Biotech
3. Fundamentals of Protein Structure and Function - Engelbert Buxbaum. Springer Science
4. Protein Engineering and Design - Sheldon J Park & Jennifer R Cochran. CRC Press.

5. Protein Purification, Principle and Practice - Robert K Skopes. Springer Link.
6. Proteins-Structure and Function - David Whitford. John Wiley & Sons.
7. Protein Formulation and Delivery - James Swarbrick. Informa Healthcare USA, Inc.
8. Formulation, Characterization, and Stability of Protein Drugs - Rodney Pearlman & Y. John Wan., Kluwer Academic Publishers.

IMMUNOTECHNOLOGY (MPB 202T)

Unit 1:

Fundamental aspects of immunology: 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. Lymphocytes and their activation. Structure and function of immunoglobulins, idiotypes and anti idiotypic antibodies. Cell mediated Immunity. 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 **12 Hours**

Unit 2:

Immune regulation and tolerance: Complement activation and types and their biological functions, cytokines and their role in immune response.

Hypersensitivity: Hypersensitivity Types I-IV, Hypersensitivity reactions and treatment. Autoimmune diseases **12 Hours**

Unit 3:

Vaccine technology: 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 applications to immunology. **12 Hours**

Unit 4:

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. **12 Hours**

Unit 5:

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

Immunodiagnosis: Antigen antibody interaction – Precipitation reaction, agglutination reactions, principles and applications of ELISA, radio immuno assay, Western blot analysis, immune-electrophoresis, immuno fluorescence, chemiluminescence assay, complement fixation reaction. **12 Hours**

REFERENCES

1. Immunology – an Introduction - J. Kubey.
2. Immunodiagonstics - S.C. Rastogi. New Age International.
3. Immunology and Immunotechnology - Ashim Chakravarthy. Oxford University Press.
4. Molecular Immunology - E. Benjamini.

BIOINFORMATICS AND COMPUTATIONAL BIOTECHNOLOGY (MPB 203T)

Unit 1:

Introduction to bioinformatics: Definition and history of bioinformatics, internet and bioinformatics, introduction to data mining. Applications of data mining to bioinformatics,

biological database. Protein and nucleic acid databases. Structural data bases. Collecting and storing the sequence and applications of bioinformatics. **12 Hours**

Unit 2:

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. **12 Hours**

Unit 3:

Protein informatics: Introduction; Force field methods; Energy, buried and exposed residues, side chains and neighbours; Fixed regions, hydrogen bonds, mapping properties onto surfaces; Fitting monomers, R & S 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: 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: Docking problems, methods for protein- ligand docking, validation studies and applications; Screening small molecule databases, docking of combinatorial libraries, input data, analyzing docking results. **12 Hours**

Unit 4:

Diversity of genomes: 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: Bacterium, nematode, plant and human

Evolution of genomes, lateral or horizontal transfer among genomes, transcriptome and proteome-general account

Phylogenetic analysis. Evolutionary change in nucleotide sequences, rates and patterns of nucleotide substitution, models for nucleotide substitution, construction of phylogenetic tree, genome annotation technique. **12 Hours**

Unit 5:

Target searching and drug designing: Target and lead, timeline for drug development, target discovery, target modulators, in silico gene expression, microarray, and lead discovery, libraries of ligands, active site analysis, and prediction of drug quality. **12 Hours**

REFERENCES

1. Bioinformatics Sequence and Genome Analysis - David W Mount. CBS Publishers, New Delhi.
2. Bioinformatics - Concepts Skill and Applications - S.C. Rastogi, Namata Mendiaratta & Parag Rastogi. CBS Publishers, New Delhi.
3. Protein Structure and Molecular Properties - T.E. Creighton. W.H. Freeman and Company.

4. Bioinformatics; A Practical Guide to the Analysis of Genes and Proteins - Andreas D Baxevanis & B.F. Francis Ouellette. John Wiley & Sons.
5. Introduction to Bioinformatics - Arthur M Lesk. Oxford University Press.
6. Bioinformatics: A Practical Approach - Shui Qing Ye. Chapman & Hall/CRC.
7. Bioinformatics for DNA Sequence Analysis - David Posada. Humana Press.
8. Introduction to Bioinformatics - A.M. Lesk. Oxford University Press.
9. Bioinformatics - S.I. Letovsky. Kluwer Academic Publishers.
10. Bioinformatics - P. Baldi & S. Brunak. The MIT Press.

BIOLOGICAL EVALUATION OF DRUG THERAPY (MPB 204T)

Unit 1:

Biological standardization: General principles, scope and limitation of bio-assay, bioassay of some official drugs.

Preclinical drug evaluation: Preclinical drug evaluation of its biological activity, potency and toxicity-Toxicity test in animals including acute, sub-acute and chronic toxicity, ED_{50} and LD_{50} determination, special toxicity test like teratogenecity and mutagenecity.

Guidelines for toxicity studies: Various guidelines for toxicity studies. Animal experiments assessing safety of packaging materials. **12 Hours**

Unit 2:

Pyrogens: Sources, chemistry and properties of bacterial pyrogens and endotoxins, official pyrogen tests. Microbiological assay. Assay of antibiotics and vitamins. Biological evaluation of drugs. Screening and evaluation (including principles of screening, development of models for diseases: In vivo models / in vitro models / cell line study). **12 Hours**

Unit 3:

Biologic medicines in development for various diseases - by therapeutic category: genetic disorders, eye related disorders, digestive disorders, diabetes related conditions, cardiovascular disease, cancer related conditions, blood disorders, autoimmune disorders, infectious diseases, neurologic disorders, skin diseases, organ transplantation.

Biologic medicines in development for various diseases by product category: Antisense, vaccines, recombinant hormones/proteins, monoclonal antibodies (MAB), interferons, growth factors, gene therapy, RNA interference. **12 Hours**

Unit 4:

Regulatory aspects of drugs, biologics and medical devices: An introduction to the regulations and documents necessary for approval of a medical product. Regulatory consideration for pre-clinical testing and clinical testing of drugs, biologics and medical devices. New Drug Applications for Global Pharmaceutical Product Approvals **12 Hours**

Unit 5:

Bioavailability: Objectives and consideration in bio-availability studies of biopharmaceuticals, 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 of biopharmaceuticals.

Pharmacokinetics: Basic consideration, Pharmacokinetic models, Application of Pharmacokinetics in new drug development of Biopharmaceuticals and designing of dosage forms and Novel drug delivery systems of Biopharmaceuticals. **12 Hours**

REFERENCES

1. Standardization and Control of Biologicals Produced by Recombinant DNA Technology - F.T. Perkins & W. Hennessen. International Association of Biological Standardization.
2. Biological Standardization - J.H. Burn. Oxford University Press.
3. Drug Discovery and Evaluation in Pharmacology assay - Vogel
4. Design and Analysis of Animal Studies in Pharmaceutical Development - Chow, Shein & Ching.
5. Animal and Clinical Pharmacologic Techniques in Drug Evaluation - Nodine & Siegler.
6. Screening Methods in Pharmacology - R.A. Turner, Vol 1 & 2.

PHARMACEUTICAL BIOTECHNOLOGY PRACTICAL - III (MPB 205P)

1. Protein identification
2. Protein characterization
3. Recombinant DNA technology
4. Protein formulations
5. Database searching
6. Sequence analysis methods
7. Protein structure prediction
8. Gene annotation methods
9. Phylogenetic analysis
10. Preparation of DNA for PCR applications – Isolation, purity and quantification
11. Introduction to PCR – working of PCR, programming
12. Introduction to RT-PCR – working, programming
13. Primer design using software
14. Gene DNA amplification by random / specific primers
15. Western Blotting

PHARMACOLOGY (MPL)

First Semester

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES (MPH 101T)

(Note: Common paper for MPA, MPC, MPH, MPB, MPL, MPG, MQA, & MIP, specializations)

Unit 1:

a. UV-visible spectroscopy: Introduction, theory, laws and instrumentation associated with UV-visible spectroscopy, choice of solvents and solvent effect and applications of UV-visible spectroscopy.

b. IR spectroscopy: Theory, modes of molecular vibrations, sample handling, instrumentation of dispersive and Fourier-Transform IR Spectrometer, factors affecting vibrational frequencies and applications of IR spectroscopy, data interpretation.

c. Spectroflourimetry: Theory of fluorescence, factors affecting fluorescence (characteristics of drugs that can be analyzed by flourimetry), quenchers, instrumentation and Applications of fluorescence spectrophotometer.

d. Flame emission spectroscopy and Atomic absorption spectroscopy: Principle, instrumentation, interferences and applications. **12 Hours**

Unit 2:

NMR spectroscopy: Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and 13C NMR. Applications of NMR spectroscopy. **10 Hours**

Unit 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. 1**0 Hours**

Unit 4:

Chromatography: Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution, isolation of drug from excipients, data interpretation and applications of the following:

a) Thin Layer chromatography **b)** High Performance Thin Layer Chromatography **c)** Ion exchange chromatography **d)** Column chromatography **e)** Gas chromatography **f)** High Performance Liquid chromatography **g)** Ultra High Performance Liquid chromatography **h)** Affinity chromatography **i)** Gel Chromatography. **14 Hours**

Unit 5:

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

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

c. Thermal Techniques: Principle, instrumentation, advantage and disadvantages, Pharmaceutical applications of DSC, DTA & TGA.

d. Microscopic techniques: Principles and applications of Scanning Electron Microscopy

and Transmission Electron Microscopy analysis. **14 Hours**

REFERENCES

1. Spectrometric Identification of Organic compounds - Robert M Silverstein. 6th ed. John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler & Timothy A. Nieman. 5th ed. Eastern Press, Bangalore, 1998.
3. Instrumental Methods of Analysis – Willards. 7th ed. CBS Publishers, New Delhi.
4. Practical Pharmaceutical Chemistry – Beckett and Stenlake. Vol 2. 4th ed. CBS Publishers, New Delhi
5. Organic Spectroscopy - William Kemp. 3rd ed. ELBS, 1991.
6. Quantitative Analysis of Drugs in Pharmaceutical Formulation – P.D. Sethi. 3rd ed. CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis - Modern Methods – Part B – J.W. Munson. Vol 11. Marcel-Dekker Series.
8. Spectroscopy of Organic Compounds - P.S. Kalsi. 2nd ed. Wiley Estern Ltd., Delhi.
9. Textbook of Pharmaceutical Analysis - K.A. Connors. 3rd ed. John Wiley & Sons.

ADVANCED PHARMACOLOGY – I ((MPL 102T)

Unit 1:

General pharmacology: Drug receptor concepts, relationship between drug concentration and effect, Structural and functional families of the receptors, quantification of drug receptor interaction. Basic concepts of pharmacokinetics. Types of adverse effects. **12 Hours**

Unit 2:

Neurohumoral transmission in peripheral nervous system: Neurotransmitters of autonomic nervous system, nonadrenergic and noncholinergic transmitters. Pharmacology of autonomous nervous system, parasympathomimetics, parsympatholytics, sympathomimetics, sympatholytics. Pharmacology of local anaesthetics. **12 Hours**

Unit 3:

Neurohumoral transmission of central nervous system- neurotransmitters of central nervous system (Detailed study of dopaminergic, serotonergic, GABA, adrenergic, glutamate, cholinergic pathways). Pharmacology of drugs acting on central nervous system- general anaesthetics, sedatives, hypnotics, antianxiety, antidepressants, antipsychotics, antiepileptics, antimaniacs, opioid and non-opioid analgesics. **12 Hours**

Unit 4:

Cardiovascular pharmacology: Diuretics, antihypertensives, antianginal drugs, antiarrythmics, antihyperlipidemics, cardiotonics, coagulants, anticoagulants, fibrinolytics, antiplatelet agents, hematinics. **12 Hours**

Unit 5:

Neurodegenerative disorders: Parkinsonism, Alzheimer's disease, Huntington's disease, concepts of free radical generation. Introduction to free radical induced disorders (diabetes, asthma, gastric ulcer, cardiovascular disorder). **12 Hours**

REFERENCES

1. Goodman and Gillman's: The Pharmacological Basis of Therapeutics - Laurence L Brunton, Randa Hilal-Dandan & Björn C Knollmann. 13th ed. Mc Graw Hill Education.
2. Principles of Pharmacology: The Pathophysiologic Basis of Drug Therapy - David E Golan, Armen H Tashjian Jr, Ehrin J Armstrong & April W Armstrong. Wolters, Kluwer-Lippincott Williams & Wilkins Publishers.

3. Oxford Textbook of Clinical Pharmacology - Graham Smith.
4. Avery Drug Treatment - Trevor M Speight & Nicholas H G Holford.
5. Dipiro Pharmacology, Pathophysiological approach.
6. Robbins & Cortan Pathologic Basis of Disease. 9th ed. (Robbins Pathology)
7. Essentials of Medical Pharmacology – K.D. Tripathi.
8. Modern Pharmacology with Clinical Applications - R. Craig Charles & E. Stitzel Robert. Lippincott.
9. Modern Pharmacology – C.R. Craig & R.E. Stitzel. Little Brown & Company.
10. Green Pathophysiology for Pharmacists.
11. A Complete Text Book of Medical Pharmacology - S.K. Srivastava. APC Avichal Publishing.

PHARMACOKINETICS AND DRUG METABOLISM (MPL 103T)

Unit 1:

ADME: Transfer of drugs through biological membranes (BBB, placental barrier), role of P-glycoprotein in drug absorption. Gastrointestinal, percutaneous and rectal absorption, factors affecting drug absorption, absorption kinetics, distribution kinetics (plasma protein binding, tissue binding). **12 Hours**

Unit 2:

Drug metabolism: Microsomal and non-microsomal biotransformation of drugs (liver, kidney and intestine), human cytochrome P450 enzymes, substrates, inducers and inhibitors. In vitro drug metabolism (liver microsomes, liver S9 fraction and hepatocytes). Physiological, pathological and genetic factors affecting drug metabolism. **12 Hours**

Unit 3:

Routes of drug excretion, factors affecting drug excretion, enterohepatic recirculation, significance of elimination rate constant, elimination half-life. **12 Hours**

Unit 4:

Clinical pharmacokinetics, population pharmacokinetic, PK-PD modeling, therapeutic drug monitoring (TDM), and dug-drug interactions, drug food and predictions of drug-drug interactions. **12 Hours**

Unit 5:

Toxicokinetics: Toxicokinetic evaluation in pre-clinical studies, importance and applications of toxicokinetic studies, alternative methods to animal toxicity studies. **12 Hours**

REFERENCES

1. Biopharmaceutics and Pharmacokinetics - An Introduction - Robert E Notari.
2. Drug metabolism - Bernard Testa & Peter Jenner.
3. Selected Chapters from: Principles of Drug Action - Gldstein, Aranow & Kalman.
4. Drug Interaction - D.G. Grahme Smith
5. Remington – The Science and Practice of Pharmacy – Loyd V Allen. 22nd ed.
6. Goodman and Gillman's The Pharmacological Basis of Therapeutics. 10th ed.
7. Hand book of Clinical Pharmacokinetics - Gibaldi and Prescott.
8. Applied Biopharmaceutics and Pharmacokinetics - Leon Shargel & Andrew B C Yu.
9. Clinical Pharmacokinetics & Pharmacodynamics - Malcolm Rowland & Tozer. 4th ed. Lippincott Publications.
10. Applied Biopharmaceutics and Pharmacokinetics, Pharmacodynamics and Drug

Metabolism for Industrial Scientists.

11. Hand Book of Essential Pharmacokinetics, Pharmacodynamics & Drug Metabolism for Industrial Scientists.

CELLULAR AND MOLECULAR PHARMACOLOGY (MPL 104T)

Unit 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 Hours**.

Unit 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: cyclicAMP signaling pathway, mitogen-activated protein kinase (MAPK) signaling, Janus kinase (JAK)/signal transducer and activator of transcription (STAT) signaling pathway. **12 Hours**

Unit 3:

Principles of recombinant DNA technology - restriction enzymes, various types of vectors. Applications of recombinant DNA technology. ELISA and Western blotting Gene therapy-Various types of gene transfer techniques, clinical applications and recent advances in gene therapy. **12 Hours**

Unit 4:

Gene mapping and cloning of disease gene. Genetic variation and its role in health/ pharmacology. Pharmacogenomics, polymorphisms affecting drug metabolism, Genetic variation in drug transporters, Genetic variation in G protein coupled receptors. **12 Hours**

Unit 5:

Cell culture techniques: Basic equipment 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. Biosimilars. **12 Hours**

REFERENCES

1. Molecular Biology of The Cell - Bruce Alberts and et al. 5th ed. Garland Science.
2. Cell and Molecular Biology - E.D.P. De Robertis & E.M.F. De Robertis Jr. 8th ed. Wolter Publications.
3. Molecular Cell Biology - Harvey Lodish et al. 6th ed. W.H. Freeman & Company.
4. Molecular Biology and Biotechnology - John M Walker & Ralph Raple. 5th ed. RSC Publications.
5. A Concise Reference Advanced Molecular Biology - R.M. Twyman, Viva Books Pvt. Ltd.
6. Principles of Gene Manipulation and Genomics - S.B. Primrose & R.M. Twyman. 7th edn.
7. The Cell, A Molecular Approach - Geoffrey M Cooper.
8. Pharmacogenomics - J. Licinio & M.L. Wong
9. Handbook of Cell Signaling – A. Ralph et al. 2nd ed.
10. Molecular Pharmacology: From DNA to Drug Discovery - John Dickenson et al.
11. Basic Cell Culture Protocols - Cheril D Helgason & Cindy L Miller

12. Basic Cell Culture (Practical Approach) - J. M. Davis.
13. Animal Cell Culture: A Practical Approach - John R Masters.
14. Current Protocols in Molecular Biology - Frederick M. Ausuvel et al. Vol 1 to 6.

PHARMACOLOGY PRACTICAL – I (MPL 105P)

1. Enzyme based in vitro assays (MPO, AChEs, α amylase, α glucosidase)
2. Handling of laboratory animals
3. Various routes of drug administration.
4. Pharmacokinetic studies and data analysis of drugs given by different routes of administration using software
5. Enzyme inhibition and induction activity
6. Extraction of drug from various biological samples and estimation of drugs in biological fluids using different analytical techniques (UV)
7. Extraction of drug from various biological samples and estimation of drug in biological fluids using different analytical techniques (HPLC)
8. Predictions of drug - drug interactions using software

PHARMACOLOGY PRACTICAL – II (MPL 106P)

1. Functional observation battery tests (modified Irwin test).
2. Evaluation of CNS stimulant, depressant, anxiogenics and anxiolytic, anticonvulsant activity.
3. Evaluation of analgesic & anti-inflammatory.
4. Evaluation of local anesthetic, mydriatic and miotic activity.
5. Evaluation of diuretic activity.
6. Evaluation of antiulcer activity models
7. Estimation of glucose and lipid parameters in blood samples.
8. Estimation of lipid levels in tissues.
9. Oral glucose tolerance test, oral fat tolerance test.

Second Semester

ADVANCED PHARMACOLOGY – II (MPL 201T)

Unit 1:

Chemotherapy: Basic concepts of chemotherapy, pharmacology of antibacterial resistance, pharmacology of antibacterial agents – β – lactams, aminoglycosides, tetracyclins, chloramphenicol, macrolide antibiotics, fluoroquinolines, antitubercular, antileprotic, antiprotozoal (antimalarial, asntiamoebics., etc.) and anthelmintics. **12 Hours**

Unit 2:

Antiviral, antifungal, anticancer drugs: Drugs acting on immune disorders (rhematoid arthritis, asthma, COPD), immunosupressants. **12 Hours**

Unit 3:

Endocrine pharmacology: Pharmacology of hormones (hormones of hypothalamic pituitary axis), pancreatic hormones, pharmacology of antithyroid drugs, oral contraceptives, oral hypoglycemic drugs, corticosteroids, drugs affecting calcium regulation. **12 Hours**

Unit 4:

GIT pharmacology: Antiulcer drugs, antiemetics, antidiarrhoeals, drugs used for intestinal bowel disorders (IBD) and constipation.

Respiratory Pharmacology: Antiasthmatics, cough suppressants, expectorants and drugs used in COPD. **12 Hours**

Unit 5:

Autacoid pharmacology: Physiological and pathological role of histamines, serotonin, prostaglandins, kinins, interleukins, substance P, neuropeptides, NFkβ. Pharmacology of antihistamines, 5 HT antagonists. Concept of chronopharmacology, circadian rhythm and its applications. **12 Hours**

REFERENCES

1. Goodman and Gillman's The Pharmacological Basis of Therapeutics. 10th ed.
2. Principles of Pharmacology: The Pathophysiologic Basis of Drug Therapy - David E Golan, Armen H Tashjian Jr, Ehrin J Armstrong & April W Armstrong. Wolters, Kluwer-Lippincott Williams & Wilkins Publishers.
3. Basic and Clinical Pharmacology - B.G. Katzung
4. Rang and Dale's Pharmacology - James Ritter, Rod Flower, Graeme Henderson, Yoon Kong Loke, David MacEwan & Humphrey Rang
5. Text book of Therapeutics, Drug and Disease Management - E T. Herfindal & Gourley.
6. Robbins & Cortan Pathologic Basis of Disease, 9th ed. (Robbins Pathology)
7. A Complete Text Book of Medical Pharmacology - S.K. Srivastava. APC Avichal Publishing.
8. Essentials of Medical Pharmacology - K.D. Tripathi.
9. Principles of Pharmacology. The Pathophysiologic basis of drug Therapy - David E Golan, H. Armen, Tashjian Jr, J. Ehrin, Armstrong, W. April & Armstrong. Wolters, Kluwer-Lippincott Williams & Wilkins Publishers.
10. Relevant Research and Review articles

PHARMACOLOGICAL AND TOXICOLOGICAL SCREENING METHODS (MPL 202T)

Unit 1:

Laboratory animals/Common laboratory animals: Description, handling and applications of different species and strains of animals. Transgenic animals: Production, maintenance and applications. Anesthesia and euthanasia of experimental animals, Maintenance and breeding of laboratory animals. CPCSEA, OECD, ICH, EPA guidelines to conduct experiments on animals. Good laboratory practice. Bioassay - Principles, scope and limitations and methods of Immunoassays. **12 Hours**

Unit 2:

Preclinical screening of new substances for the pharmacological activity using in vivo, in vitro, and other possible animal alternative models. General principles of preclinical screening. **12 Hours**

CNS Pharmacology: Behavioral and muscle co ordination, CNS stimulants and depressants, anxiolytics, anti-psychotics, anti epileptics and nootropics. Drugs for neurodegenerative diseases like Parkinsonism, Alzheimer's and multiple sclerosis. Screening of drugs acting on Autonomic Nervous System

Unit 3:

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

Respiratory pharmacology: Anti-asthmatics, drugs for COPD and anti-allergics. **Reproductive pharmacology:** Aphrodisiacs and antifertility agents. Analgesics, anti-

inflammatory and antipyretic agents.

Gastrointestinal drugs: Anti-ulcer, anti-emetic, anti-diarrheals and laxative. **12 Hours**

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

Cardiovascular pharmacology: Antihypertensives, antiarrythmics, antianginal, antiatherosclerotic agents and diuretics. Drugs for metabolic disorders like anti-diabetic, anti-dyslipidemic agents. Anti-cancer agents. Hepatoprotective screening methods. **12 Hours**

Unit 5:

Toxicity studies (acute, sub acute and chronic) oral, inhalation and dermal toxicity studies. Reproductive toxicity – Teratogenicity, genotoxicity (Ames test, in vitro, in vivo micronucleus, chromosomal aberrations) carcinogenicity. Introduction to IND Studies.

12 Hours

REFERENCES

1. Biological Standardization - J.H. Burn, D.J. Finney & I.G. Goodwin.
2. Screening Methods in Pharmacology - A. Robert Turner.
3. Evaluation of Drugs Activities - Laurence & Bachrach.
4. Fundamentals of Experimental Pharmacology - M.N. Ghosh.
5. Pharmacological Experiments on Intact Preparations - Churchill Livingstone
6. Drug Discovery and Evaluation – H.G. Vogel.
7. Experimental Pharmacology - R.K. Goyal.
8. Handbook of Experimental Pharmacology – S.K. Kulkarni
9. Practical Pharmacology and Clinical Pharmacy - S.K. Kulkarni, 3rd ed.
10. Screening Methods in Pharmacology - Robert A Turner.
11. Rodents for Pharmacological Experiments - Tapan Kumar Chatterjee.
12. Practical Manual of Experimental and Clinical Pharmacology - Bikash Medhi & Ajay Prakash.
13. Methods in Pharmacology - Arnold Schwartz.
14. Preclinical Evaluation of New Drugs - S.K. Guta.
15. Animal Models in Cardiovascular Research - David R Gross, 2nd ed. Kluwer Academic Publishing.
16. OECD Test Guidelines.
17. Relevant Research and Review articles and guidelines

PRINCIPLES OF DRUG DISCOVERY (MPL 203T)

Unit 1:

An overview of modern drug discovery process: Target identification, target validation, lead identification and lead Optimization. Economics of drug discovery. Target Discovery and validation. **12 Hours**

Unit 2:

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. Lead identification - combinatorial chemistry & high throughput screening, in silico lead discovery techniques. Assay development for hit identification. **12 Hours**

Unit 3:

Rational drug design - Traditional vs. rational drug design. Methods followed in traditional drug design. High throughput screening, Concepts of rational drug design. **12 Hours**

Unit 4:

Rational drug design methods: Structure and pharmacophore based approaches. Molecular docking - rigid docking, flexible docking, manual docking; Docking based screening. De novo drug design. Quantitative analysis of structure activity relationship. **12 Hours**

Unit 5:

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. **12 Hours**

REFERENCES

1. Target Discovery and Validation Reviews and Protocols - Emerging Molecular Targets and Treatment Options - Mouldy Sioud. Vol 2. Humana Press Inc., 2007.
2. Silico Technologies in Drug Target Identification and Validation - Darryl León. Scott Markel In., 2006. Taylor and Francis Group, LLC.
3. Disease Gene Identification: Methods and Protocols - Johanna K DiStefano. Springer New York Dordrecht Heidelberg, London.
4. QSAR: Hansch Analysis and Related Approaches: Methods and Principles in Medicinal Chemistry - Hugo Kubiny. Wiley-VCH.
5. Structure - Based Ligand Design: Methods and Principles in Medicinal Chemistry - Klaus Gubernator & Hans-Joachim Böhm. Wiley-VCH.
6. Rational Drug Design: Novel Methodology and Practical Applications - Abby L Parrill. M. Rami Reddy. ACS Symposium Series; American Chemical Society: Washington, DC, 1999.
7. New Drug Development Design, Methodology and Analysis - J. Rick Turner. John Wiley & Sons, Inc., New Jersey.
8. Relevant Research and Review articles and guidelines

CLINICAL RESEARCH AND PHARMACOVIGILANCE (MPL 204T)

Unit 1:

Regulatory perspectives of clinical trials: Origin and principles of International Conference on Harmonization - Good Clinical Practice (ICH-GCP) guidelines.

Ethical committee: Institutional Review Board, ethical guidelines for biomedical research and human participant - Schedule Y. ICMR informed consent process: structure and content of an informed consent process, ethical principles governing informed consent process.

12 Hours

Unit 2:

Clinical trials: Types and design of experimental study- RCT and non RCT.

Observation study: Cohort, case control, cross sectional clinical trial study - Team roles and responsibilities of clinical trial personnel: Investigator, Study Coordinator, Sponsor, Contract Research Organization and its management. **12 Hours**

Unit 3:

Clinical trial documentation: Guidelines to the preparation of documents, preparation of protocol, Investigator Brochure, Case Report Forms, Clinical Study Report.

Clinical trial monitoring - Safety monitoring in clinical trial adverse drug reactions: Definition and types. Detection and reporting methods. Severity and seriousness assessment. Predictability and preventability assessment, Management of adverse drug reactions;

Terminologies of ADR. **12 Hours**

Unit 4:

Basic aspects, terminologies and establishment of pharmacovigilance: History and progress of pharmacovigilance. Significance of safety monitoring. Pharmacovigilance in India and international aspects, WHO international drug monitoring programme, WHO and Regulatory terminologies of ADR, evaluation of medication safety, establishing pharmacovigilance centres in hospitals, industry and national programmes related to pharmacovigilance. Roles and responsibilities in pharmacovigilance, guidelines for ADR reporting, Argus, Aris G Pharmacovigilance, Vigi Flow. Statistical methods for evaluating medication safety data. Methods, ADR reporting and tools used in pharmacovigilance. **12 Hours**

Unit 5:

Pharmacoepidimology and pharmacoeconomics: Definition and scope, measurement of outcomes, Pharmacoepidimology methods, Definition evaluation and applications of pharmacoeconomic methods. **12 Hours**

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 - David Machin, Simon Day & Sylvan Green. John Wiley and Sons, March 2005.
5. Clinical Data Management – R.K. Rondels, S.A. Varley & C.F. Webbs. 2nd ed. Wiley Publications, Jan 2000.
6. Handbook of Clinical Research - Julia Lloyd & Ann Raven. Churchill Livingstone.
7. Principles of Clinical Research - Giovanna di Ignazio & Di Giovannaand Haynes.
8. Relevant Research and Review articles and guidelines

PHARMACOLOGY PRACTICAL – III (MPL 205P)

1. Recording of rat BP, heart rate and ECG
2. Recording of rat ECG
3. Drug absorption studies by averted rat ileum preparation
4. Acute oral toxicity studies as per OECD guidelines
5. Acute dermal toxicity studies as per OECD guidelines
6. Repeated dose toxicity studies- Serum biochemical, haematological, urine analysis, functional observation tests and histological studies
8. Protocol design for clinical trial.(3 Nos.)
9. To record the DRC of agonist using suitable isolated tissues preparation
10. To study the effects of antagonist/potentiating agents on DRC of agonist using suitable isolated tissue preparation
11. To determine to the strength of unknown sample by matching bioassay by using suitable tissue preparation
12. To determine to the strength of unknown sample by interpolation bioassay by using suitable tissue preparation

13. To determine to the strength of unknown sample by bracketing bioassay by using suitable tissue preparation
14. To determine to the strength of unknown sample by multiple point bioassay by using suitable tissue preparation
15. Estimation of PA2 values of various antagonists using suitable isolated tissue preparations
16. To study the effects of various drugs on isolated heart preparations

Note: Minimum 10 Experiments from the above is mandatory

PHARMACOGNOSY (MPG)

First Semester

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES (MPA 101T)

(Note: Common paper for MPA, MPC, MPH, MPB, MPL, MPG, MQA, & MIP, specializations)

Unit 1:

a. UV-visible spectroscopy: Introduction, theory, laws and instrumentation associated with UV-visible spectroscopy, choice of solvents and solvent effect and applications of UV-visible spectroscopy.

b. IR spectroscopy: Theory, modes of molecular vibrations, sample handling, instrumentation of dispersive and Fourier-Transform IR Spectrometer, factors affecting vibrational frequencies and applications of IR spectroscopy, data interpretation.

c. Spectroflourimetry: Theory of fluorescence, factors affecting fluorescence (characteristics of drugs that can be analysed by flourimetry), quenchers, instrumentation and Applications of fluorescence spectrophotometer.

d. Flame emission spectroscopy and Atomic absorption spectroscopy: Principle, instrumentation, interferences and applications. **12 Hours**

Unit 2:

NMR spectroscopy: Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and 13C NMR. Applications of NMR spectroscopy. **10 Hours**

Unit 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. 1**0 Hours**

Unit 4:

Chromatography: Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution, isolation of drug from excipients, data interpretation and applications of the following:

a) Thin Layer chromatography **b)** High Performance Thin Layer Chromatography **c)** Ion exchange chromatography **d)** Column chromatography **e)** Gas chromatography **f)** High Performance Liquid chromatography **g)** Ultra High Performance Liquid chromatography **h)** Affinity chromatography **i)** Gel Chromatography. **14 Hours**

Unit 5:

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

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

c. Thermal Techniques: Principle, instrumentation, advantage and disadvantages, Pharmaceutical applications of DSC, DTA & TGA.

d. Microscopic techniques: Principles and applications of Scanning Electron Microscopy

and Transmission Electron Microscopy analysis. **14 Hours**

REFERENCES

1. Spectrometric Identification of Organic compounds - Robert M Silverstein. 6th ed. John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler & Timothy A. Nieman. 5th ed. Eastern Press, Bangalore, 1998.
3. Instrumental Methods of Analysis – Willards. 7th ed. CBS Publishers, New Delhi.
4. Practical Pharmaceutical Chemistry – Beckett and Stenlake. Vol 2. 4th ed. CBS Publishers, New Delhi
5. Organic Spectroscopy - William Kemp. 3rd ed. ELBS, 1991.
6. Quantitative Analysis of Drugs in Pharmaceutical Formulation – P.D. Sethi. 3rd ed. CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis - Modern Methods – Part B – J.W. Munson. Vol 11. Marcel-Dekker Series.
8. Spectroscopy of Organic Compounds - P.S. Kalsi. 2nd ed. Wiley Estern Ltd., Delhi.
9. Textbook of Pharmaceutical Analysis - K.A. Connors. 3rd ed. John Wiley & Sons.

ADVANCED PHARMACOGNOSY - I (MPG 102T)

Unit 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 Hours**

Unit 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 Hours**

Unit 3:

Nutraceuticals: Current trends and future scope. Inorganic mineral supplements, vitamin supplements, digestive enzymes, dietary fibres, cereals and grains, health drinks of natural origin, antioxidants, polyunsaturated fatty acids, herbs as functional foods. Formulation and standardization of 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 Hours**

Unit 4:

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

a) Carotenoids – i) α and β - Carotene ii) Xanthophyll (Lutein)
b) Limonoids – i) d-Limonene ii) α – Terpineol
c) Saponins – i) Shatavarins
d) Flavonoids – i) Resveratrol ii) Rutin iii) Hesperidin iv) Naringin v) Quercetin
e) Phenolic acids- Ellagic acid
f) Vitamins
g) Tocotrienols and Tocopherols
h) Andrographolide, Glycolipids, Gugulipids, Withanolides, Vascine, Taxol

i) Miscellaneous **12 Hours**

Unit 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 Hours**

REFERENCES

1. Pharmacognosy - G. E. Trease & W.C. Evans. Saunders Edinburgh, New York.
2. Pharmacognosy - Tyler, Brady & Robbers.
3. Modem Methods of Plant Analysis - Peach & M.V. Tracey. Vol 1 & 2
4. Text Book of Pharmacognosy - T.E. Wallis.
5. Marine Natural Products -Vol. 1 to 6.
6. Natural Products: A Lab Guide - Raphael Ikan. Academic Press, 1991.
7. Glimpses of Indian Ethano Pharmacology - P. Pushpangadam. U.L.F. Nyman & V. George. Tropical Botanic Garden & Research Institute, 1995.
8. Medicinal Natural Products (A Biosynthetic Approach) - Paul M Dewick. John Wiley & Sons Ltd., England, 1998.
9. Chemistry of Marine Natural Products - Paul J Schewer. 1973.
10. Herbal Drug Industry – R.D. Choudhary. Eastern Publisher, New Delhi, 1996.
11. Cultivation of Medicinal Plants - C.K. Atal & B.M. Kapoor.
12. Cultivation and Utilization of Aromatic Plants - C.K. Atal & B.M. Kapoor.
13. Cultivation of Medicinal and Aromatic Crops – A.A. Farooqui & B.S. Sreeramu. University Press, 2001.
14. Natural Products from Plants - Peter B Kaufman. 1st ed. CRC Press, New York, 1998.
15. Recent Advances in Phytochemistry - Scikel Runeckles. Vol. 1 & 4. Appleton Century Crofts.
16. Text book of Pharmacognosy - C.K. Kokate, Purohit & Ghokhale. Nirali Prakasshan, 1996.
17. Pharmacognosy and Pharmacobiotechnology – Ashutoshkar. New Age Publications, New Delhi.

PHYTOCHEMISTRY (MPG 103T)

Unit 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 phytopharmaceuticals containing drugs:

a) Alkaloids: Ephedrine, quinine, strychynine, piperine, berberine, taxol, vinca alkoloids.
b) Glycosides: Digitoxin, glycyrrhizin, sennosides, bacosides, quercitin.
c) Steroids: Hecogenin, guggulosterone and withanolides
d) Coumarin: Umbelliferone.
e) Terpenoids: Cucurbitacins **12 Hours**

Unit 2:

Drug discovery and development: History of herbs as source of drugs and drug discovery, the lead structure selection process, structure development, product discovery process and drug registration. Selection and optimization of lead compounds with suitable examples from

the following sources: artemesin, morphine, taxol, andrographolides. Clinical studies emphasising on phases of clinical trials, protocol design for lead molecules. **12 Hours**

Unit 3:

Extraction and phytochemical studies: Recent advances in extractions with emphasis on selection of method and choice of solvent for extraction, successive and exhaustive extraction and other methods of extraction commonly used like microwave assisted extraction, methods of fractionation. Separation of phytoconstituents by latest CCCET, SCFE techniques including preparative HPLC and flash column chromatography. **12 Hours**

Unit 4:

Phytochemical finger printing: HPTLC and LCMS/GCMS applications in the characterization of herbal extracts. Structure elucidation of phytoconstituents. **12 Hours**

Unit 5:

Structure elucidation of the following compounds by spectroscopic techniques like UV, IR, MS, NMR (^{1}H, ^{13}C)

a) Carvone, citral, menthol;
b) Luteolin, kaempferol;
c) Nicotine, caffeine
d) Glycyrrhizin. **12 Hours**

REFERENCES

1. Organic chemistry - I.L. Finar. Vol.II
2. Pharmacognosy - G. E. Trease & W.C. Evans. Saunders Edinburgh, New York.
3. Pharmacognosy - Tyler, Brady & Robbers
4. Text Book of Pharmacognosy - T.E. Wallis.
5. Clark's isolation and Identification of drugs - A.C. Mottal.
6. Plant Drug Analysis - H. Wagner & S. Bladt. Springer, Berlin.
7. Wilson and Gisvolds text book of Organic Medicinnal and Pharmaceutical Chemistry - R.F. Deorge.
8. The Chemistry of Natural Products - R.H. Thomson. Springer International ed. 1994.
9. Natural Products Chemistry Practical Manual - Anees A Siddiqui & Seemi Siddiqui.
10. Organic Chemistry of Natural Products - Gurdeep R Chatwal. Vol. 1 & 2.
11. Chemistry of Natural Products – IWPAC, Vol. 1 onwards.
12. Modem Methods of Plant Analysis - Peach & M.V. Tracey, Vol. I & II
13. Medicinal Natural Products (A Biosynthetic Approach) - Paul M Dewick. John Wiley & Sons Ltd., England, 1998.
14. Chemistry of Natural Products - S.V. Bhat, B.A. Nagasampagi & S. Meenakshi. Narosa Publishing House, New Delhi.
15. Pharmacognosy & Phytochemistry of Medicinal Plants – J. Bruneton. 2nd ed. Intercept Ltd., New York, 1999.

INDUSTRIAL PHARMACOGNOSTICAL TECHNOLOGY (MPG 104T)

Unit 1:

Herbal drug industry: Infrastructure of herbal drug industry involved in production of standardized extracts and various dosage forms. Current challenges in upgrading and modernization of herbal formulations. Entrepreneurship development, Project selection, project report, technical knowledge, capital venture, plant design, layout and construction. Pilot plant scale up techniques, case studies of herbal extracts. Formulation and production

management of herbals. **12 Hours**

Unit 2:

Regulatory requirements for setting herbal drug industry: Global marketing management. Indian and international patent law as applicable herbal drugs and natural products. Export - Import (EXIM) policy, TRIPS. Quality assurance in herbal/natural drug products. Concepts of TQM, GMP, GLP, ISO-9000. **12 Hours**

Unit 3:

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

Unit 4:

Testing of natural products and drugs: Herbal medicines - clinical laboratory testing. Stability testing of natural products, protocols. **12 Hours**

Unit 5:

Patents: Indian and international patent laws, proposed amendments as applicable to herbal/natural products and process. Geographical indication, copyright, patentable subject maters, 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 Hours**

REFERENCES

1. Herbal Drug Industry - R.D. Choudhary. Eastern Publisher, New Delhi, 1996.
2. GMP for Botanicals - Regulatory and Quality Issues on Phytomedicine - Pulok K Mukharjee. 1st ed. Business Horizons Pharmaceutical Publisher, New Delhi, 2003.
3. Quality Control of Herbal Drugs - Pulok K Mukarjee, Business Horizons Pharmaceutical Publisher, New Delhi, 2002.
4. PDR for Herbal Medicines. Medicinal Economic Company, New Jersey, 2000.
5. Indian Herbal Pharmacopoeia - 2002, IDMA, Mumbai.
6. Text Book of Pharmacognosy - C.K. Kokate, Purohit & Gokhlae, Nirali Prakashan, New Delhi, 1996.
7. Text Book of Pharmacognosy and Phytochemistry - Vinod D. Rangar, Part I & II. Career Publication, Nasik, India, 2002.
8. Plant Drug Analysis - H. Wagner & S. Bladt. Springer, Berlin.
9. Standardization of Botanicals: Testing and Extraction Methods of Medicinal Herbs - V. Rajpal, Vol. I. Eastern Publisher, New Delhi, 2004.
10. Phytochemical Dictionary: Handbook of Bioactive Compounds from Plants - J.B. Harborne. 2nd ed. Taylor and Francis Ltd, UK, 1999.
11. Herbal Medicine: Expanded Commission E Monographs - M. Blumenthal. IST Edition, 2004.
12. Drug Formulation Manual - D.P.S. Kohli and D.H. Shah. Eastern Publisher, New Delhi, 1998.

PHARMACOGNOSY PRACTICAL - I (MPG I05P)

1. Analysis of Pharmacopoeial compounds of natural origin and their formulations by UV Vis spectrophotometer
2. Analysis of recorded spectra of simple phytoconstituents
3. Experiments based on Gas Chromatography

4. Estimation of sodium/potassium by flame photometry
5. Development of fingerprint of selected medicinal plant extracts commonly used in herbal drug industry viz. ashwagandha, tulsi, bael, amla, ginger, aloe, vidang, senna, lawsonia by TLC/HPTLC method.
6. Methods of extraction

PHARMACOGNOSY Practical – II (MPG 106P)

1. Phytochemical screening
2. Demonstration of HPLC - estimation of glycerrhizin
3. Monograph analysis of clove oil
4. Monograph analysis of castor oil
5. Identification of bioactive constituents from plant extracts
6. Formulation of different dosage forms and their standardisation

Semester 2

MEDICINAL PLANT BIOTECHNOLOGY (MPG 201T)

Unit 1:

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 signalling, DNA recombinant technology. **12 Hours**

Unit 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 Hours**

Unit 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 Hours**

Unit 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 Hours**

Unit 5:

Fermentation technology: Application of fermentation technology, production of ergot alkaloids, single cell proteins, enzymes of pharmaceutical interest. **12 Hours**

REFERENCES

1. Plant Tissue Culture - Bhagwani, Vol. 5. Elsevier Publishers.
2. Plant Cell and Tissue Culture (Lab. Manual), JRMM. Yeoman.
3. Elements in Biotechnology - P.K. Gupta. Rastogi Publications, New Delhi.
4. An introduction to Plant Tissue Culture - M.K. Razdan. Science Publishers.

5. Experiments in Plant Tissue Culture - John HD & W.R. Lorin. Cambridge University Press.
6. Pharmaceutical Biotechnology - S.P. Vyas and V.K. Dixit. CBS Publishers, New Delhi.
7. Plant Cell and Tissue Culture - Jeffrey W. Pollard & John M Walker, Humana Press.
8. Plant Tissue Culture - Dixon, Oxford Press, Washington DC, 1985
9. Plant Tissue Culture - Street.
10. Pharmacognosy - G. E. Trease & W.C. Evans. Saunders Edinburgh, New York.
11. Biotechnology - Purohit & Mathur, Agro-Bio, 3rd Revised Edition.
12. Biotechnological Applications to Tissue Culture – Shargool & D. Peter. CKC Press.
13. Pharmacognosy - Varo E Tyler, Lynn R Brady & James E Robberrt. That Tjen, NGO.
14. Plant Biotechnology - Ciddi Veerasham.

ADVANCED PHARMACOGNOSY - II (MPG 202T)

Unit 1:

Herbal remedies: Toxicity and regulations. Herbals vs. conventional drugs, efficacy of herbal medicine products, validation of herbal therapies, pharmacodynamic and pharmacokinetic issues. **12 Hours**

Unit 2:

Adulteration and deterioration: Introduction, types of adulteration/ substitution of herbal drugs, causes and measures of adulteration, sampling procedures, determination of foreign matter, DNA finger printing techniques in identification of drugs of natural origin, detection of heavy metals, pesticide residues, phytotoxin, microbial contamination in herbs and their formulations. **12 Hours**

Unit 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 Hours

Unit 4:

Analytical profiles of herbal drugs: Andrographis paniculata, Boswellia serata, Coleus forskholii, Curcuma longa, Embelica officinalis, Psoralea corylifolia. **12 Hours**

Unit 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. Toxicity studies as per OECD guidelines. **12 Hours**

REFERENCES

1. Glimpses of Indian Ethano Pharmacology - P. Pushpangadam. U.L.F. Nyman & V. George. Tropical Botanic Garden & Research Institute, 1995.
2. Natural Products: A Lab Guide - Raphael Ikan. Academic Press.
3. Pharmacognosy - G. E. Trease & W.C. Evans. Saunders Edinburgh, New York.
4. Pharmacognosy - Tyler, Brady & Robbers. Lee & Febiger.
5. Modem Methods of Plant Analysis - Peach & M.V. Tracey. Vol I & II. Springer Publishers.
6. Herbal Drug Industry – R.D. Choudhary, Eastern Publishers, New Delhi.

7. Text book of Pharmacognosy - C.K. Kokate, Purohit & Ghokhale. Nirali Prakasshan, 1996.
8. Text Book of Pharmacognosy - T.E. Wallis.
9. Quality Control of Herbal Drugs - Pulok K Mukarjee. Business Horizons Pharmaceutical Publisher, New Delhi, 2002.
10. Indian Herbal Pharmacopoeia, IDMA, Mumbai.
11. Text Book of Pharmacognosy and Phytochemistry - Vinod D. Rangar, Part I & II. Career Publication, Nasik, India, 2002.
12. Plant Drug Analysis - H. Wagner & S. Bladt. Springer, Berlin.
13. Standardization of Botanicals: Testing and Extraction Methods of Medicinal Herbs - V. Rajpal. Vol 1. Eastern Publisher, New Delhi, 2004.
14. Herbal Medicine - Expanded Commission E Monographs - M. Blumenthal.

INDIAN SYSTEMS OF MEDICINE (MPG 203T)

Unit 1:

Fundamental concepts of Ayurveda, Siddha, Unani and Homoeopathy systems of medicine. Different dosage forms of the Indian system of medicine (ISM).

Ayurveda: Ayurvedic Pharmacopoeia. Analysis of formulations and bio crude drugs with references to: Identity, purity and quality. Siddha: Gunapadam (Siddha Pharmacology), raw drugs/Dhatu/Jeevam in Siddha system of medicine, purification process (Suddhi).

12 Hours

Unit 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 Hours**

Unit 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 Hours**

Unit 4:

Schedule T – Good Manufacturing Practice of ISM. Components of GMP (Schedule – T) and its objectives, infrastructural requirements, working space, storage area, machinery and equipment, standard operating procedures, health and hygiene, documentation and records.

Quality assurance in ISM formulation industry - GAP, GMP and GLP. Preparation of documents for new drug application and export registration.

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

Unit 5:

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

REFERENCES

1. Ayurvedic Pharmacopoeia, The Controller of Publications, Civil Lines, Govt. of India, New Delhi.
2. Hand Book on Ayurvedic Medicines - H. Panda. National Institute of Industrial Research, New Delhi.
3. Ayurvedic System of Medicine - Kaviraj Nagendranath Sengupata. Sri Satguru Publications, New Delhi.
4. Ayurvedic Pharmacopoeia - Formulary of Ayurvedic Medicines. IMCOPS, Chennai.
5. Homeopathic Pharmacopoeia - Formulary of Homeopathic Medicines. IMCOPS, Chennai.
6. Homeopathic Pharmacy: An Introduction & Hand Book - Steven B Kayne. Churchill Livingstone, New York.
7. Indian Herbal Pharmacopoeia. IDMA, Mumbai.
8. British Herbal Pharmacopoeia. British Herbal Medicine Association, UK.
9. GMP for Botanicals - Regulatory and Quality Issues on Phytomedicine - Pulok K Mukharjee. Business Horizons, New Delhi.
10. Indian System of Medicine and Homeopathy in India. Planning and Evaluation Cell, Govt. of India, New Delhi.
11. Essential of Food and Nutrition – Swaminathan. Bappco, Bangalore.
12. Clinical Dietetics and Nutrition - F.P. Antia. Oxford University Press, Delhi.
13. Yoga - The Science of Holistic Living - V.K. Yoga & Vivekananda Yoga. Prakashna Publishing, Bangalore.

HERBAL COSMETICS (MPG 204T)

Unit 1:

Introduction: Herbal/natural cosmetics. Classification & Economic aspects.

Regulatory Provisions in 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 Hours**

Unit 2:

Commonly used herbal cosmetics, raw materials, preservatives, surfactants, humectants, oils, colors and some functional herbs. Preformulation studies, compatibility studies, possible interactions between chemicals and herbs, design of herbal cosmetic formulation. **12 Hours**

Unit 3:

Herbal Cosmetics: Physiology and chemistry of skin and pigmentation, hairs, scalp, lips and nail, cleansing cream, lotions, face powders, face packs, lipsticks, bath products, soaps and baby product. Preparation and standardisation of tonic, bleaches, dentifrices (mouth washes & tooth pastes), cosmetics for nails. **12 Hours**

Unit 4:

Cosmeceuticals of herbal and natural origin: Hair growth formulations, shampoos, conditioners, colorants & hair oils, fairness formulations, vanishing & foundation creams, anti-sun burn preparations, moisturizing creams, deodorants. **12 Hours**

Unit 5:

Analysis of cosmetics, toxicity screening and test methods: Quality control and toxicity studies as per Drugs and Cosmetics Act. **12 Hours**

REFERENCES

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

PHARMACOGNOSY PRACTICAL – III (MPG 205P)

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

PHARMACEUTICAL REGULATORY AFFAIRS (MRA)

First Semester

GOOD REGULATORY PRACTICES (MRA 101T)

Unit 1:

Current Good Manufacturing Practices (cGMP): 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 device and IVDs Global Harmonization Task Force (GHTF) Guidance docs. **12 Hours**

Unit 2:

Good Laboratory Practices (GLP): Introduction, USFDA GLP Regulations (Subpart A to Subpart K). Controlling the GLP inspection process, documentation, audit, goals of Laboratory Quality Audit, Audit tools. Future of GLP regulations, relevant ISO and Quality Council of India (QCI) Standards. **12 Hours**

Unit 3:

Good Automated Laboratory Practices (GALP): Introduction to GALP, principles of GALP, GALP requirements, SOPs of GALP, Training Documentation, 21 CFR Part 11, General check list of 21 CFR Part 11, Software Evaluation checklist, relevant ISO and QCI Standards. **12 Hours**

Unit 4:

Principles, personnel, documentation, premises and equipment, deliveries to customers, returns, self-inspection, provision of information, stability testing principles, WHO Good Distribution Practices. USP GDP (Supply chain integrity), relevant CDSCO guidance and ISO standards. **6 Hours**

Unit 5:

Quality management systems: Concept of quality, Total Quality Management, quality by design, six sigma concept, Out of Specifications (OOS), change controls.

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 Council for Harmonization (ICH) process, ICH guidelines to establish quality, safety and efficacy of drug substances and products, ISO 13485, Schedule M-III and other relevant CDSCO regulatory guidance documents.

ICH Guidelines: Emphasis on Q2, Q3, Q7, Q8, Q9, Q10 & Q11 (draft Form) **18 Hours**

REFERENCES

1. Good Laboratory Practice Regulations - Sandy Weinberg, 4th ed. Drugs and The Pharmaceutical Sciences, Vol.168.
2. How to Practice GLP – P.P. Sharma. Vandana Publications.
3. Laboratory Auditing for Quality and Regulatory Compliance - Donald C Singer. Drugs and The Pharmaceutical Sciences, Vol. 150.
4. Drugs & Cosmetics Act, Rules & Amendments, Government of India.
5. Good Pharmaceutical Manufacturing Practice, Rationale and Compliance - John Sharp. CRC Press.
6. Establishing a cGMP Laboratory Audit System, A Practical Guide - David M Bleisner. Wiley.

DOCUMENTATION AND REGULATORY WRITING (MRA 102T)

Unit 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). **12 Hours**

Unit 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. Submission in Sugam system of CDSCO. Pharmaceutical Inspection & Convention Scheme and Pharmaceutical Inspection & Cooperation Scheme (PIC/S), ASEAN Pharmaceutical harmonization on initiative. **12 Hours**

Unit 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, audit analysis, audit report, audit follow up. Auditing/inspection of manufacturing facilities by regulatory agencies. Timelines for audits/inspection. GHTF study group 4 guidance document. ISO 13485. **12 Hours**

Unit 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)

. **12 Hours**

Unit 5:

Product life cycle management: ICH life cycle management (Q12), post approval labeling changes, lifecycle management, FDA inspection and enforcement, Establishment Inspection Report (EIR), warning letters, recalls, seizure and injunctions. ISO risk management standard. **12 Hours**

REFERENCES

1. Laboratory Auditing for Quality and Regulatory Compliance - Donald C Singer, Raluca-loana Stefan & Jacobus F Van Staden. Taylor and Francis, 2005.
2. Handbook of Microbiological Quality Control - Rosamund M Baird, Norman A Hodges & Stephen P Denyar. CRC Press, 2000.
3. Juran's Quality Handbook - Joseph M Juran & Joseph A De Feo. 6th ed. ASQ Publications.
4. Compliance Auditing for Pharmaceutical Manufacturers - Karen Ginsbury & Gil Bismuth. Interpharm/CRC, Boca Raton, London New York, Washington D.C.
5. Pharmaceutical Manufacturing Handbook: Regulations and Quality - Shayne Cox Gad. Wiley-Interscience, A John Wiley and Sons, Inc., Publications.

6. Implementing Juran's Road Map for Quality Leadership: Benchmarks and Results - Al Endres. Wiley, 2000.
7. Understanding, Managing and Implementing Quality: Frameworks, Techniques and Cases - Jiju Antony. David Preece, Routledge, 2002.
8. Organizing for High Performance: Employee Involvement, TQM, Reengineering, and Knowledge Management in the Fortune 1000: The CEO Report - Edward E Lawler III, Susan Albers Mohrman & George Benson. Jossey-Bass, 2001.
9. Corporate Culture and the Quality Organization - James W Fairfield-Sonn. Quorum Books, 2000.
10. The Quality Management Sourcebook: An International Guide to Materials and Resources By Christine Avery & Diane Zabel. Routledge, 1997.
11. The Quality Toolbox - Nancy R Tague. 2nd ed. ASQ Publications.
12. Root Cause Analysis, The Core of Problem Solving and Corrective Action - Duke Okes. ASQ Publications.
13. International Medical Device Regulators Forum (IMDRF) Medical Device Single Audit Program (MDSAP).

CLINICAL RESEARCH REGULATIONS (MRA 103T)

Unit 1:

Clinical drug development process: Different types of clinical studies. 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 endpoints. 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 studies - PMS), clinical investigation and evaluation of medical devices & IVDs different types of studies, key concepts of medical device, clinical evaluation, key concepts of clinical investigation. **12 Hours**

Unit 2:

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. Ethical principles governing informed consent process. Patient information sheet and informed consent form the informed consent process and documentation. **12 Hours**

Unit 3:

Regulations governing clinical trials in India: Clinical research regulations in India – Schedule Y & Medical Device Guidance USA: Regulations to conduct drug studies in USA (FDA). NDA505(b)(1) of the FD&C Act (Application for approval of a new drug) NDA505(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). **12 Hours**

Unit 4:

Clinical research related guidelines: Good Clinical Practice Guidelines (ICHGCP E6), Indian GCP Guidelines. ICMR Ethical Guidelines for biomedical research. CDSCO guidelines GHTF study group 5 guidance documents, 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. General biostatistics principle applied in clinical research. **12 Hours**

Unit 5:

USA & EU Guidance: FDA Guidance. CFR 21 Part 50: Protection of human subjects. CFR 21 Part 54: Financial disclosure by clinical investigators. CFR 21 Part 312: IND Application. CFR 21 Part 314: Application for FDA Approval to market a new drug. CFR 21 Part 320: Bioavailability and bioequivalence requirements. CFR 21 Part 812: Investigational device exemptions. CFR 21 Part 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 (EMEA) Volume 3 – Scientific guidelines for medicinal products for human use. EU Annual Safety Report (ASR) Volume 9A – Pharmacovigilance for medicinal products for human use. EU MDD with respect to clinical research · ISO 14155. **12 Hours**

REFERENCES

1. Clinical Trials and Human Research: A Practical Guide to Regulatory Compliance - Fay A Rozovsky & Rodney K Adams.
2. FDA Regulatory Affairs: a Guide for Prescription Drugs, Medical Devices, and Biologics - Douglas J Pisano & David Mantus. CRC Press, USA.
3. New Drug Approval Process: The Global Challenge – Guarino & A. Richard. Marcel Dekker Inc.
4. HIPAA and Human Subjects Research: A Question and Answer Reference Guide - J.D. Mark Barnes & J.D. Jennifer Kulynych.
5. Principles and Practices of Clinical Research, John I Gallin & Frederick P Ognibene. 2nd ed.
6. Reviewing Clinical Trials: A Guide for the Ethics Committee - Johan P E Karlberg & Marjorie A Speers. Hong Kong.
7. International Pharmaceutical Product Registration: Aspects of Quality, Safety and Efficacy - Anthony C Cartwright. Taylor & Francis Inc., USA.

REGULATIONS AND LEGISLATION FOR DRUGS & COSMETICS, MEDICAL DEVICES, BIOLOGICALS, HERBALS, FOOD & NUTRACEUTICALS IN INDIA AND INTELLECTUAL PROPERTY RIGHTS (MRA 104T)

Unit 1:

Drugs Biologicals & Herbals, and Food & Nutraceuticals Acts and Rules (with latest amendments): 1) Drugs and Cosmetics Act 1940 and Rules 1945: Schedule M, DPCO & NPPA. 2) Other relevant provisions (rules schedules and guidelines for approval of Drugs & Cosmetics, Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals in India Other relevant Acts: Narcotic Drugs and Psychotropic Substances Act; Pharmacy Act, 1948; Drugs and Magic Remedies (Objectionable Advertisements) Act, 1955; Prevention of Cruelty to Animals Act. **12 Hours**

Unit 2:

Regulatory requirements and approval procedures for Drugs & Cosmetics Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals CDSCO (Central Drug Standard Control Organization) and State Licensing Authority: Organization, Responsibilities. Rules, regulations, guidelines and standards for regulatory filing of Drugs & Cosmetics, Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals. Format and contents of Regulatory dossier filing Clinical trial/investigations. **12 Hours**

Unit 3:

Indian Pharmacopoeial Standards, BIS standards and ISO and other relevant standards. Regulations for packaging material, packaging requirements & labeling requirements as per Rules 94, 95, 96, 97 & 105 D& C Rules 1945. **12 Hours**

Unit 4:

Bioavailability and bioequivalence data (BA &BE), 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 Hours**

Unit 5:

Intellectual property rights: Patent, trademark, copyright, industrial designs and geographical indications, Indian patent scenario, IPR vs regulatory affairs. **12 Hours**

REFERENCES

1. Manual of Patent Practice & Procedure - The Patent Office of India. 3rd ed.
2. Patent Failure How Judges, Bureaucrats, and Lawyers put Innovators at Risk - James Bessen & Michael J Meurer.
3. Principles and Practice of Clinical Trial Medicine - Richard Chin & Bruce Y. Lee.
4. Ethical Guidelines for Biomedical Research on Human Participants - 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 Guidelines — Good Clinical Practice - 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).
9. Guidance for Industry on Requirement of Chemical & Pharmaceutical Information including Stability Study Data before approval of clinical trials / BE studies by CDSCO.
10. Guidelines for Import and Manufacture of Medical Devices – CDSCO.
11. Guidelines from official website of CDSCO.

REGULATORY AFFAIRS PRACTICAL – I (MRA 105P)

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 and submission in SUGAM
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

REGULATORY AFFAIRS PRACTICAL – II (MRA 106P)

1. Case studies on response with scientific rationale to USFDA Warning Letter
2. Preparation of submission check list of IMPD for EU submission
3. Comparison study of marketing authorization procedures in EU
4. Comparative study of DMF system in US, EU and Japan
5. Preparation of regulatory submission using eCTD software
6. Preparation of Clinical Trial Application (CTA) for US submission
7. Preparation of Clinical Trial Application (CTA) for EU submission
8. Comparison of Clinical Trial Application requirements of US, EU and Japan of a dosage form
9. Regulatory requirements check list for conducting clinical trials in India
10. Regulatory requirements check list for conducting clinical trials in Europe
11. Regulatory requirements check list for conducting clinical trials in USA
12. Writing Stability Protocols as per ICH
13. Writing Validation Protocol of Water & AHU Systems
14. Writing & Compiling a Dossier
15. Writing & Compiling Site Master File

Second Semester

REGULATORY ASPECTS OF DRUGS & COSMETICS (MRA 201T)

Unit 1:

USA & Canada: Organization and functions of FDA. Federal register and Code of 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. Legislation and regulations for import, manufacture, distribution and sale of cosmetics in USA and Canada. **12 Hours**

Unit 2:

European Union & 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. Legislation and regulations for import, manufacture, distribution and sale of cosmetics in European Union & Australia. **12 Hours**

Unit 3:

Emerging market: Introduction, countries covered, study of the world map, study of various committees across the globe (ASEAN, APEC, EAC, GCC, PANDRH, SADC). 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 (India, South Africa, Egypt, Algeria and Morocco, Nigeria, Kenya and Botswana. **12 Hours**

Unit 4:

Brazil, ASEAN, CIS and GCC Countries: 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. **12 Hours**

Unit 5:

CIS (Commonwealth Independent States): Regulatory prerequisites related to marketing authorization requirements for drugs and post approval requirements in CIS countries i.e. Russia, Kazakhstan and Ukraine and sale of cosmetics in Brazil, ASEAN, CIS and GCC Countries. **12 Hours**

REFERENCES

1. Generic Drug Product Development: Solid Oral Dosage Forms - Leon Shargel. Marcel Dekker Series, Vol. 143.
2. The Pharmaceutical Regulatory Process - Ira R Berry. Marcel Dekker Series, Vol.144.
3. Guidebook for Drug Regulatory Submissions - Sandy Weinberg. John Wiley & Sons. Inc.
4. New Drug Approval Process: Accelerating Global Registrations - Richard A Guarino, Vol 190. 5th ed. Drugs and the Pharmaceutical Sciences.
5. Drugs and the Pharmaceutical Sciences. Vol.185. Informa Health Care Publishers.
6. Drugs: From Discovery to Approval – N.G. Rick. 2nd ed.
7. New Drug Development: A Regulatory Overview - Mark Mathieu. 8th ed.
8. Pharmaceutical Risk Management - Jeffrey E Fetterman, Wayne L Pines & Gary H Slatko.
9. Preparation and Maintenance of the IND Application in eCTD Format - William K Sietsema.
10. http://www.who.int/medicines/areas/quality_safety/regulation_legislation/List MRAWebsites
11. Roadmap to an ASEAN economic community - Denis Hew. ISEAS Publications. Singapore, 2005.
12. ASEAN - Rodolfo C. Severino. ISEAS Publications, Singapore.
13. Building a Future with Brics: The Next Decade for Offshoring - Mark Kobayashi-Hillary.
14. Outsourcing to India: The Offshore Advantage - Mark Kobayashi-Hillary. Springer Trade Performance and Regional Integration of the CIS Countries - Lev Freinkman.
15. The World Bank, Washington DC.
16. Global Pharmaceutical Policy: Ensuring Medicines for Tomorrow's World - Frederick M Abbott & Graham Dukes. Edward Elgar Publishing Inc.
17. The Gulf Cooperation Council: A Rising Power and Lessons for ASEAN by Linda Low

& Lorraine Carlos Salazar. ISEAS Publishing.
18. Doing Business in the Asean Countries - Balbir Bhasin. Business Expert Press.
19. Realizing the ASEAN Economic Community: A Comprehensive Assessment - Michael G Plummer & Chia Siow Yue. Published by Institute of Southeast Asian studies, Singapore.
20. Country Specific Guidelines from official websites.

REGULATORY ASPECTS OF HERBAL AND BIOLOGICS (MRA 202T)

Unit 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 Hours**

Unit 2:

USA & European Union: Introduction to biologics; biologics, biological and biosimilar, 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, labeling and packing of biologics in USA and EU. **12 Hours**

Unit 3:

Vaccine regulations in India, US and European Union: Clinical evaluation, marketing authorization, registration or licensing, quality assessment, pharmacovigilance, additional requirements. Blood and blood products regulations in India, US and European Union.

12 Hours

Unit 4:

Regulatory Requirements of Blood and/or its components including blood products, label requirements, ISBT (International Society of Blood Transfusion) and IHN (International Haemo vigilance Network). **12 Hours**

Unit 5:

Herbal Products: Quality, safety and legislation for herbal products in India, USA and European Union. **12 Hours**

REFERENCES

1. FDA Regulatory Affairs: A Guide for Prescription Drugs, Medical Devices, and Biologics - Douglas J. Pisano & David S Mantus. Taylor and Francis, 2008.
2. Biological Drug Products: Development and Strategies - Wei Wang. Wiley, 2013.
3. Development of Vaccines: From Discovery to Clinical Testing - Manmohan Singh. Wiley, 2011.
4. www.who.int/biologicals/en
5. www.fda.gov/Biologics Blood Vaccines/Guidance Compliance Regulatory Information/
6. www.ihn-org.com
7. www.isbtweb.org
8. Guidelines on Similar Biologics: Regulatory Requirements for Marketing Authorization in India
9. www.cdsco.nic.in
10. www.ema.europa.eu›scientific guidelines›Biologicals

REGULATORY ASPECTS OF MEDICAL DEVICES (MRA 203T)

Unit 1:

Medical devices: Introduction, definition, risk based classification and essential principles of medical devices and IVDs. Differentiating medical devices, IVDs and combination products from that of pharmaceuticals. History of medical device regulation. Product Life cycle of medical devices and 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)**.** **12 Hours**

Unit 2:

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 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. **12 Hours**

Unit 3:

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.

12 Hours

Unit 4:

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. **12 Hours**

Unit 5:

ASEAN, China & Japan: Medical devices and IVDs, regulatory registration procedures. Quality system requirements and clinical evaluation and investigation. IMDRF study groups and guidance documents. Medical Devices Act, 2017 Regulations. **12 Hours**

REFERENCES

1. Medical Product Regulatory Affairs: Pharmaceuticals, Diagnostics, Medical Devices - John J Tobin & Gary Walsh**.**
2. Medical Device Development: A Regulatory Overview - Jonathan S Kahan.
3. Compliance Handbook for Pharmaceuticals, Medical Devices and Biologics - Carmen Medina.
4. Country Specific Guidelines from official websites.

REGULATORY ASPECTS OF FOOD AND NUTRACEUTICALS (MRA 204T)

Unit 1:

Nutraceuticals: Introduction, history of Food and Nutraceutical Regulations, meaning of nutraceuticals, dietary supplements, functional foods, medical foods. Scope and opportunities in nutraceutical market**.** **12 Hours**

Unit 2:

Global aspects: WHO guidelines on nutrition. NSF International, its role in the dietary supplements and nutraceuticals industries, NSF certification, NSF standards for food and

dietary supplements. Good Manufacturing Practices for nutraceuticals, Hazard Analysis & Critical Control Point (HACCP). **12 Hours**

Unit 3:

India: Food Safety and Standards Act, Food Safety and Standards Authority of India: Organization and functions, regulations for import, manufacture and sale of nutraceutical products in India. Recommended dietary allowances (RDA) in India. **12 Hours**

Unit 4:

USA: US FDA Food Safety Modernization Act, Dietary Supplement Health and Education Act. U.S. regulations for manufacture and sale of nutraceuticals and dietary supplements. Labeling requirements and label claims for dietary supplements, Recommended dietary allowances (RDA) in the U.S. **12 Hours**

Unit 5:

European Union: European Food Safety Authority (EFSA), Organization and Functions. EU directives and regulations for manufacture and sale of nutraceuticals and dietary supplements. Nutrition labeling. European regulation on novel foods and novel food ingredients. Recommended dietary allowances (RDA) in Europe. **12 Hours**

REFERENCES

1. Regulation of Functional Foods and Nutraceuticals: A Global Perspective - Clare M Hasler. Wiley Online Library.
2. Nutraceutical and Functional Food Regulations in the United States and Around the World - Debasis Bagchi. Academic Press, Elsevier.
3. http://www.who.int/publications/guidelines/nutrition/en/
4. http://www.europarl.europa.eu/RegData/etudes/STUD/2015/536324/IPOLSTU (2015)536324_EN.pdf
5. Handbook of Nutraceuticals - Yashwant Pathak. CRC Press.
6. Food Regulation: Law, Science, Policy and Practice - Neal D Fortin. Wiley.
7. Country Specific Guidelines from official websites.

REGULATORY AFFAIRS PRACTICAL – III (MRA 205P)

Case studies on:

1. Change Management/ Change control. Deviations
2. Corrective & Preventive Actions (CAPA)
3. Documentation of raw materials analysis as per official monographs
4. Preparation of audit checklist for various agencies
5. Preparation of submission to FDA using eCTD software
8. Preparation of submission to EMA using eCTD software
9. Preparation of submission to MHRA using eCTD software
10. Preparation of Biologics License Applications (BLA)
11. Preparation of documents required for Vaccine Product Approval
12. Comparison of clinical trial application requirements of US, EU and India of Biologics.
13. Preparation of Check list for Registration of Blood and Blood Products
14. Registration requirement comparison study in 5 emerging markets (WHO) and preparing check list for market authorization
15. Registration requirement comparison study in emerging markets (BRICS) and preparing check list for market authorization

16. STED Application for Class III Devices
17. Audit Check list for Medical Device Facility
18. Clinical Investigation Plan for Medical Devices.

PHARMACEUTICAL QUALITY ASSURANCE (MQA)

First Semester

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES (MQA 101T)

(Note: Common paper for MPA, MPC, MPH, MPB, MPL, MPG, MQA, & MIP, specializations)

Unit 1:

a. UV-visible spectroscopy: Introduction, theory, laws and instrumentation associated with UV-visible spectroscopy, choice of solvents and solvent effect and applications of UV-visible spectroscopy.

b. IR spectroscopy: Theory, modes of molecular vibrations, sample handling, instrumentation of dispersive and Fourier-Transform IR Spectrometer, factors affecting vibrational frequencies and applications of IR spectroscopy, data interpretation.

c. Spectroflourimetry: Theory of fluorescence, factors affecting fluorescence (characteristics of drugs that can be analyzed by flourimetry), quenchers, instrumentation and Applications of fluorescence spectrophotometer.

d. Flame emission spectroscopy and Atomic absorption spectroscopy: Principle, instrumentation, interferences and applications. **12 Hours**

Unit 2:

NMR spectroscopy: Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and 13C NMR. Applications of NMR spectroscopy. **10 Hours**

Unit 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. 1**0 Hours**

Unit 4:

Chromatography: Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution, isolation of drug from excipients, data interpretation and applications of the following:

a) Thin Layer chromatography **b)** High Performance Thin Layer Chromatography **c)** Ion exchange chromatography **d)** Column chromatography **e)** Gas chromatography **f)** High Performance Liquid chromatography **g)** Ultra High Performance Liquid chromatography **h)** Affinity chromatography **i)** Gel Chromatography. **14 Hours**

Unit 5:

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

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

c. Thermal Techniques: Principle, instrumentation, advantage and disadvantages, Pharmaceutical applications of DSC, DTA & TGA.

d. Microscopic techniques: Principles and applications of Scanning Electron Microscopy

and Transmission Electron Microscopy analysis. **14 Hours**

REFERENCES

1. Spectrometric Identification of Organic compounds - Robert M Silverstein. 6th ed. John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler & Timothy A. Nieman. 5th ed. Eastern Press, Bangalore, 1998.
3. Instrumental Methods of Analysis – Willards. 7th ed. CBS Publishers, New Delhi.
4. Practical Pharmaceutical Chemistry – Beckett and Stenlake. Vol 2. 4th ed. CBS Publishers, New Delhi
5. Organic Spectroscopy - William Kemp. 3rd ed. ELBS, 1991.
6. Quantitative Analysis of Drugs in Pharmaceutical Formulation – P.D. Sethi. 3rd ed. CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis - Modern Methods – Part B – J.W. Munson. Vol 11. Marcel-Dekker Series.
8. Spectroscopy of Organic Compounds - P.S. Kalsi. 2nd ed. Wiley Estern Ltd., Delhi.
9. Textbook of Pharmaceutical Analysis - K.A. Connors. 3rd ed. John Wiley & Sons.

QUALITY MANAGEMENT SYSTEM (MQA 102T)

Unit 1:

Introduction to quality: Evolution of quality, definition of quality, dimensions of quality, 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 behaviour, 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 Hours**

Unit 2:

Pharmaceutical quality management: Basics of quality management, Total Quality Management (TQM), principles of six sigma, ISO 9001:2015. 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 Hours**

Unit 3:

Six sigma system inspection model: quality management system, production system, facility and equipment system, laboratory control system, materials system, packaging and labelling 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 Hours**

Unit 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 (FMEA, fish bone diagram), HACCP, risk ranking and filtering according to ICH Q9 guidelines. **12 Hours**

Unit 5:

Statistical process control (SPC): a) 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. b) regulatory compliance through quality management and development of quality culture benchmarking: Definition of benchmarking, reasons for benchmarking, types of benchmarking, benchmarking process, advantages of bench marking, limitations of benchmarking. **12 Hours**

REFERENCES

1. Juran's Quality Handbook - Joseph M Juran & Joseph A De Feo. 6th ed. ASQ Publications.
2. Implementing Juran's Road Map for Quality Leadership and Results - Al Endres. John Wiley & Sons.
3. Understanding, Managing and Implementing Quality: Frameworks, Techniques and Cases - Jiju Antony. David Preece, Routledge, 2002.
4. Organizing for High Performance: Employee Involvement, TQM, Reengineering, and Knowledge Management in the Fortune 1000: The CEO Report - Edward E Lawler, Susan Albers Mohrman & George Benson. Jossey-Bass, 2001.
5. Corporate Culture and the Quality Organization - James W Fairfield-Sonn.
6. The Quality Management Sourcebook: An International Guide to Materials and Resources - Christine Avery & Diane Zabel. Routledge, 1997.
7. The Quality Toolbox - Nancy R. Tague. 2nd ed. ASQ Publications.
8. Root Cause Analysis, The Core of Problem Solving and Corrective Action - Duke Okes. ASQ Publications, 2009.
9. Pharmaceutical QA and Management - Quality Management System for APIs – K.P. Bhusari.

PHARMACEUTICAL VALIDATION (MQA 103T)

(Note: Common paper for MPA and MQA specializations)

Unit 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 Hours**

Unit 2:

Qualification of analytical instruments/Equipment: Training & qualification of analyst. qualification of UV-visible spectrophotometer, FTIR, DSC, GC, HPLC, HPTLC, and dissolution test apparatus. **10 Hours**

Unit 3:

Validation of utility systems: Pharmaceutical water system, HVAC system, compressed air and nitrogen. Facility qualification, AHU validation, clean room validation.

Cleaning validation: Cleaning method development, sampling techniques, 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 significance-21 CFR part 11 and GAMP 5, LIMS, audit trail and data integrity. **12 Hours**

Unit 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 (Q2A) and USP. Preparation & qualification of working standards and reference standards. **12 Hours**

Unit 5:

General principles of intellectual property: Concepts of intellectual property (IP), intellectual property protection (IPP), intellectual property rights (IPR); economic importance, mechanism for protection of intellectual property – patents, copyright, trademark; factors affecting choice of IP protection; penalties for violation; role of IP in pharmaceutical industry; global ramification and financial implications. Filing a patent application; patent application forms and guidelines. Types of patent applications-provisional and non-provisional, PCT and convention patent applications; International patenting requirement procedures and costs; rights and responsibilities of a patentee; practical aspects regarding maintaining of a patent file; patent infringement meaning and scope. Significance of transfer of technology (TOT), IP and ethics-positive and negative aspects of IPP; societal responsibility, avoiding unethical practices. **14 Hours**

REFERENCES

1. Pharmaceutical Process Validation - B. T. Loftus & R. A. Nash. Drugs and Pharm Sci. Series, Vol. 129, 3rd ed. Marcel Dekker.
2. The Theory & Practice of Industrial Pharmacy, 3rd ed. Leon Lachman, Herbert A Lieberman & Joseph L Kanig, Varghese Publishing House, Bombay.
3. Validation of Aseptic Pharmaceutical Processes - Carleton & Agalloco. 2nd ed. Marcel Dekker.
4. Pharmaceutical Process Scale-Up - Michael Levin, Drugs and Pharm. Sci. Series, Vol. 157, 2nd ed. Marcel Dekker.
5. Validation Standard Operating Procedures: A Step by Step Guide for Achieving Compliance in the Pharmaceutical, Medical Device, and Biotech Industries, Syed Imtiaz Haider.
6. Validation of Pharmaceutical Processes: Sterile Products - Frederick J Carlton and James Agalloco. 2nd ed. Marcel Dekker.
7. Pharmaceutical Equipment Validation: The Ultimate Qualification Handbook, Phillip A Cloud, Interpharm Press.
8. Analytical Method Validation and Instrument Performance Verification - Churg Chan, Heiman Lam, Y.C. Lee, Yue. Zhang. Wiley Inter Science.

PRODUCT DEVELOPMENT AND TECHNOLOGY TRANSFER (MQA 104T)

Unit 1:

Principles of drug discovery and development: Introduction, clinical research process. Development and informational content for Investigational New Drug 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 Hours**

Unit 2:

Pre-formulation studies: Introduction/concept, organoleptic properties, purity, impurity profiles, particle size, shape and surface area.

Solubility: Methods to improve solubility of drugs, surfactants and their importance, co-solvency. Techniques for the study of crystal properties and polymorphism. Pre-formulation protocol, stability testing during product development. **12 Hours**

Unit 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 Hours**

Unit 4:

Pharmaceutical packaging: Pharmaceutical dosage forms and their packaging requirements. Pharmaceutical packaging materials, medical device packaging, external packaging, aseptic packaging systems, container closure systems, issues facing modern drug packaging, selection and evaluation of pharmaceutical packaging materials-safety to the drug product/drug substance.

Quality control tests: Containers, closures and secondary packing materials. **12 Hours**

Unit 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 Hours**

REFERENCES

1. The Theory & Practice of Industrial Pharmacy, 3rd ed. Leon Lachman, Herbert A. Lieberman & Joseph L Kanig, Varghese Publishing House, Bombay.
2. Good Manufacturing of Pharmaceuticals (A Plan for Total Quality Control) - Sidney H Willig, Murray M, Tuckerman & Williams Hitchings IV. 3rd ed. Bhalani Publishing House, Mumbai.
3. Pharmaceutical Dosage Forms : Tablets - Herbert A. Lieberman and Leon Lachman, Volume 1 - 3. Marcel Dekker, Inc.
4. Biopharmaceutics and Clinical Pharmacokinetics - Milo Gibaldi. 3rd ed. Pharma Book Syndicate.
5. Remington – The Science and Practice of Pharmacy – Loyd V Allen. 22nd ed.
6. The Pharmaceutical Sciences - The Pharma Path Way - D.A. Sawant. Pragathi Books Pvt. Ltd.
7. Pharmaceutical Packaging Technology - D.A. Dean & E.R. Evans. Taylor & Francis, London.

8. The process of New Drug Discovery and Development - Charles G Smith, James T & O. Donnell. CRC Press.
9. Pharmaceutical Product Development - Vandana V Patrevale, John I Disouza & Maharukh T Rustomji. CRC Press.
10. Dissolution, Bioavailability and Bio-Equivalence - H.M. Abdou. Mack Publishing.
11. Guide Book for Drug Regulatory Submissions - Sandy Weinberg.

PHARMACEUTICAL QUALITY ASSURANCE PRACTICAL – I (MQA 105P)

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.

PHARMACEUTICAL QUALITY ASSURANCE PRACTICAL -II (MQA 106P)

1. In process and finished product quality control tests for tablets, capsules, parenterals and semisolid dosage forms.
2. Assay of raw materials as per official monographs
3. Testing of related and foreign substances in drugs and raw materials
4. To carry out pre-formulation study for tablets, parenterals (2 experiments).
5. To study the effect of pH on the solubility of drugs, (1 experiment)
6. Quality control tests for Primary and secondary packaging materials
7. Accelerated stability studies (1 experiment)
8. Improved solubility of drugs using surfactant systems (1 experiment)
9. Improved solubility of drugs using co-solvency method (1 experiment)
10. Determination of pKa and Log p of drugs.

Second Semester

HAZARDS AND SAFETY MANAGEMENT (MQA 201T)

Unit 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 Hours**

Unit 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 Hours**

Unit 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 Hours**

Unit 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, electrical passivation, ventilation, and sprinkling, proofing, relief systems - relief valves, flares, scrubbers.

12 Hours

Unit 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. Physico-chemical measurements of effluents, BOD, COD. Determination of some contaminants, effluent treatment procedure, role of emergency services. **12 Hours**

REFERENCES

1. Environmental Science - Y.K. Sing. 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. The Biodiversity of India - Bharucha Erach. Mapin Publishing Pvt. Ltd., Ahmedabad.
4. Hazardous Chemicals: Safety Management and Global Regulations - T.S.S. Dikshith. CRC Press.

AUDITS AND REGULATORY COMPLIANCE (MQA 202T)

Unit 1:

Introduction: Objectives, types of audit, management of audit, responsibilities, planning process, information gathering, administration, classification of deficiencies. **12 Hours**

Unit 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, continuous process verification.

12 Hours

Unit 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. Audits of large volume parenterals, small volume parenterals, sterile dry powders and lyophilised product manufacturing. **12 Hours**

Unit 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 Hours**

Unit 5:

Auditing of quality assurance and engineering department: quality assurance maintenance. Critical systems: HVAC, water, water for injection systems, ETP. **12 Hours**

REFERENCES

1. Compliance Auditing for Pharmaceutical Manufacturers - Karen Ginsbury & Gil Bismuth. Interpharm /CRC, Boca Raton, London, New York, Washington D.C.
2. Pharmaceutical Manufacturing Handbook, Regulations and Quality - 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.

QUALITY CONTROL AND QUALITY ASSURANCE (MQA 203T)

(Common paper for MPA and MQA specializations)

Unit 1:

Introduction: Concept and evolution of quality control and quality assurance. Good laboratory practice, GMP, overview of ICH guidelines - QSEM, with special emphasis on Q-series guidelines.

Good laboratory practices: Scope of GLP, definitions, quality assurance unit, protocol for conduct of non-clinical testing.

CPCSEA guidelines: Control on animal house, report preparation and documentation.

12 Hours

Unit 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, clean room validation, control of contamination, sterility assurance, AHU system & qualification, and Good Warehousing Practice. **12 Hours**

Unit 3:

Developing specification (ICH Q6 and Q3), sampling methods for raw and packing materials. Purchase specifications, vendor qualification and maintenance of stores for various materials.

Testing of primary packing materials as per IP & USP: Glass containers, plastics, rubber.

Analysis of raw materials, packaging materials: In-process quality control and finished products quality control for following formulations in pharma industry according to Indian, US and British pharmacopoeias: tablets, capsules, ointments, suppositories, creams,

parenterals, ophthalmic and surgical products. Quality control test for containers, closures and secondary packing materials. **12 Hours**

Unit 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 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). **12 Hours**

Unit 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 Hours**

REFERENCES

1. Quality Assurance Guide by Organization of Pharmaceutical Procedures of India. 3rd Revised ed. Vol I & II, Mumbai, 1996.
2. Good Laboratory Practice Regulations - Sandy Weinberg Vol 69. 2nd ed. Marcel Dekker.
3. Quality Assurance of Pharmaceuticals - A Compedium of Guidelines and Related Materials. Vol 1 & 2. 2nd ed. WHO Publications, 1999.
4. How to Practice GMP's – P.P. Sharma, Vandana Publications, Agra, 1991.
5. The International Pharmacopoeia – General Methods of Analysis and Quality Specification for Pharmaceutical Substances, Excipients and Dosage forms. Vol 1-5. 3rd ed. WHO, Geneva, 2005.
6. Good Laboratory Practice Regulations – Allen F. Hirsch. Vol 38, Marcel Dekker.
7. ICH guidelines
8. ISO 9000 and Total Quality Management
9. The Drugs and Cosmetics Act 1940 – Deshpande & Nilesh Gandhi. 4th ed. Susmit Publishers.
10. QA Manual – D.H. Shah. 1st ed. Business Horizons, 2000.
11. Good Manufacturing Practices for Pharmaceuticals; A Plan for Total Quality Control – Sidney H Willig. Vol. 52. 3rd ed. Marcel Dekker.
12. GMP/ISO Quality Audit Manual for Healthcare Manufacturers and Their Suppliers - Steinborn L. Vol 1 - With Checklists and Software Package. 6th ed. Taylor & Francis.
13. Quality Systems and Controls for Pharmaceuticals – D.K. Sarker. John Wiley & Sons, 2008.

PHARMACEUTICAL MANUFACTURING TECHNOLOGY (MQA 204T)

Unit 1:

Pharmaceutical industry developments: Legal requirements and licenses for API and formulation industry. Plant location and plant layout, factors influencing. Special provisions, storage space requirements, sterile and aseptic area layout.

Production planning: General principles, production systems, calculation of standard cost,

process planning, routing, loading, scheduling, dispatching of records, production control.

12 Hours

Unit 2:

Aseptic process technology: Manufacturing, manufacturing flowcharts, in process-quality control tests for dosage forms: Ointment, suspension and emulsion, dry powder, solutions, sterile dosage forms (small volume & large volume).

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

Process automation in pharmaceutical industry: With specific reference to manufacturing of sterile semisolids, Small Volume Parenterals & Large Volume Parenterals (SVP & LVP),

Monitoring of parenteral manufacturing facility, Cleaning in Place (CIP), Sterilization in Place (SIP), prefilled syringe, powdered jet, needle free injections, and Form Fill Seal Technology (FFS).

Lyophilization technology: Principles, process, equipment **12 Hours**

Unit 3:

Non sterile manufacturing process technology: Manufacturing, manufacturing flowcharts, in-process-quality control tests for non-sterile solid dosage forms: Tablets (compressed & coated), capsules (hard & soft).

Advanced non-sterile solid product manufacturing technology: Process automation in pharmaceutical industry with specific reference to manufacturing of tablets and coated products.

Improved tablet production: Tablet production process, granulation and palletization equipment, continuous and batch mixing, rapid mixing granulators, rota granulators, spheronizers and marumerisers, and other specialized granulation and drying equipments. Problems encountered.

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

Unit 4:

Containers and closures for pharmaceuticals: Types, performance, assuring quality of glass; types of plastics used, drug plastic interactions, biological tests, modification of plastics by drugs; different types of closures and closure liners; film wrapper; blister packs; bubble packs; shrink packaging; foil /plastic pouches, bottle seals, tape seals, breakable seals and sealed tubes; quality control of packaging material and filling equipment, flexible packaging, product package compatibility, transit worthiness of package, Stability aspects of packaging. Evaluation of stability of packaging material. **12 Hours**

Unit 5:

Quality by design (QbD) and process analytical technology (PAT): Current approach and its limitations. Why QbD is required, advantages, elements of QbD, terminology: QTPP. CMA, CQA, CPP, RLD, design space, design of experiments, risk assessment and mitigation /minimization. Quality by Design, formulations by design, QbD for drug products, QbD for drug substances, QbD for excipients, analytical QbD. FDA initiative on process analytical technology. PAT as a driver for improving quality and reducing costs: quality by design (QbD), QA, QC and GAMP. PAT guidance, standards and regulatory requirements.

12 Hours

REFERENCES

1. The Theory & Practice of Industrial Pharmacy, 3rd ed. Leon Lachman, Herbert A.

Lieberman & Joseph L Karig, Varghese Publishing House, Bombay.
2. Martin's Physical Pharmacy and Pharmaceutical Sciences - Patrick J Sinko. 6th ed. BI Publications Pvt. Ltd.
3. Pharmaceutical Dosage Forms : Tablets - Herbert A Lieberman & Leon Lachman, Volume 1 - 3. Marcel Dekker, Inc.
4. Modern Pharmaceutics - Gilbert S Banker & Christopher T. Rhodes. 4th ed.
5. Good Manufacturing of Pharmaceuticals (A Plan for Total Quality Control) - Sidney H Willig, M. Murray, Tuckerman & Williams Hitchings IV. 3rd ed. Bhalani Publishing House, Mumbai.
6. Indian Pharmacopoeia-2018. Controller of Publication. Delhi.
7. British Pharmacopoeia. British Pharmacopoeia Commission Office, London, 2017.
8. United States Pharmacopoeia. United States Pharmacopeial Convention, Inc, USA, 2019.
9. Pharmaceutical Packaging Technology – D.A. Dean, E.R. Evans & I.H. Hall. 1st ed. Taylor & Francis, London.
10. Pharmaceutical Packaging Handbook - Edward J Bauer. Informa Health Care USA Inc., 2009.
11. Pharmaceutical Manufacturing Handbook - Shaybe Cox Gad. John Willey and Sons.

PHARMACEUTICAL QUALITY ASSURANCE PRACTICAL – III (MQA 205P)

1. Organic contaminants residue analysis by HPLC
2. Estimation of Metallic contaminants by Flame photometer
3. Identification of antibiotic residue by TLC
4. Estimation of Hydrogen Sulphide in Air.
5. Estimation of Chlorine in Work Environment.
6. Sampling and analysis of SO_2 using Colorimetric method
7. Qualification of following Pharma equipment
   - Autoclave
   - Hot air oven
   - Powder Mixer (Dry)
   - Tablet Compression Machine
8. Validation of an analytical method for a drug
9. Validation of a processing area
10. Qualification of at least two analytical instruments
11. Cleaning validation of one equipment
12. Qualification of Pharmaceutical Testing Equipment (Dissolution testing apparatus, Friability Apparatus, Disintegration Tester)
13. Check list for Bulk Pharmaceutical Chemicals vendors
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

INDUSTRIAL PHARMACY (MIP)

First Semester

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES (MIP 101T)

(Note: Common Paper for MPA, MPC, MPH, MPB, MPL, MPG, MQA, & MIP, specializations)

Unit 1:

a. UV-visible spectroscopy: Introduction, theory, laws and instrumentation associated with UV-visible spectroscopy, choice of solvents and solvent effect and applications of UV-visible spectroscopy.

b. IR spectroscopy: Theory, modes of molecular vibrations, sample handling, instrumentation of dispersive and Fourier-Transform IR Spectrometer, factors affecting vibrational frequencies and applications of IR spectroscopy, data interpretation.

c. Spectroflourimetry: Theory of fluorescence, factors affecting fluorescence (characteristics of drugs that can be analyzed by flourimetry), quenchers, instrumentation and Applications of fluorescence spectrophotometer.

d. Flame emission spectroscopy and Atomic absorption spectroscopy: Principle, instrumentation, interferences and applications. **12 Hours**

Unit 2:

NMR spectroscopy: Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and 13C NMR. Applications of NMR spectroscopy. **10 Hours**

Unit 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. 1**0 Hours**

Unit 4:

Chromatography: Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution, isolation of drug from excipients, data interpretation and applications of the following:

a) Thin Layer chromatography **b)** High Performance Thin Layer Chromatography **c)** Ion exchange chromatography **d)** Column chromatography **e)** Gas chromatography **f)** High Performance Liquid chromatography **g)** Ultra High Performance Liquid chromatography **h)** Affinity chromatography **i)** Gel Chromatography. **14 Hours**

Unit 5:

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

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

c. Thermal Techniques: Principle, instrumentation, advantage and disadvantages, Pharmaceutical applications of DSC, DTA & TGA.

d. Microscopic techniques: Principles and applications of Scanning Electron Microscopy and Transmission Electron Microscopy analysis. **14 Hours**

REFERENCES

1. Spectrometric Identification of Organic compounds - Robert M Silverstein. 6th ed. John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler & Timothy A. Nieman. 5th ed. Eastern Press, Bangalore, 1998.
3. Instrumental Methods of Analysis – Willards. 7th ed. CBS Publishers, New Delhi.
4. Practical Pharmaceutical Chemistry – Beckett and Stenlake. Vol 2. 4th ed. CBS Publishers, New Delhi
5. Organic Spectroscopy - William Kemp. 3rd ed. ELBS, 1991.
6. Quantitative Analysis of Drugs in Pharmaceutical Formulation – P.D. Sethi. 3rd ed. CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis - Modern Methods – Part B – J.W. Munson. Vol 11. Marcel-Dekker Series.
8. Spectroscopy of Organic Compounds - P.S. Kalsi. 2nd ed. Wiley Estern Ltd., Delhi.
9. Textbook of Pharmaceutical Analysis - K.A. Connors. 3rd ed. John Wiley & Sons.

ADVANCED BIOPHARMACEUTICS & PHARMACOKINETICS (MIP 102T)

(Common paper for MPH and MIP specializations)

Unit 1:

Drug absorption from the gastrointestinal tract and other routes of administration: Mechanisms and factors affecting drug absorption from different routes, influence of pH–partition theory on drug absorption. Factors affecting dissolution rate and its process, Noyes-Whitney equation. dissolution testing methods for solids - tablets, capsules and for suspensions. Correlation of in vivo and in vitro dissolution data. **12 Hours**

Unit 2:

Biopharmaceutical considerations in drug product design and in vitro drug product performance. Introduction - biopharmaceutical factors affecting bioavailability, rate limiting steps in drug absorption, physicochemical nature of drug, formulation factors affecting drug product performance. In vitro dissolution and drug release testing, dissolution test apparatus and methods as per IP and USP for different types of drug delivery systems, design of dissolution testing for conventional and controlled release products. Data handling and correction factor, bio relevant media, similarity and dissimilarity factors f_1 & f_2, alternative methods of dissolution testing, problems of variable control in dissolution testing performance of drug products. Drug product stability during dissolution testing, in vitro evaluation of drug release from different dosage forms. **12 Hours**

Unit 3:

Pharmacokinetics: Basic considerations, pharmacokinetic models, compartment modeling: one compartment model - IV bolus, IV infusion, extra-vascular. Multi compartment models in brief, calculation of parameters in two compartment models. Non-linear pharmacokinetics: causes of non-linearity, Michaelis – Menten equation, estimation of k_m and V_{max}. Concept of clearance and its applications. Problems related to the above. **12 Hours**

Unit 4:

Drug Product Performance: Bioavailability and bioequivalence, drug product performance, purpose of bioavailability studies, relative and absolute availability. Methods, protocol design for assessing bioavailability, bioequivalence studies, design and evaluation of bioequivalence studies, study designs, cross over study designs, evaluation of the data, bioequivalence

example, study submission and drug review process. In vitro - in vivo correlations in protocol design, levels of correlation, biopharmaceutical classification system, methods. Permeability: Generic biologics (biosimilar drug products), clinical significance of bioequivalence studies. **12 Hours**

Unit 5:

Application of pharmacokinetics: Modified-release drug products, targeted drug delivery systems and biotechnological products. Significance of pharmacokinetic and pharmacodynamic drug interactions in the design of the modified release products. **12 Hours**

REFERENCES

1. Pharmacokinetics - Milo Gibaldi. 2nd ed.
2. Applied Biopharmaceutics and Pharmacokinetics - Leon Shargel. 5th ed.
3. Biopharmaceutics and Clinical Pharmacokinetics - Robert E. Notari. 4th ed.
4. Modern Pharmaceutics - Gilbert S. Banker, Christopher T. Rhodes. 4th ed.
5. Clinical Pharmacokinetics & Pharmacodynamics - Malcolm Rowland & Tozer. 4th ed. Lippincott Publications.
6. Drug Disposition and Pharmacokinetics - Stephen H Curry. 3rd ed.
7. Current Concepts in the Pharmaceutical Sciences:Biopharmaceutics - James Swarbrick
8. Current Concepts in the Pharmaceutical Sciences:Dosage Form Design and Bioavailability - James Swarbrick.

NOVEL DRUG DELIVERY SYSTEMS (MIP 103T)

Unit 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 Hours**

Unit 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, ocular delivery systems

Transdermal drug delivery systems: Theory, design, formulation & evaluation including iontophoresis and other latest developments in skin delivery systems. **12 Hours**

Unit 3:

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. **12 Hours**

Unit 4:

Protein/peptide drug delivery systems: Concepts, delivery techniques, formulation, stability testing, causes of protein destabilization, stabilization methods.

Biotechnology in drug delivery systems: Brief review of major areas-recombinant DNA technology, monoclonal antibodies, gene therapy. **12 Hours**

Unit 5:

New trends for personalized medicine: Introduction, definition, pharmacogenetics, categories of patients for personalized medicines: customized drug delivery systems, bioelectronic medicines, 3D printing of pharmaceuticals, telepharmacy.

Sub micron cosmeceuticals: Biology, formulation science and evaluation of various cosmetics for skin, hair, nail, eye etc. and their regulatory aspects. **12 Hours**

REFERENCES

1. Novel Drug Delivery Systems - Y.W. Chein. Vol 50, Marcel Dekker, NY.
2. Controlled Drug Delivery: Fundamentals and Applications – Joseph R Robinson & Vincent H L Lee. Vol 29. Marcel Dekker, NY.
3. Transdermal Controlled Systemic Medications – Y.W. Chein. Vol 31. Marcel Dekker, New York.
4. Bioadhesive Drug Delivery Systems - 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 – P. Tyle. Vol 32. Marcel Dekker, NY.
7. Polymers for Controlled Drug Delivery - P.J. Tarcha. CRC Press.
8. Pharmaceutical Biotechnology - S.P.Vyas and V.K. Dixit. CBS Publishers, New 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 (MIP 104T)

Unit 1:

Patents: Definition, need for patenting, types of patents. Conditions to be satisfied by an invention to be patentable, Introduction to patent search. Parts of patents. Filling of patents. The essential elements of patent; Guidelines for preparation of laboratory note book, Non-obviousness in patent. **12 Hours**

Unit 2:

Role of GATT, TRIPS, and WIPO **12 Hours**

Unit 3:

Brief introduction to Trademark protection and WHO Patents. IPR's and its types, Major bodies regulating Indian Pharmaceutical sector. **12 Hours**

Unit 4:

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

12 Hours

Unit 5:

Regulatory requirements for contract research organization. Regulations for biosimilars.

12 Hours

REFERENCES

1. Pharmaceutical Process Validation - Fra R Berry & Robert A Nash. Vol 57. 2nd ed. Marcel Dekker, NY.
2. Applied Production and Operation Management – James R Evans. 4th ed.
3. GMP for Pharmaceuticals Material Management - K.K. Ahuja. CBS Publishers, New Delhi.
4. ISO 9000-Norms and explanations

5. GMP for Pharmaceuticals: A Plan for Total Quality Contorl – S.H. Willing. Marcel Dekker.

INDUSTRIAL PHARMACY PRACTICAL - I (MIP 105P)

1. Analysis of pharmacopoeial compounds and their formulations by UV-visible spectrophotometer
2. Estimation of riboflavin/quinine sulphate by fluorimetry
3. Estimation of sodium/potassium by flame photometry
4. Effect of surfactants on the solubility of drugs
5. Effect of pH on the solubility of drugs
6. Stability testing of solution and solid dosage forms for photo degradation
7. Stability studies of drugs in dosage forms at 25ºC, 60% RH 40ºC, 75% RH
8. Compatibility evaluation of drugs and excipients (DSC & FTIR).
9. Preparation and evaluation of different polymeric membranes

INDUSTRIAL PHARMACY PRACTICAL - II (MIP 106P)

1. Formulation and evaluation of sustained release oral matrix tablet/oral reservoir system
2. Formulation and evaluation of microspheres/microcapsules
3. Formulation and evaluation of transdermal drug delivery systems
4. Design and evaluation of face wash, body wash, creams, lotions, shampoo, toothpaste, lipstick
5. Electrophoresis of protein solution
6. Preparation and evaluation of liposome delivery system
7. Experiments based on HPLC/GC
8. Simultaneous estimation of multi component containing formulations by UV spectrophotometry

Second Semester

SCALE UP AND TECHNOLOGY TRANSFER (MIP 202T)

Unit 1:

Pilot plant design: Basic requirements for design, facility, equipment selection, for tablets, capsules, liquid orals, parentral 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, parentral, NDDS products – stress on formula, equipment, product uniformity, stability, raw materials, physical layout, input, in-process and finished product specifications, problems encountered during transfer of technology **12 Hours**

Unit 2:

Validation: General concepts, types, procedures & protocols, documentation. Validation Management Forum (VMF). Analytical method validation. Cleaning validation and vender qualification. **12 Hours**

Unit 3:

Equipment qualification: Importance, IQ, OQ, PQ for equipment – autoclave, dry heat sterilization, membrane filter, rapid mixer granulator, cone blender, fluidized bed dryer, tablet compression machine, liquid filling and sealing machine. Aseptic room validation. **12 Hours**

Unit 4:

Process validation: Importance, validation of mixing, granulation, drying, compression,

tablet coating, liquid filling and sealing, sterilization, water process systems, environmental control. **12 Hours**

Unit 5:

Industrial safety: Hazards – fire, mechanical, electrical, chemical and pharmaceutical, their. monitoring & prevention systems. Industrial effluent testing and treatment. Control of environmental pollution. **12 Hours**

REFERENCES

1. Pharmaceutical Process Validation - Fra R. Berry & Robert A. Nash. Vol 57. 2nd ed. Marcel Dekker, NY.
2. Pharmaceutical Production Facilities, Design and Applications – G.C. Cole. Taylor and Francis.
3. Pharmaceutical Project Management - T.Kennedy. Vol 86. Marcel Dekker, NY.
4. The Theory & Practice of Industrial Pharmacy, 3rd ed. Leon Lachman, Herbert A Lieberman & Joseph L Karig, Varghese Publishing House, Bombay.
5. Tablet Machine Instruments in Pharmaceuticals – P.R. Watt. John Wiley & Sons.
6. Pharmaceutical Dosage Forms: Tablets - Herbert A Lieberman & Leon Lachman, Volume 1 - 3. Marcel Dekker, Inc.
7. Pharmaceutical Dosage Forms : Disperse Systems - Herbert A Lieberman, Martin M Rieger & Gilbert S Banker, Vol 1 – 3. Informa Healthcare.
8. Pharmaceutical Dosage Forms : Parenteral Medication – Sandeep Nema & John Ludwig, Vol 1 – 3. 3rd ed. Informa Healthcare.
9. Pharmaceutical Production and Management – C.V.S. Subrahmanyam. Vallabh Prakashan, Dehli, 2007.

PHARMACEUTICAL PRODUCTION TECHNOLOGY (MIP 202T)

Unit 1:

Improved tablet production: Tablet production process, unit operation improvements, granulation and pelletization equipment, continuous and batch mixing, rapid mixing granulators, rota granulators, spheronizers and marumerisers, and other specialized granulation and drying equipments. Problems encountered.

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

Unit 2:

Parenteral production: Area planning and environmental control, wall and floor treatment, fixtures and machineries, change rooms, personnel flow, utilities & utilities equipment location, engineering and maintenance. **12 Hours**

Unit 3:

Lyophilization and spray drying technology: Principles, process, freeze-drying and spray drying equipment. **12 Hours**

Unit 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 equipment including fine solids dispersion, problems encountered. **12 Hours**

Packaging technology: Types of packaging materials, machinery, labeling, package printing for different dosage forms. **12 Hours**

Unit 5:

Air handling systems: Study of air handling units (AHUs), humidity and temperature control, air filtration systems, dust collectors.

Water treatment process: Techniques and maintenance – RO, DM, ultra – filtration, water for injection. **12 Hours**

REFERENCES

1. The Theory & Practice of Industrial Pharmacy, 3rd ed. Leon Lachman, Herbert A. Lieberman, Joseph. L. Karig, Varghese Publishing House, Bombay.
2. Modern Pharmaceutics - Gilbert S. Banker, Christopher T. Rhodes. 4th ed.
3. Pharmaceutical Dosage Forms: Tablets - Herbert A. Lieberman and Leon Lachman, Volume 1 - 3. Marcel Dekker, Inc..
4. Pharmaceutical Dosage Forms : Disperse Systems - Herbert A Lieberman, Martin M Rieger & Gilbert S Banker, Vol 1 – 3. Informa Healthcare.
5. Pharmaceutical Dosage Forms : Parenteral Medication – Sandeep Nema & John Ludwig, Vol 1 – 3. 3rd ed. Informa Healthcare.
6. Pharmaceutical Production Facilities, Design and Applications – G.C. Cole. Taylor and Francis.
7. Product Design and Testing of Polymeric Materials - N.P. Chezerisionoff.
8. Pharmaceutical Project Management - T.Kennedy. Vol 86. Marcel Dekker, NY.
9. Packaging of Pharmaceutical and Health Care - H. Lockhart & F.A. Paine.
10. Quality Control of Packaging Materials in the Pharmaceutical Industry – Kenneth Harburn. Marcel Dekker, NY.
11. Freeze drying / Lyophilization of Pharmaceuticals & Biological Products - L. Ray. Vol 96. Marcel Dekker, NY.
12. Tablet Machine Instruments in Pharmaceuticals – P.R. Watt. John Wiley & Sons.

ENTREPRENEURSHIP MANAGEMENT (MIP 203T)

Unit 1:

Conceptual frame work: Concept need and process in entrepreneurship development. Role of enterprise in national and global economy. Types of enterprises, merits and demerits. Government policies and schemes for enterprise development. Institutional support in enterprise development and management. **12 Hours**

Unit 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. **12 Hours**

Unit 3:

Launching and organizing an enterprise: Environment scanning, information, sources, schemes of assistance, problems. Enterprise selection, market assessment, enterprise feasibility study, SWOT analysis. Resource mobilization - finance, technology, raw material, site and manpower. Costing and marketing management and quality control. Feedback, monitoring and evaluation. **12 Hours**

Unit 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. **12 Hours**

Unit 5:

Preparing project proposal to start on new enterprise project work – feasibility report. Planning, resource mobilization and implementation. **12 Hours**

REFERENCES

1. Entrepreneurship for Women in India - M.M.P. Akhauri. NIESBUD, New Delhi, 1990.
2. The Women Entrepreneurs - R.D. Hisrich, & C.G. Brush. D.C. Health & Co., Toranto, 1996.
3. Entrepreneurship: Starting, Developing and Managing a New Enterprise – Robert A Hisrich & Michael P Peters. 4th ed. McGraw Hill Education, 1997.
4. Practice of Entrepreneurship – G.G. Meredith, Robert E Nelson & Philip A Neck. ILO, Geneva, 1982.
5. Women Entrepreneurship – Developing New Entrepreneurs - V.C. Patel. Entrepreneurship Development Institute of India, Ahmedabad, 1987.

PHARMACEUTICAL FORMULATION DEVELOPMENT (MIP 204T)

Unit 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 Hours**

Unit 2:

Formulation additives: Study of different formulation additives, factors influencing their incorporation, role of formulation development and processing, new developments in excipient science. Design of experiments – factorial design for product and process development. **12 Hours**

Unit 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 Hours**

Unit 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. Biorelevent media, in vitro and in vivo correlations, levels of correlations. **12 Hours**

Unit 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. **12 Hours**

REFERENCES

1. The Theory & Practice of Industrial Pharmacy, 3rd ed. Leon Lachman, Herbert A Lieberman & Joseph L Karig. Varghese Publishing House, Bombay.
2. Martin's Physical Pharmacy and Pharmaceutical Sciences - Patrick J Sinko. 6th ed. BI Publications Pvt. Ltd.

3. Pharmaceutical Dosage Forms: Tablets - Herbert A Lieberman & Leon Lachman. Volume 1 - 3. Marcel Dekker, Inc.
4. Pharmaceutical Preformulation: The Physicochemical Properties of Drug Substances - Ellis Horwood Ltd., England, 1998.
5. Techniques of Solubilization of Drugs – S.H. Yalkowsky. Vol - 12. Marcel Dekker Inc., New York, 1981.
6. Pharmaceutical Dissolution Testing – J. Dressman & J. Kramer. Saurah Printers Pvt. Ltd., New Delhi, 2005.
7. Drug Stability Principles and Practices – J.T. Carstensen & C.T. Rhodes. CBS Publishers, New Delhi, 2005.
8. Stability of Drugs and Dosage Forms – S. Yoshioka & V.J. Stella. Springer (India) Pvt. Ltd., New Delhi, 2006.
9. Modern Pharmaceutics - Gilbert S. Banker, Christopher T Rhodes. 4th ed.
10. Stability Testing of Drug Products - W. Grimm.
11. International Stability Testing – D.J. Mazzo. Eastern Press Pvt. Ltd., Bangalore,
12. Indian Pharmacopoeia-2018. Controller of Publication. Delhi.
13. British Pharmacopoeia. British Pharmacopoeia Commission Office, London, 2017.
14. United States Pharmacopoeia. United States Pharmacopeial Convention, Inc, USA, 2019.
17. Encyclopedia of Pharmaceutical Technology – James Swarbrick. Vol 1-3.
18. Pharmaceutical Preformulation: The Physicochemical Properties of Drug Substances - J. I. Wells. Ellis Horwood Ltd. England, 1988.

INDUSTRIAL PHARMACY PRACTICAL - III (MIP 205P)

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 (Animal)
5. Pharmacokinetic and IVIVC data analysis by WinNolin® 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
13. Preparation and evaluation of a freeze dried formulation
14. Preparation and evaluation of a spray formulation

PHARMACY PRACTICE (MPP)

First Semester

CLINICAL PHARMACY PRACTICE (MPP 101T)

Unit 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 Hours**

Unit 2:

Clinical pharmacy services: Patient medication history interview, basic concept of medicine and poison information services. Basic concept of pharmacovigilance, hemovigilance, materiovigilance and active surveillance of adverse events following immunization (AEFI). Patient medication counselling, drug utilization evaluation. Documentation of clinical pharmacy services, quality assurance of clinical pharmacy services. **12 Hours**

Unit 3:

Patient data analysis & 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, their applications in patient care services. **12 Hours**

Unit 4:

Lab data interpretation: Hematological tests, renal function tests, liver function tests. Tests associated with cardiac disorders, pulmonary function tests, thyroid function tests. Fluid and electrolyte balance, microbiological culture sensitivity tests. **12 Hours**

Unit 5:

Medicines information services: 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 Hours**

REFERENCES

1. A Textbook of Clinical Pharmacy Practice – Essential Concepts and Skills – G. Parthasarathi, Karin Nyfort-Hansen & Milap Nahata.
2. Practice Standards and Definitions - The Society of Hospital Pharmacists of Australia
3. Basic Skills in Interpreting Laboratory Data – L.T. Scott. American Society of Health System Pharmacists Inc.
4. Relevant review articles from recent medical and pharmaceutical literature.

PHARMACOTHERAPEUTICS-I (MPP 102T)

Etiopathogenesis and pharmacotherapy of diseases associated with following systems:

Unit 1:

Cardiovascular system: Hypertension, congestive cardiac failure, acute coronary syndrome, arrhythmias, hyperlipidemias. **12 Hours**

Unit 2:

Respiratory system: Asthma, chronic obstructive airways disease, drug induced pulmonary diseases

Endocrine system: Diabetes, thyroid diseases **12 Hours**

Unit 3:

Gastrointestinal system: Peptic ulcer diseases, reflux esophagitis, inflammatory bowel diseases, jaundice & hepatitis. **12 Hours**

Unit 4:

Gastrointestinal system: Cirrhosis, diarrhea and constipation, drug-induced liver disease.

Hematological diseases: Anemia, deep vein thrombosis, drug induced hematological disorders. **12 Hours**

Unit 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 Hours**

REFERENCES

1. Clinical Pharmacy and Therapeutics - Roger & Walker. Churchill Livingstone Publication
2. Pharmacotherapy: A Pathophysiologic Approach - Joseph T DiPiro et al. Appleton & Lange.
3. Robbins and Cotran Pathologic Basis of Disease – Kumar, Abbas & Fausto. 8th ed. Elsevier Publications.
4. Clinical Pharmacy and Therapeutics - Eric T Herfindal. Williams and Wilkins Publications.
5. Koda-Kimble & Young's Applied Therapeutics: The clinical Use of Drugs - K.A. Brian et al. Lippincott Williams and Wilkins.
6. Pharmacotherapy Principles and Practice – M.A. Chisholm-Burns, T.L. Schwinghammer B.G. Wells, P.M. Malone, J.M. Kolesar & Joseph P Dipiro. McGraw Hill Publications.
7. Essentials of Pathophysiology: Concepts of Altered Health States - Carol Mattson Porth. Lippincott Williams and Wilkins
8. Harrison's. Principles of Internal Medicine - McGraw Hill Publication.
9. Relevant review articles from recent medical and pharmaceutical literature

HOSPITAL & COMMUNITY PHARMACY (MPP 103T)

Unit 1:

Hospital pharmacy: Definition, classification, organizational structure. Relationship of hospital pharmacy department with other departments. Legal requirements, work load statistics, Infrastructural requirements. Hospital pharmacy budget and hospital pharmacy management.

Hospital drug policy: Pharmacy & Therapeutics Committee, Infection Control Committee, Research & Ethics Committee, Management of medicines as per NABH. **12 Hours**

Unit 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 Hours**

Unit 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, and their relationship with other health care providers.

Community pharmacy management: Legal requirements to start community pharmacy, site selection, layout and design, drug display, super drug store model, accounts and audits. Good dispensing practices, different software and databases used in community pharmacies. Entrepreneurship in community pharmacy. **12 Hours**

Unit 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 counseling and use of patient information leaflets.

Medication adherence: Definition, factors influencing adherence behavior, strategies to improve medication adherence. Patient referrals to the doctors. ADR monitoring in community pharmacies. **12 Hours**

Unit 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.

National Health Programs: Role of community pharmacist in malaria and TB control programs

Home medicines review program: Definition, objectives, guidelines, method and outcomes

Research in community pharmacy practice. **12 Hours**

REFERENCES

1. Hospital Pharmacy – W.E. Hassan. Lea and Febiger Publications.
2. Textbook of Hospital Pharmacy – M.C. Allwood & Blackwell.
3. Avery's Drug Treatment. Adis International Limited.
4. Community Pharmacy Practice – Ramesh Adepu. BSP Publishers, Hyderabad
5. Remington – The Science and Practice of Pharmacy – Loyd V Allen. 22nd ed.
6. Relevant review articles from recent medical and pharmaceutical literature

CLINICAL RESEARCH (MPP 104T)

Unit 1:

Drug development process: Introduction, various approaches to drug discovery, investigational new drug application submission.

Ethics in biomedical research: Ethical issues in biomedical research, principles of ethics in biomedical research. Ethical committee [institutional review board] - its constitution and functions. Challenges in implementation of ethical guidelines, ICH GCP guidelines and ICMR guidelines in conduct of clinical trials, drug safety reporting. **12 Hours**

Unit 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 Hours**

Unit 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 Hours**

Unit 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

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 Hours**

Unit 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

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 Hours**

REFERENCES

1. Principles and Practice of Pharmaceutical Medicine - Lionel D Edward, Aadrew J Flether, Anthony W Fos & Peter D Sloaier. 2nd ed. Wiley Publications.
2. Handbook of Clinical Research - Julia Lloyd & Ann Raven. Churchill Livingstone.
3. Principles of Clinical Research - Giovanna di Ignazio, Di Giovanna & Haynes.
4. Textbook of Clinical Trials - David Machin, Simon Day & Sylvan Green. John Wiley & Sons.
5. Clinical Data Management – R.K. Rondels, S.A. Varley & C.F. Webbs. 2nd ed. Wiley Publications, 2000.
6. Goodman and Gillman's: The Pharmacological Basis of Therapeutics - Laurence L Brunton, Randa Hilal-Dandan, Björn C Knollmann, 13th ed. Mc Graw Hill Education.
7. Central Drugs Standard Control Organization. Good Clinical Practices - Guidelines for Clinical Trials on Pharmaceutical Products in India. New Delhi: Ministry of Health & Family Welfare.
8. International Council for Harmonization of Technical requirements for Pharmaceuticals

for human use - ICH Harmonized Tripartite Guideline - Guideline for Good Clinical Practice. E6; May 1996.

9. Ethical Guidelines for Biomedical Research on Human Subjects. Indian Council of Medical Research, New Delhi.
10. Relevant review articles from recent medical and pharmaceutical literature.

PHARMACY PRACTICE PRACTICAL – I (MPP 105P)

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. ABC Analysis of a given list of medications (one)

PHARMACY PRACTICE PRACTICAL – II (MPP 106P)

1. Presentation of clinical cases of various disease conditions adopting pharmaceutical Care Plan Model (eight)
2. Preparation of content of a medicine, with proper justification, for the inclusion in the hospital formulary (one)
3. Formulation and dispensing of a given IV admixtures (one)
4. Preparation of a patient information leaflet (two)
5. Preparation of study protocol (one)
6. Preparation of informed consent form (one)

Second Semester

PRINCIPLES OF QUALITY USE OF MEDICINES (MPP 201T)

Unit 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 QUM, communication in QUM, cost effective prescribing. **12 Hours**

Unit 2:

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 Hours**

Unit 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 Hours**

Unit 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 Hours**

Unit 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 Hours**

REFERENCES

1. A Textbook of Clinical Pharmacy Practice – Essential Concepts and Skills – G. Parthasarathi, Karin Nyfort-Hansen & Milap Nahata.
2. Mann's Pharmacovigilance – E.B. Andrews & N. Moore.
3. Pharmacotherapy: A Pathophysiologic Approach – J.T. Dipiro, R.L. Talbert & G.C. Yee.
4. Evidence-Based Medicine: How to Practice and Teach It – S.E. Straus, W.S. Richardson, P. Glasziou & R.B. Haynes.
5. Medication Errors – M.R. Cohen.
6. Online:
   - http://medicinesaustralia.com.au/files/2012/05/MA_QUM_External_Red uced.pdf
   - http://curriculum.racgp.org.au/statements/quality-use-of-medicines/
   - http://www.rug.nl/research/portal/files/14051541/Chapter_2.pdf
7. Relevant review articles from recent medical and pharmaceutical literature.

PHARMACOTHERAPEUTICS - II (MPP 202T)

Unit 1:

Nervous system: Epilepsy, Parkinson's disease, stroke, headache, Alzheimer's disease, neuralgias and pain pathways and pain management. **12 Hours**

Unit 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 Hours**

Unit 3:

Infectious diseases: General guidelines for the rational use of antibiotics and surgical prophylaxis, urinary tract infections, respiratory tract infections, gastroenteritis, tuberculosis, malaria, bacterial endocarditis, septicemia. **12 Hours**

Unit 4:

Infectious diseases: meningitis, HIV and opportunistic infections, rheumatic fever, dengue fever, H1N1, helmenthiasis, fungal infections, gynecological disorders, dysmenorrhea, hormone replacement therapy. **12 Hours**

Unit 5:

Oncology: General principles of cancer chemotherapy, pharmacotherapy of breast cancer, lung cancer, head & neck cancer, hematological malignancies, management of nausea and vomiting, palliative care. **12 Hours**

REFERENCES

1. Clinical Pharmacy and Therapeutics - Roger & Walker. Churchill Livingstone Publication

2. Pharmacotherapy: A Pathophysiologic Approach - Joseph T. DiPiro et al. Appleton & Lange.
3. Pathologic basis of disease – S.L. Robins. W.B. Saunders Publication.
4. Clinical Pharmacy and Therapeutics - Eric T. Herfindal. Williams and Wilkins Publication.
5. Koda-Kimble & Young's Applied Therapeutics: The clinical Use of Drugs - K.A. Brian et al. Lippincott Williams and Wilkins.
6. Pharmacotherapy Principles and Practice – M.A. Chisholm-Burns, T.L. Schwinghammer B.G. Wells, P.M. Malone, J.M. Kolesar & Joseph P Dipiro. McGraw Hill Publications.
7. Essentials of Pathophysiology: Concepts of Altered Health States - Carol Mattson Porth. Lippincott Williams and Wilkins
8. Harrison's. Principles of Internal Medicine - McGraw Hill Publication.
9. Relevant review articles from recent medical and pharmaceutical literature

CLINICAL PHARMACOKINETICS AND THERAPEUTIC DRUG MONITORING (MPP 203T)

Unit 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 Hours

Unit 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 Hours**

Unit 3:

Non linier mixed effects modeling: 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 Hours**

Unit 4:

Altered pharmacokinetics: Drug dosing in the elderly, drug dosing in the paediatrics, drug dosing in the obese patients, drug dosing in the pregnancy and lactation, drug dosing in the renal failure and extracorporeal removal of drugs, drug dosing in the in hepatic failure.

12 Hours

Unit 5:

Therapeutic Drug Monitoring (TDM): 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-flouro uracil, cisplatin;

Antibiotics: Vancomycin, gentamicin, meropenem. **12 Hours**

REFERENCES

1. Applied Biopharmaceutics and Pharmacokinetics - Leon Shargel & Andrew B C Yu.
2. Pharmacokinetic - Pharmacodynamic Modeling and Simulation - Peter L Bonate. Springer Publications.
3. Applied Pharmacokinetics & Pharmacodynamics: Principles of Therapeutic Drug Monitoring - Michael E Burton, Leslie M Shaw, Jerome J Schentag & William E Evans. Lippincott Williams & Wilkins.
4. Handbook of Analytical Therapeutic Drug Monitoring and Toxicology - Steven How-Yan Wong & Irving Sunshine. CRC Press.
5. Clinical Pharmacokinetics - Soraya Dhillon & Andrzej Kostrzewski. 1st ed. Pharmaceutical Press, London.
6. Concepts in Clinical Pharmacokinetics - Joseph T Dipiro, William J Spruill, William E Wade, Robert A Blouin & Jane M Pruemer. American Society of Health-System Pharmacists, USA.
7. Clinical Pharmacokinetics & Pharmacodynamics - Malcolm Rowland & Tozer. 4th ed. Lippincott Publications.
8. Applied Pharmacokinetics & Pharmacodynamics: Principle of Therapeutic Drug Monitoring – M.E. Burton, L.M. Shaw, J.J. Schentag & W.E. Evans. American Society of Health System Pharmacists, USA.
9. Basic Clinical Pharmacokinetics - Michael E. Winter. Lippincott Williams & Wilkins, USA.
10. Biopharmaceutics and Clinical Pharmacokinetics - Milo Gibaldi. 3rd ed. Pharma Book Syndicate.
11. Clinical Pharmacokinetics - Dhillon and Kostrzewski. Pharmaceutical Press, London.
12. Clinical Pharmacokinetics - John E Murphy. 5th ed. American Society of Health System Pharmacists, USA.
13. Relevant review articles from recent medical and pharmaceutical literature

PHARMACOEPIDEMIOLOGY & PHARMACOECONOMICS (MPP 204T)

Unit 1:

Introduction to pharmacoepidemiology: Definition, scope, need, aims & applications; 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 Hours**

Unit 2:

Pharmacoepidemiological methods:

Qualitative models: Drug utilization review;

Quantitative models: Case reports, case series, cross sectional studies, cohort and case control studies, calculation of Odds' ratio, meta analysis models, drug effects study in populations: spontaneous reporting, prescription event monitoring, post marketing surveillance, record linkage systems, applications of pharmacoepidemiology. **12 Hours**

Unit 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 Hours**

Unit 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 Hours**

Unit 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 Hours**

REFERENCES

1. Essentials of Pharmacoeconomics – K.L. Rascati. Woulters Kluwer Lippincott Williams & Wilkins, Philadelphia.
2. Health economics: Fundamentals and Flow of Funds - Thomas E Getzen. John Wiley & Sons, USA.
3. Decision Modelling for Health Economic Evaluation - Andrew Briggs, Karl Claxton & Mark Sculpher. Oxford University Press, London.
4. Methods for the Economic Evaluation of Health Care Programmes - Michael Drummond, Mark Sculpher, George Torrence, Bernie O'Brien & Greg Stoddart. Oxford University Press, London.
5. Understanding Health Outcomes and Pharmacoeconomics - George E Mackinnon III.
6. Pharmacoeconomics and outcomes: Applications for patient care – D.W. Grauer & Thomas S Jane. American College of Clinical Pharmacy.
7. Pharmacoeconomics – Tom Walley, Allan Haycox & Angela Boland. Elsevier Publications.
8. Pharmacoeconomics – E. Nowakowska. University of Medical Sciences, Poznan.
9. Relevant review articles from recent medical and pharmaceutical literature

PHARMACY PRACTICE PRACTICAL - III (MPP 205P)

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)

Third Semester

RESEARCH METHODOLOGY & BIOSTATISTICS (MRM 301T)

(Note: Common Paper for all specializations)

Unit 1:

General research methodology: Research, objective, requirements, practical difficulties, review of literature, study design, types of studies, strategies to eliminate errors/bias, controls, randomization, crossover design, placebo, blinding techniques. **12 Hours**

Unit 2:

Biostatistics: Definition, application, sample size, importance of sample size, factors influencing sample size, dropouts, statistical tests of significance, type of significance tests, parametric tests (students "t" test, ANOVA, Correlation coefficient, regression), non-parametric tests (Wilcoxan rank tests, analysis of variance, correlation, Chi-square test), null hypothesis, P values, degree of freedom, interpretation of P values. **12 Hours**

Unit 3:

Medical Research: History, values in medical ethics, autonomy, beneficence, non-maleficence, double effect, conflicts between autonomy and beneficence/non-malfeasance, euthanasia, informed consent, confidentiality, criticisms of orthodox medical ethics, importance of communication, control resolution, guidelines, ethics committees, cultural concerns, truth telling, online business practices, conflicts of interest, referral, vendor relationships, treatment of family members, sexual relationships, fatality. **12 Hours**

Unit 4:

CPCSEA guidelines for laboratory animal facility: Goals, veterinary care, quarantine, surveillance, diagnosis, treatment and control of disease, personal hygiene, location of animal facilities to laboratories, anesthesia, euthanasia, physical facilities, environment, animal husbandry, record keeping, SOPs, personnel and training, transport of lab animals. **12 Hours**

Unit 5:

Declaration of Helsinki: History, introduction, basic principles for all medical research, and additional principles for medical research combined with medical care. **12 Hours**

REFERENCES

1. Pharmaceutical Statistics: Practical and Clinical Applications - Stanford Bolton & Charles Bon. 5th ed. CRC Press.
2. Biostatistics: A Foundation for Analysis in the Health Sciences - Wayne W Daniel. 10th ed. John Wiley & Sons.
3. Introduction to Research in the Health Sciences - Stephen Polgar & Shane Thomas. 7th ed. Elsevier.
4. www.cpcsea.nic.in
5. www.wma.net